EXPLORING THE EXPERIENCES OF WOMEN PARTICIPATING IN A LIFESTYLE INTERVENTION PROGRAMME (IINDIAGO) WHO HAD HYPERGLYCAEMIA FIRST DETECTED IN PREGNANCY

By

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KEYWORDS

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Postpartum Care

Support Group Session

Delivery

Well Baby Clinic

Lifestyle Behaviour Change

Capability

Opportunity

Motivation

Affability

Gestational Diabetes Mellitus

Behaviour Change Wheel

COM-B

DECLARATION

I, Takalani Tshikovhi declare that this thesis, entitled, **"Exploring the experiences of women participating in a lifestyle intervention programme (IINDIAGO) who had hyperglycaemia first detected in pregnancy"** is my own work, and that all the sources used or quoted in this research study have been indicated and acknowledged by means of complete references. I further declare that this work has not been submitted for any other degree at any other institution.

Researcher's signature

03 December 2021

Date

ABBREVIATIONS

HFDP	Hyperglycaemia First Detected in Pregnancy
GDM	Gestational Diabetes Mellitus
DIP	Diabetes in Pregnancy
T2DM	Type 2 Diabetes Mellitus
NCDs	Non-Communicable Diseases
LMICs	Low-and Middle-Income Countries
BCW	Behaviour Change Wheel
IDF	International Diabetes Foundation
TDF	Theoretical Domain Framework

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DEFINITION OF KEY TERMS

Term	Definition
Antenatal Hospital	Refers to a secondary level maternity hospital for women with medium risk complications during pregnancy
Postpartum	Refers to the time after women have given birth
Postpartum care	Health care provision for mothers who recently gave birth
Obstetric outcome	These are outcomes related to the delivery of a baby, how the baby was delivered, morbidity, and mortality.
Intervention	Refers to a process of intervening in a situation to alter its outcome
Physical activity	Physical activity is defined as all bodily movements induced by the skeletal muscle that requires the use of energy
Healthy Lifestyle	Refers to ways of living that reduce the risk of diseases while increasing life expectancy
Affability	Refers to the attributes of friendliness, relatability, and good manners that individuals present when interacting with others.
Diabetes in Pregnancy (DIP)	Refers to a person diagnosed with diabetes for the first during pregnancy.
Gestational Diabetes Mellitus (GDM)	Refers to any blood glucose intolerance identified for the first-time during pregnancy.
Hyperglycaemia First Detected in Pregnancy (HFDP)	Refers to high blood glucose first detected in pregnancy, and it can be classified as either Gestational Diabetes Mellitus or Diabetes in Pregnancy

ABSTRACT

Introduction

Diabetes has become the second leading cause of death in South Africa. It accounts for 5.5% of South Africa's total mortality. One of the major risk factors is Hyperglycaemia First Detected in Pregnancy (HFDP). The prevalence of HFDP is increasing, and it has become one of the common conditions found in women during their pregnancy. It is a significant risk factor for Gestational Diabetes Mellitus (GDM) in subsequent pregnancies and Type 2 Diabetes Mellitus (T2DM) in both mother and offspring. Emerging evidence suggests that a lifestyle change focused on healthier diets and increased physical activity can reduce the risk of progression to T2DM amongst women who had HFDP. Such interventions are usually provided to women with GDM as part of antenatal care. This study aims to explore the experiences of women who received the IINDIAGO intervention and understand what participation meant to them. IINDIAGO is a health system intervention that seeks to integrate the provision of a lifestyle intervention programme into the scheduled routine antenatal and post-partum care of the mother and her baby to decrease the risk of progression to T2DM in the mother.

Methodology

This study was conducted using a descriptive qualitative study design to investigate the experiences of women who received the IINDIAGO intervention by exploring opinions from women about the challenges, benefits, and perceived importance of sustaining a healthy lifestyle. Using purposive sampling we recruited 17 women who had been randomly recruited into the IINDIAGO lifestyle intervention programme. We conducted in-depth interviews via a telephone call using a series of open-ended questions in a flexible way to guide the conversation. Data analysis was done using qualitative thematic analysis. We used an inductive approach to allow our collected data to generate themes and a deductive approach using the Capability Opportunity Motivation and Behaviour (COM-B) theoretical framework of behaviour change outlined in the Behaviour Change Wheel (BCW) to structure the themes into broad conceptual categories.

Results

Affability was a significant influence on how women experienced the intervention programme. It was a common finding that was associated with women feeling capable of participating in the intervention programme. The social and emotional support that women experienced during their participation in the intervention influenced a positive experience. Knowledge about HFDP

and how to lead a healthy life was another key factor contributing to women's experiences. Gaining knowledge was consistent with their decision to remain part of the programme.

Conclusion

The intervention activities assisted women in realising their capability to change their behaviour and to lead a healthy lifestyle. It provided women with opportunities to learn, engage and draw support during their pregnancy and at postpartum. These opportunities and support resulted in women feeling motivated and having an overall positive experience.

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Chapter 1: Introduction

1.1.Introduction

The prevalence of Hyperglycaemia First Detected in Pregnancy (HFDP) is increasing, and it has become one of the common conditions found in women during their pregnancy (Parsons *et al.*, 2018). It is a major risk factor for Gestational Diabetes Mellitus (GDM) in subsequent pregnancies and Type 2 Diabetes Mellitus (T2DM) for both mother and offspring (Lee *et al.*, 2018). Lifestyle modification has been shown to curb the early stages of the disease effectively, however as the condition progresses, one needs pharmacological interventions (Dunkley *et al.*, 2014). The diagnosis of HFDP and GDM are often accompanied by highly emotionally distressing pregnancies due to factors such as lack of information and skills to control blood glucose and the fear of not having positive obstetric outcomes, amongst others (Parsons *et al.*, 2018).

HFDP is described as either GDM or Diabetes in pregnancy (DIP) by the World Health Organization (WHO, 2013). The pathophysiological description of HFDP is associated with a change in hormones where the progression of gestation causes a decrease in insulin sensitivity resulting in increased blood glucose levels (Farahvar, Walfisch and Sheiner, 2019). When the body cannot secrete enough insulin to overcome the degree of insulin resistance, the result is HFDP (Butte, 2000). This project is embedded in the IINDIAGO study, which specifically addressed GDM; we will focus on GDM. The prevalence of GDM in South Africa is 9.1%, and it is seen to be increasing along with obesity amongst women of childbearing age (Macaulay et al., 2018). The approximate global prevalence of GDM is 7.0% (Lee *et al.*, 2018). However, there are various diagnostic criteria for determining the prevalence of GDM in different countries. The prevalence ranges from 5.4% in European countries to 14% in African countries. However, in Asia, the prevalence ranges between 0.7% to 51.0%; this may be due to various ethnicities and population characteristics, as well as inconsistent diagnostic criteria (Lee *et al.*, 2018).

Global data suggest that women diagnosed with GDM have a seven times higher risk of developing T2DM (Leanne Bellamy et al., 2009). These women often recover, and they present normal glucose tolerance levels after delivery. However, 20% to 70% of them have a risk of progressing to T2DM in the first ten years of being diagnosed with GDM (Paschou *et al.*, 2020). Song et al. suggest that the risk of progression to T2DM is highest within 3 to 6 years post-

pregnancy in individuals diagnosed with GDM (Song *et al.*, 2018). Chivese et al. (2019) presented evidence showing that half of the women who were previously diagnosed with DIP and GDM were characterised as HFDP attending antenatal care at Groote Schuur Hospital in Cape Town between 1 September 2010 and 31 August 2011 progressed to T2DM within 5 to 6 years of the diagnosis.

Major risk factors of HFDP include ethnic origin, family history of diabetes, advanced maternal age, history of GDM, numerous pregnancies, excessive weight gain during the first trimester of pregnancy, as well as pre-pregnancy weight and obesity (Song *et al.*, 2018). Studies suggest that obesity amongst women over the age of 25 is associated with the development of GDM (Mamabolo *et al.*, 2007) (Pastakia *et al.*, 2017). Obesity is described as an increase in body mass index (BMI) caused by factors such as sedentary behaviours, diet or poor nutrition, and genetics, amongst many others (Kengne *et al.*, 2017). It is argued that ethnicity is a major risk factor (Girgis, Gunton and Cheung, 2012).

South Africa is one of the five countries in sub-Saharan Africa, with the highest prevalence of T2DM at 9.3% (Lachat et al., 2013). In 2016, the prevalence of obesity amongst South African women was 70% (World Obesity Day, 2016). Obesity is one of the most significant risk factors of diabetes and has increased worldwide, more so amongst African women (Kengne *et al.*, 2017). In addition, Kengne et al. (2017) presented meta-analysis data showing that the mean BMI increased by 3 kg/m² between 1980 (22 kg/m²) and 2014 (25 kg/m²). Obesity is one of the most critical risk factors for T2DM and cardiovascular diseases (CVD), which are the second leading cause of death in South Africa (StatsSA, 2016). T2DM combined with cardiovascular diseases (CVD) account for 47.6% of non-communicable diseases (NCDs) globally. NCDs are responsible for 71% of deaths worldwide (WHO, 2020). About 85% of these deaths occur in low-income to middle-income countries (WHO, 2020).

There is an emergence of reliable evidence suggesting that a lifestyle change focused on diet and physical activity can reduce the risk of progression to T2DM amongst women who had HFDP (Dunkley *et al.*, 2014). Lifestyle interventions involving increased physical activity and the adoption of a healthier diet can effectively prevent or slow down the onset of T2DM (Morrison et al., 2010). Such interventions are usually provided to GDM women as part of antenatal care. In addition, a continuation of this kind of intervention post-partum is vital in lowering the risk of progression to T2DM (Song *et al.*, 2018).

Women need continued support to sustain long-term healthy lifestyle choices. This is even more important because opportunities for a lifestyle change are significantly reduced during the post-partum period due to the increased responsibilities that come with a new-born baby (Muhwava *et al.*, 2019). Therefore, it is crucial for public health practitioners to develop suitable interventions for the targeted population. In 2015 a team of researchers from the Chronic Disease Initiative for Africa (CDIA) (Department of Medicine, University of Cape Town, Cape Town, South Africa), the MRC/WITS Developmental Pathways for Health Research Unit (DPHRU) (Department of Paediatrics, University of Witwatersrand), University of Montreal Hospital Research Centre (CR CHUM) and Department of Social and Preventive Medicine (School of Public Health, University of Montreal) developed a convergent parallel mixed-methods study comprising an exploratory, individually randomised control trial to evaluate the uptake and outcomes of postpartum screening and prevention of T2DM among women with recent GDM. This trial was named IINDIAGO (UCT CDIA, 2020). IINDIAGO is a health system intervention that aims to integrate the provision of antenatal and post-natal care to prevent progression to T2DM in new mothers. The IINDIAGO integrated health system intervention includes a lifestyle modification programme aimed at supporting women during their GDM pregnancy and during the first nine months post-partum. The trial commenced in April 2018, and it has reached the analysis stage. The trial has two intervention sites in South Africa: Cape Town in the Western Cape and Soweto in Gauteng Province. Focusing on the Cape Town intervention group, we aimed to explore the experiences of women who participated in the intervention and how this affected their lives (UCT CDIA, 2020).

1.2.Problem Statement

Low- and Middle-income countries (LMICs) lack studies that explore lifestyle intervention for HFDP and GDM (Youngwanichsetha & Phumdoung, 2017). However, research in high-income countries has provided evidence that shows positive effects of lifestyle change on women with GDM (Parsons *et al.*, 2018). Lacking are studies that explore lifestyle changes in the context of the vastly different socio-economic statuses in the population, considering food security, unemployment, poverty, and physical inactivity (Bhurosy & Jeewon, 2014). Barriers to lifestyle change amongst women living in LMICs should be explored and studied to provide an evidence base for relevant and sustainable interventions. The impact of the IINDIAGO lifestyle intervention programmewill be measured by assessing differences in a composite diabetes risk score between the control and intervention group at the 12 months post-partum

endpoint. However, it is also essential to investigate the personal experiences of women participating in the intervention to gain insight into how the intervention assisted them in changing and maintaining better lifestyle behaviour or any other potential unanticipated impacts to their lives.

1.3. Purpose

This research will form part of the process evaluation for the IINDIAGO intervention. The evaluation outcomes will provide insight into the feasibility and effectiveness of such an intervention from the perspective of the women who participated in the study. Furthermore, it will elicit opinions from women about the challenges, benefits, and perceived importance of sustaining a healthy lifestyle. Lastly, the study will highlight barriers to leading a healthy lifestyle that may not have been addressed by the IINDIAGO intervention and those that may exist within the IINDIAGO intervention.

1.4.Theoretical Framework

We chose the COM-B Model outlined in the Behaviour Change Wheel (BCW) framework to structure the analysis into factors influencing women's experiences during the intervention. The COM-B Model comprises three primary components to assess sources of behaviour (Michie, Stralen and West, 2019). The three primary components are Capability (C), Opportunity (O) and Motivation (M). Behavioural scientists argued that behaviour is a product of reciprocated interactions occurring among these three components of the COM-B Model (Cane, O'Connor and Michie, 2012). The IINDIAGO Intervention employed the COM-B Model to develop its intervention (Muhwava *et al.*, 2019). The intervention involved behaviour change interventions that comprised of coordinated activities directed at enabling and supporting women with GDM to change targeted behavioural patterns. The COM-B model framework helped us unpack determinants of behaviour and experiences amongst women who participated in the intervention. Furthermore, the COM-B Model allowed us to see the reflective processes that affect beliefs and feelings amongst individuals (Handley *et al.*, 2016).

1.5.Outline of the thesis chapters

Chapter 1 introduces the study and presents the background, conceptualisation of the problem statement and rationale for the research study, including the theoretical framework used to analyse the findings. Chapter 2 outlines relevant literature on risk factors and treatment for

HFDP and T2DM, while Chapter 3 presents the methodology used in the research study, including the study design, aim, objectives, and the relationship between the chosen theoretical framework and the study objectives. Chapter 4 presents the findings of the study, which are discussed in Chapter 5. Lastly, Chapter 6 presents the conclusion of the research study and makes recommendations regarding lifestyle modification programs for treating HFDP.

Chapter 2. Literature Review

2.1. Introduction

In this chapter, we briefly introduce the broader public health issue of NCDs that underpins the broader purpose of this study. This is followed by an overview of T2DM, focusing on the prevalence of T2DM, risk factors, and its impact on individuals and the healthcare system at large. The aim of this overview on T2DM is to is provide information that is necessary to understand the need to prevent T2DM. An overview of HFDP/GDM follows this as a risk factor for T2DM. Here, we discuss the prevalence of GDM, experiences of women with a history of GDM, and interventions tailored to reduce the risk of developing T2DM with a particular focus on lifestyle behaviour change in women with a history of GDM. Finally, we give an overview of the theoretical domains' framework used to facilitate lifestyle modification. In this final topic, we discuss the background of the framework we use in this study and how it can be used to understand sources of behaviours, including socio-economic factors that may hinder a behaviour change.

2.2. Non-Communicable Diseases

NCDs are responsible for 71% of all deaths worldwide (WHO, 2020). In recent years there has been a rise in NCDs in sub-Saharan Africa (Dalal *et al.*, 2011). These include diabetes, cardiovascular diseases, and obesity. The high prevalence of NCDs contributes to the multiple burdens of disease that South Africa experiences, including HIV and tuberculosis (Von Elm *et al.*, 2007).

2.3. The prevalence of type 2 diabetes mellitus

T2DM is a medical condition classified by an increase in blood glucose level due to a relative insulin deficiency resulting from a disorder of insulin secretion or action in target organs. (Pheiffer *et al.*, 2018). T2DM is one of the biggest - NCDs contributing to the cause of death globally (World Health Organization-WHO, 2018). The rise in obesity, physical inactivity and the prevalence of energy-dense food has highly contributed to the increase of T2DM (Chatterjee, Khunti and Davies, 2017). There are approximately 537 million people are living with diabetes worldwide (International Diabetes Federation, 2021) .

In 2009 the prevalence of diabetes in South Africa was estimated to be 9% for individuals aged 30 years and above (Pheiffer *et al.*, 2018). Data from the 2012 National Health and Nutrition and Examination Survey shows the prevalence of diabetes to be 9%, with a 90% and 10% split between Type 2 and type 1 diabetes, respectively (Maluleke *et al.*, 2013). Moreover, some high-income countries reported a similar trend between type 1 and type 2 diabetes ranging from 7-12% and 87 – 91%, respectively (Ogurtsova *et al.*, 2017).

The prevalence of diabetes globally has been growing with time, with a global estimation of diabetes reported being 10.5% by the International Diabetes Federation (IDF) (International Diabetes Federation, 2021). The IDF predicted that approximately 642 million individuals will have diabetes by the year 2040. Findings suggest that the largest number of individuals living with diabetes are found in South-East Asia, and projections estimate that Sub-Saharan Africa, the Middle East, and North African Regions will encounter the highest increase in the prevalence of diabetes by 2040 (Ogurtsova et al., 2017). The IDF has estimated that by 2030, 98% of individuals in the African continent will have diabetes (Burgess et al., 2013).

2.4. Risk factors of Type 2 Diabetes Mellitus

Obesity is one of the highest risk factors of T2DM, particularly among women. The South Africa Department of Health Survey of 2016 showed that 70% of women were either overweight or obese in 2016 (South Africa. Department of Health, World Obesity Day, 2016). Obesity is determined by an excessive accumulation of body fat that results in negative effects on physical and psychological wellness. It is defined by a body mass index =/> 30kg/m^2 (Al-Goblan et al., 2014). It suggests that approximately 55% of all T2DM cases are attributable to the incidence of obesity (Chivese et al., 2019). High body mass index (obesity) is a risk factor of HFDP alongside factors such as maternal age, family history of T2DM, previous fetal birth weight, and increased waist circumference (Rayanagoudar et al., 2016). Many studies suggest that bodyweight management is a critical intervention tool to controlling T2DM. Different diets have shown improvement in metabolic conditions that may assist in T2DM prevention (Bharara *et al.*, 2009).

GDM is another risk factor of T2DM that is prevalent in women. The risk is associated with failure to recover normal weight after birth, a high body mass index, an increase in waist-to-hip ratio, and other known factors (Bellamy et al., 2009). It is suggested that the risk of progression to T2DM is at its peak between 3 to 6 years after HFDP (Song et al., 2018).

2.5. The impact of T2DM on individuals

T2DM demands a life-long self-care approach to life, where the patients are constantly taking measures such as monitoring their blood glucose levels, watching their diet intake and physical activity to ensure a well-controlled blood glucose level (Daya, Bayat and Raal, 2016). It is suggested that diabetes status is associated with an individual's poor quality of life and disability, resulting from socio-economic status such as low education and low household income (Werfalli *et al.*, 2018).

When diabetic individuals fail to ensure a well-controlled blood sugar level, complications such as blindness, kidney failure, loss of limbs through amputations may occur (Ramkisson, 2014). As a result of the need to maintain a well-controlled blood glucose level, individuals may have to restrict portion size, type, and timing of meal intake. Furthermore, having to schedule eating time, being aware of the glycaemic index of foods and to wait for medication to take effect before they can consume food. These considerations are deemed to negatively affect their quality of life, social and professional interactions (Daya, Bayat and Raal, 2016). T2DM individuals can experience burnout and overwhelming feelings (diabetes distress) due to the demands of having to keep the blood glucose level under control (Ramkisson, 2014). A study suggests that high diabetes distress on individuals can negatively influence their self-management and compliance to medication leading to adverse co-morbidities such as diabetes retinopathy amongst many others (Ramkisson, 2014).

Furthermore, the onset of T2DM reduces the and productivity of the workforce, absence from work due to routine and none-routine medical appointments (The Lancet Diabetes & Endocrinology, 2018).

2.6. The Impact of T2DM on the healthcare system

The epidemic of diabetes has emerged alongside HIV/AIDS and tuberculosis (TB) in South Africa, putting a strain on the already burdened South African health services that provide care to approximately 80% of the population (Council for Medical Schemes, 2017). Estimates suggest that approximately 80.6% of the population have unfulfilled health care requirements (Stokes *et al.*, 2017). Diabetes presents a significant burden on the South African health system. It is associated with microvascular and macrovascular complications, resulting in T2DM co-morbidities that strain health services (Erzse *et al.*, 2019). An editorial published in 2017 by the University of Cape Town proposed that diabetes and its complications can reverse

the health progress seen in Sub-Saharan Africa, arguing that it is crippling the health systems in these countries, including South Africa (Cardiovascular Diabetes Education, 2017). A study conducted in 2017 reported dissatisfaction in services and poor compliance with the management of diabetes at primary health care in South Africa.

There is a notable shortage of healthcare human resources to adequately address the burden presented by T2DM (Dubrulle *et al.*, 2017). It is estimated that out of 3.1 million T2DM patients, 240 000 are treated within the South African public health services. The cost of their care was estimated to be R 2.7 billion for 2018 (Erzse *et al.*, 2019).

2.7. The prevalence of Hyperglycaemia First Detected in Pregnancy

The World Health Organization describes HFDP as GDM and DIP (WHO, 2013). Its pathophysiological description is associated with a change in hormones where the progression of pregnancy causes a decrease in insulin sensitivity resulting in an increased blood glucose level (Farahvar, Walfisch and Sheiner, 2019). When the body cannot secrete enough insulin to regulate this increased resting glucose, it results in HFDP (Butte, 2000). The diagnosis of GDM is defined by an oral glucose tolerance test (OGTT) with fasting glucose values ranging between 5.1 to 6.9 mmol/L and 2 hours glucose values ranging between 8.5 and 11.0 mmol/L (WHO, 2013). There are common risk factors between HFDP and T2DM (Song *et al.*, 2018).

Findings from a systematic review on global GDM prevalence suggests that the prevalence of GDM varies globally, with it being at its lowest in Europe and higher among the Middle East, North Africa, Southeast Asia and the Western Pacific regions (Zhu and Zhang, 2016). In another systematic review of the available GDM studies conducted in Africa, it is suggested that the prevalence of GDM ranges from 0% to 14% (Macaulay, Dunger and Norris, 2014). Two studies conducted in Gauteng, South Africa, reported a GDM prevalence of 9.1% in Soweto (Macaulay *et al.*, 2018) and 25.8% in Johannesburg (Adam and Rheeder, 2017). However, it is important to note that there were variations in the GDM diagnosis criterion used in determining these GDM prevalence. The 9.1 % GDM prevalence was determined using the WHO 1999 diagnostic criteria described by a fasting plasma glucose of ≥7.0 mmol/l or a two-hour plasma glucose of ≥7.8 mmol/l (Macaulay *et al.*, 2018). The 25.8% prevalence was determined using the WHO 2013 criteria adopted from the International Association of Diabetes in Pregnancy Study Groups (IADPSG) described by a fasting plasma glucose of 5.1–

6.9 mmol/l, or, one-hour plasma glucose of ≥10.0 mmol/l or two-hour plasma glucose of 8.5–11.0 mmol/l (Adam and Rheeder, 2017).

There are several studies from North America and Europe exploring women's perspectives about HFDP and possible interventions or treatments (Muhwava *et al.*, 2019). A study conducted by Morrison et al. (2012), representing 1176 Australian women with a history of HFDP, reported that most women lacked knowledge about HFDP and associated risks. Furthermore, the findings suggested that a third of this group considered themselves to have a low risk of progressing to T2DM (Morrison, Lowe and Collins, 2010).

2.8. Experiences amongst women with a history of GDM

Experiences amongst women with a history of HFDP vary. A systematic review of available data on the experiences of women with GDM identified five main themes that presented when exploring women's experiences (Parsons *et al.*, 2014): emotional response, loss of normal pregnancy experience, privileging the baby, information and health care support, and personal control. The Parsons et al. (2014) literature review on the perceptions among women with HFDP expounded upon these themes. The themes covered included 1) shock from the new diagnosis, 2) being upset about not being healthy, 3) feeling depressed, 4) denial about the diagnosis, 5) child health being a motivating factor to treatment adherence, 6) positive responses to lifestyle change, and 7) loss of normal pregnancy and 8) having to adapt to a planned lifestyle, prioritising child's health by sacrificing what mothers feel they need. Another study representing a population in London(UK) presented the following experiences; 1) women feeling that their pregnancy was disrupted, 2) projected anxiety from healthcare providers, 3) reproductive asceticism where women experience emotional challenges to maintain and control their health behaviours for a positive obstetric outcome, 4) feeling like a 'baby-making machine', 5) feeling stigmatised for having HFDP, 6) poor relation and understanding between patients and healthcare providers, 7) feeling abandoned at post-partum (Parsons *et al.*, 2018). In addition, Muhwava et al. (2019) presented evidence that shows how HFDP imposes a significant burden on the psychological and physical well-being of women, arguing that women are often confused about how to treat HFDP and usually focus their finances and efforts on delivering a healthy baby.

2.9. Lifestyle intervention programmes to reduce the risk of T2DM

The World Health Organization (WHO) provides an outline of an action plan with evidence-based policy options aimed at global prevention and control of NCDs, with a vision of having a world that is liberated from the burden of NCDs (WHO, 2013). Six objectives to reinforce intervention for NCDs were outlined and can be directly applied to each NCD. For example, one of the six objectives for interventions involves having a country-led multisectoral response to the prevalence of NCDs. Such an objective can directly be used to address the prevalence of T2DM multisectorally. Thus, the national department of health, the food industry, the corporate world, and the education department can contribute to various aspects of T2DM interventions. T2DM interventions are aimed at preventing and delaying complications for patients living with diabetes and those who are at risk of getting diabetes. Furthermore, such interventions are often directed at maintaining the quality of life for those diagnosed with T2DM (Davies et al., 2019).

Studies suggest that managing body weight can be an effective intervention for T2DM control (Pfeiffer & Klein, 2014). Lifestyle modification interventions focusing on diet and physical activity are considered cost-effective methods of reducing the risk of T2DM (Alouki et al., 2016). Further, a systematic review shows consistent findings recommending that prevention of T2DM amongst women with a history of GDM should be prioritized through lifestyle interventions by using early predictors such as HFDP (Gilinsky et al., 2015).

HFDP is a strong predictor for T2DM and researchers suggest that health care providers should have continuous care programmes that apply equal focus on antenatal care and post-partum care while providing evidence-based lifestyle behaviour change interventions that are contextual to the target population to reduce progression to T2DM (Morrison et al., 2010). LIMCs lack studies that explore lived experiences of women with HFDP and lifestyle behaviour interventions (Ge et al., 2017). Most studies concerning lifestyle behaviour change for HFDP do not represent women living in low-middle-income countries (LIMCs) and of poor socio-economic status, with high rates of unemployment and poor food security (Parsons et al., 2018). The lack of evidence-based lifestyle intervention studies for LIMCs may present barriers to the development of lifestyle intervention.

The improvement of treatment and interventions for HFDP will come from an increase in understanding the experiences of women with HFDP, their perceptions and how the diagnosis affects them (Parsons *et al.*, 2014). A meta-synthesis showed that women with a history of

GDM preferred treatment that is contextual, non-judgemental and holistically focused care due to the emotional impact that comes with the GDM diagnosis (Van Ryswyk *et al.*, 2015). It is essential to begin building evidence in these settings to inform policy makers, healthcare providers and intervention developers about what types of lifestyle interventions are acceptable, feasible, appropriate, and cost-effective for lower-socio-economic populations.

2.10. Theoretical Domains Framework for lifestyle modification

The Theoretical Domain Framework (TDF) combines thirty-three theories of behaviour and behaviour change that are grouped into 14 domains (Cane, O'Connor and Michie, 2012). It was developed by behavioural scientists alongside implementation researchers to make scientific theories more accessible to those who develop interventions (Michie *et al.*, 2005). The framework allows researchers to view cognitive, affective and environmental influences affecting behaviours (Atkins *et al.*, 2017).

Recent studies have shown that using the theoretical domains framework allows researchers to explore behaviours without overlooking important domains that may aid in understanding certain behaviours (Michie *et al.*, 2005). Furthermore, it facilitates insight into underlying issues that may be influencing existing behaviours. It is suggested that behaviour change is a requirement when implementing evidence-based public health interventions (Michie, Van Stralen and West, 2011).

The domains that underpin the TDF included social influences, environmental context and resources, social/professional role and identity, beliefs about capabilities, personal optimism, intentions, goals, beliefs about consequences, reinforcement, emotions, knowledge, cognitive and interpersonal skills, memory, attention and decision processes, behavioural regulation, and physical skills. These domains were grouped under sources of behaviour, namely, opportunity, motivation, and capabilities (Atkins *et al.*, 2017). This strengthened TDF solidifies the bases for the development of interventions, further providing methods to theoretically assess implementation problems, professional and public health behaviours as a foundation to develop remedial interventions (Cane, O'Connor and Michie, 2012).

Alongside the TDF, researchers had developed the Behaviour Change Wheel (BCW) from a combination of 19 frameworks through a systematic review. It comprises three interconnected layers (Handley *et al.*, 2016). Layer one includes the same components found in the TDF; Capability (C), Opportunity (O), and Motivation (M). The second layer comprises of nine

intervention bases namely: Training, Modelling, Enablement, Coercion, Incentivisation, Persuasion, Education, Restrictions, and Environmental Restructuring. These intervention bases, provide options that are suitable in addressing behaviour challenges and identifying possible enablers. The third layer provides seven policy options that can be used to achieve the required interventions (Michie, Van Stralen and West, 2011). The available policies within the third layer are marketing/communication, service provision, financial measures, policy guidelines, legislation, and environmental/social planning.

The TDF domains provided the basis for the COM-B Model, which argues that three components influence behaviour. The COM-B Model requires a change on one or more of its components to facilitate an effective and sustainable behaviour change (Michie, Stralen and West, 2019). Therefore, if there is a change within capabilities and an opportunity to achieve a task, motivation for a complete behaviour change is developed. When the COM-B Model is applied effectively, Michie et al. (2019) argue that it can give clear insights on what change is required to provide suitable interventions and lifestyle changes.

2.11. The components of the COM-B model

2.11.1. Capability

Capability is defined as the physical and psychological capacity to engage in the specified activity (Handley *et al.*, 2016). Physical capabilities are concerned with the physical ability required to execute the desired behaviour. In contrast, psychological capabilities refer to the mental capacity to comprehend and engage with the processes necessary for behaviour change (Michie *et al.*, 2005). For example, using the CAPABILITY component of the COM-B model, we can 1) describe how women perceive the information they received while interacting with intervention activities, 2) explore how the intervention affected their beliefs and attitudes about behaviour change, 3) explore both the physical and psychological capabilities to integrate the intervention guidance into their daily lives contextually. The experiences can further allow us to understand whether the intervention modelled a good lifestyle to aspire to, whether it was restrictive and preventing opportunities for a behaviour change or restructuring the physical or social environments of these women.

2.11.2. Opportunity

Opportunity refers to all external factors that prompt and make behaviour change possible for the individual (Handley *et al.*, 2016). These factors are referred to as socio-economic factors.

They can either encourage or discourage a behaviour change due to physical or social factors (Michie, Van Stralen and West, 2011). The physical factor is related to the availability of resources, time to participate, access to resources and physical environmental barriers, whereas social factors refer to personal beliefs, social and cultural norms, family influences and pressures (Michie *et al.*, 2005). For example, the Opportunity layer of the COM-B model allows us to explore how women integrated and adapted the intervention guidance into their daily lives and circumstances by unpacking physical and social factors that enabled or prohibited women from integrating the advice they received. In addition, we can explore how women perceived the information they received and how the intervention affected their beliefs and attitudes regarding behaviour change. Furthermore, allowing us to understand whether social factors (e.g., beliefs or cultural norms including gender dynamics) affected their experience within the programme.

2.11.3. Motivation

Motivation is defined as all mental processes that stimulate and control behaviour (Handley *et al.*, 2016). Such include analytical and conscious decision-making, habitual processes, and emotional responses (Michie *et al.*, 2005). These decision-making processes are categorised into two types of motivations: reflective motivation (Conscious decision-making, setting goals and plans) and automatic (habits, reflex and impulsive behaviours triggered by external factors) motivation. For example, when we explore how women perceive the interactions they had with the intervention, we can understand whether the programme was a motivating factor or not. In addition, we can describe how women report having received the intervention, including what they found to be appealing, acceptable and helpful or not, and the reasons why they remained or dropped out of the programme.

2.12. Conclusion

This chapter shows the significance and impact of T2DM on a global scale and how its prevalence is growing rapidly in African countries. We give an overview of GDM as a risk factor for T2DM. Furthermore, we show how a change in lifestyle can be used in reducing the risk of progressing to T2DM. In addition, we highlight the gap in the literature on GDM prevalence and lifestyle modifications in Africa. Finally, we present tools that can be used to facilitate lifestyle intervention treatments to address T2DM.

Chapter 3: Methodology

3.1. Introduction

This chapter provides a road map for the reader to understand how this research study was conducted. It outlines steps and choices of the procedures that were followed in conducting this research study, including the motivations behind them. Qualitative research methods underpin the methods and procedures outlined in this chapter. The study aims to explore the experiences of women who participated in a lifestyle intervention program. Qualitative research methods can provide a holistic perspective representing the true complexities of human relationships and the environment (Black, 1994). In addition, these procedures ensure that the findings report on complete information that reflect the true phenomena and realities of society (Creswell & Miller 2000). This chapter outlines aims and objectives, study design, sampling procedure and setting, data collection and analysis, the framework for analysis and trustworthiness or rigour.

3.2.Aim and Objectives

3.2.1. Aim

This study aims to explore the experiences of women who were part of the IINDIAGO intervention and understand what participation in the intervention study meant to them.

3.2.2. Objectives

1. To describe how women report having received the intervention, by outlining: what they found to be appealing, acceptable, and impractical or useless.
2. To describe the reasons why women remained or dropped out of the intervention programme.
3. To explore how women perceive the information they received in the intervention activities they participated in.
4. To explore how the intervention affected women's beliefs and attitudes about behaviour change.
5. To explore how women integrated the intervention guidance into their daily lives and adapted it to their circumstances.

3.3.Study Design

This was a descriptive, qualitative study using semi structured telephonic interviews. We used telephonic interviews because COVID-19 pandemic control measures precluded face to face interviews during the period of the study. We used a series of open-ended questions in a flexible way to guide the conversation. The method was appropriate because it allowed the participants to share their personal experiences and how they derived meaning out of the different intervention tools and activities they encountered in the lifestyle intervention programme.

3.4.Sampling

Purposive sampling was used in the selection of our research participants. Purposive sampling increases the probability to obtain quality data and provides great prospects for complex and rich data (Etikan, 2016). Our sample comprised 17 women who were randomly recruited into the IINDIAGO lifestyle intervention programme between 24 and 36 weeks of their pregnancy. These are women of childbearing age living within the Cape-Metro district and had received antenatal care from one of the following hospitals: Mowbray Maternity Hospital, Groote Schuur Hospital and Somerset Hospital. This group of participants consisted of women who speak English, IsiXhosa or Afrikaans. They reside within the following Cape Metro areas; Southern suburbs, Phillipi, Khayelitsha, Mitchells Plain and Gugulethu.

We recruited 17 women from the IINDIAGO Intervention programme. The IINDIAGO intervention programme has data (Microsoft Excel spreadsheet) that identifies the level of exposure of each participant to the different milestones within the intervention programme. These milestones represent various intervention activities. The activities were:

1) Two hospital-based antenatal counselling sessions by IINDIAGO counsellors focusing on the nature of HFDP, its associated risks, opportunities for a good prognosis, assessing lifestyle and family issues, breastfeeding, and how to deal with stress and anxiety.

2) Post-partum clinic-based intervention taking place at the wellness-baby clinic during and subsequent to the 6-weeks immunisation appointment of the new-born baby.

This 6-week post-partum activity included an oral glucose tolerance test for the mother, support to maintain and achieve a healthy lifestyle through behaviour change counselling and behaviour change goal setting. The component of the behaviour-change counselling dimension

of the IINDIAGO intervention continued throughout the visits for the routine baby immunisation dates that occur at 10, 14 and 36 weeks after the baby is born.

3) A community-based intervention that included a discretionary home visit by the lay counsellor, occurring at 8-, 12-, and 16-weeks post-partum. The visit was focused on assisting the family with support to achieve a healthy lifestyle change. In addition to the home visit, the counsellor organised support group sessions tailored to address specific needs that are common for a particular group of women.

Using this existing dataset, we purposively built our sample to include the following groups: a group of women who completed the 6-, 10- and 14-weeks post-partum counselling sessions; a group of women who only participated in the antenatal counselling sessions; a group of women who participated in all 6-,10- and 14 weeks post-partum follow up and at least one support group session. This stratification was influenced by the attendance of the various intervention activities by the participants. This was done to ensure that our confined sample size included women who participated in different components of the IINDIAGO intervention programme and had experienced different intervention intensities. Participants were contacted telephonically and invited to participate in the study. Some participants were interviewed on the same day of the invitation call, and others preferred to schedule an appointment that suited their commitments. There was no direct refusal to participate. However, 4 participants who scheduled appointments never accepted our follow-up phone calls and 3 participants' phones were unreachable. This information was recorded in a logbook.

Due to the interviews being conducted telephonically, we read and explained the study information to the participants and subsequently asked for consent to conduct our interviews. The IINDIAGO research team had also permitted us to use the obtained consent from participants, which included the process evaluation component of their trial and under which participants had agreed to be contacted for further interviews. However, they could freely decline to participate in such interviews. The permission to use participant consent obtained by IINDIAGO research team was done due to the significant role that this study contributes to the IINDIAGO trial process evaluation.

Contacting and interviewing participants was challenging. Our challenges were reaching women to recruit them into the study, inability to get the participants who made appointments, cellular network reception problems disrupting interviews, poor quality audio from

participants' cellular phones. To overcome these challenges, we obtained updated contact details from IINDIAGO counsellors who were still in contact with some participants. We received help from a professional sound engineer who helped clean and enhance the audio quality.

We intended to have an equal representation among all levels of exposure to the different milestones within the IINDIAGO intervention programme. However, those with minimal exposure were significantly difficult to track down or reach via telephone.

3.5.Data Collection

Data on all women who participated in the IINDIAGO intervention was used to obtain contact details for our potential participants. Participants were recruited and interviewed via a telephone call. The telephone call was conducted in a private room, where the phone was connected to a computer-controlled recording device for optimal audio quality. The decision to conduct the interviews telephonically was informed by the COVID-19 lockdown regulations that did not favour in-person interviews.

Data was collected through in-depth interviews using a semi-structured guide. In-depth interviews are optimal for collecting data on individuals' personal histories, perspectives, and experiences (Mack et al., 2011). The advantages of in-depth interviews are that they are flexible, responsive and they provoke in-depth thinking for research participants, which gives the researcher deep insights into the problems being studied (Farrelly, 2013). Open-ended questions and probes guided the in-depth interviews. The interview guide employed open-ended questions and probes that were developed in context to the study's objectives. The aim was to have questions and probes that would allow us to gather great information to address our objectives.

The interviews were conducted by one researcher who is fluent in English and isiXhosa. Although some participants indicated that their first language was Afrikaans or IsiXhosa, they were comfortable with interacting in English. A few IsiXhosa speaking women used both English and IsiXhosa languages during the interview. These interviews lasted between 15 and 25 minutes. The recorded interviews were saved into a local disk drive and backed up into a secured cloud drive, including transcriptions and translations.

A case record file in the form of a logbook was made to record contact details, phone call attempts and interview notes. A study number was allocated immediately after each interview. Information in the logbook was kept for reference and use during analysis.

A copy of the interview guide and format of the logbook is attached as Annex 12.

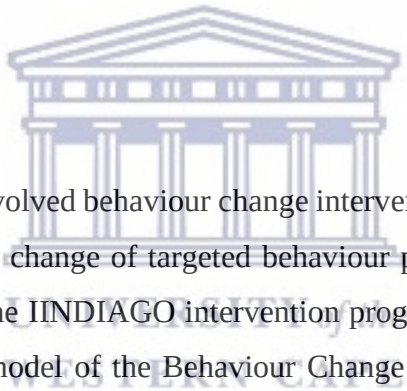
3.6.Data Analysis

Data analysis was done using qualitative thematic analysis. We used an inductive approach to allow our collected data to generate themes and a deductive approach to structure the themes into broad conceptual categories theorised to be the foundation of behaviour change in the COM-B model (Michie, Stralen and West, 2019).

The inductive approach allowed us to draw interpretations from the data without applying preconceived themes. The inductive approach consisted of open coding, creation of categories, identification, and separation of patterns. Open coding included reading and re-reading all transcribed data, listening to audio recordings of the interviews to ensure that the researcher is familiar with the collected data while recording notes of the themes and headings that are arising from the data.

We had four debriefing sessions with two senior researchers from the IINDIAGO trial. The reason for involving the IINDIAGO researchers was centred around; their knowledge on this topic; their extensive understanding of this population; and their availability to participate in a peer debriefing for a master's thesis paper. The debriefing sessions consisted of; presentation of findings; perceptions drawn from the interviews; and any significant emerging themes from the collected data. The first session involved; presenting the first batch (after 7 interviews) of findings to the IINDIAGO researchers; familiarization with the data; and understanding whether it suitable to address the study's objectives. In the second session (after 12 interviews) was a discussion around emerging themes and their meaning in context to the study's objectives. The third session (after 17 interviews) involved further discussions about the themes, emerging patterns, and a coding framework that will allow us to present the findings in a systematic way. The final session was centred around assessing whether the chosen framework is an appropriate tool to analyse and present findings in a way that addresses the research question and the study's objectives.

The identified headings and themes, including a short description, were recorded on a Microsoft word table (see appendix 13). The themes were colour coded to allow and aid data extraction from each interview. Further grouping of categories with similar themes and headings was done to generate broader categories or themes, which were then categorised into pre-existing conceptual categories of the COM-B model. The creation of categories is to increase the prospects of generating knowledge and to provide a means of describing and interpreting phenomena to aid understanding for both the researcher and the reviewer of the data (Cavanagh, 1997). The overall coding for this study was done manually using basic Microsoft office programmes to record, store and visualise the coded categories, themes, and patterns. For example, knowledge (gain or lack of knowledge) was a theme categorised under the Capability layer of the COM-B model. In addition, figure 2 is an illustration of the relationship between the themes and categories derived from the COM-B model.



3.7. Framework for Analysis

The IINDIAGO Intervention involved behaviour change interventions comprising coordinated activities directed at supporting change of targeted behaviour patterns amongst women with HFDP. See the description of the IINDIAGO intervention programme attached as Annex 11. We have chosen the COM-B model of the Behaviour Change Wheel (BCW) framework to analyse our findings.

3.7.1. Visual illustration of the relationship between the study's objective and analysis framework

Figure 1 is a visual illustration of the analysis framework, showing the relationship between the COM-B components and the study's objectives.

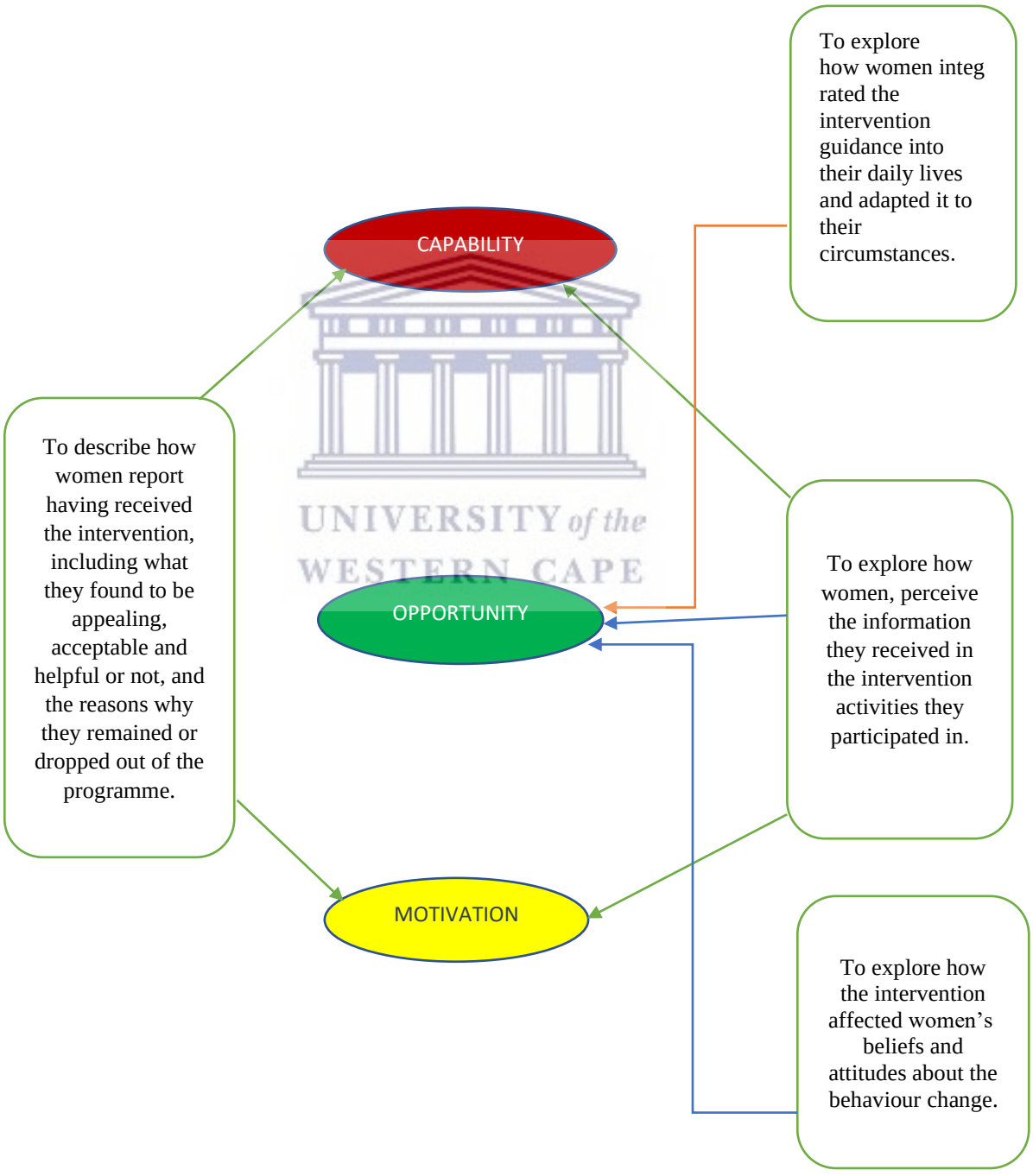


Figure 1: The relationship between study objectives and components of the COM-B

3.8.Trustworthiness

We aimed to ensure that the findings followed a criterion that is credible, authentic, transferable, dependable and can be confirmed (Court, 2018). Furthermore, the five dimensions were used to evaluate our findings (How Qualitative Data Analysis Happens : Moving Beyond 'Themes Emerged'. First edit, 2018). These five dimensions are fairness, ontological authenticity, educative authenticity, catalytic authenticity, and tactical authenticity. The telephonically conducted interviews required researchers to continually assess the meaningfulness and usefulness of the interaction processes that occurred during data collection.

3.8.1 Dependability

Dependability refers to the measure in which the findings are repeatable and reconcilable (Robson and McCartan, 2016). Dependability of finding allow for other researchers to employ and follow the same research procedure to obtain similar results and reach the same conclusions. Creating an audit trail is another way of achieving confirmability (Nakkeeran and Zodpey, 2012). The process of an audit trail is described as having a logical and traceable research procedure that is documented (Robson and McCartan, 2016). An audit trail can either be an intellectual account of events where the researcher accounts for how the research process evolved through reflective thinking; or a physical audit trail achieved through documentation of the decision process that influenced the study's methodology (Daniel, 2019). For this study, we have included this information within the methodology chapter under the appropriate headings.

Transferability

Transferability is achieved by ensuring that there is a detailed description of the environment and context of the research so that the readers can assess whether the results are transferable to their context (Maher et al., 2018). A detailed description of how the research was conducted was outlined throughout the methodology section. This includes the description of the IINDIAGO intervention programme and the methods underpinning it, and how data was collected.

3.8.2 Credibility

Credibility ensures that the research findings are what the researcher intended while reflecting the true social environment of the participants (Maher *et al.*, 2018). This process involves triangulation, member checking and peer debriefing (Creswell and Miller, 2000). This study employed the use of peer debriefing

The advantageous aspect of this study is that it draws interest from the IINDIAGO team of researchers who are interested in the outcomes of the study. The IINDIAGO researchers had expressed interest in assisting with the process of data analysis, specifically in ensuring credibility. This is important because the findings of this study form part of the process evaluation of the IINDIAGO trial. During the analysis process, we had peer debrief sessions where findings were presented to two senior researchers from the IINDIAGO trial. The IINDIAGO researchers were involved in the debriefing process because they carry valuable knowledge and understanding of the topic, study population and demographic characteristics. This enhances the ability of the researcher to draw deeper meanings from the data to increase the prospects of reflecting the true social environment of the participants in the findings. The first researcher is a medical doctor and anthropologist with a long-standing experience in clinical and public health research in the African setting. The second researcher is a clinical endocrinologist with long term experience in public health and research within the African context. The debriefing sessions consisted of a presentation of findings, perceptions drawn from the interviews and any significant emerging themes from the collected data. These sessions occurred at four instances; after having transcribed the first batch (seven interviews), second batch (after twelve interviews), last batch (after 17 interviews) and after having introduced the COM-B model to aid in structuring the findings.

3.8.3 Reflexivity

In order to enhance validity/credibility, we self-reported assumptions, perceptions, beliefs, and biases regarding the research work throughout the process. This process is referred to as researcher reflexivity (Creswell & Miller, 2000). Creswell & Miller (2000) argue that this process is the most crucial strategy to presenting a confirmable audit trail. The researcher is encouraged to acknowledge and keep a journal of all assumptions, biases, and beliefs that will continually be updated throughout the research process. During the data collection process, we had an intentional informal debrief about each interview with IINDIAGO counsellors to self-

report and aid self-reflection to assess assumptions, biases, and beliefs critically. The researcher was the project coordinator for the IINDIAGO trial. There had been some interactions between the researcher and some of the women during recruitment for the trial. Some of these women were subsequently randomized into the intervention and control groups. However, the researcher was blinded to the intervention activities. The study protocol required the study coordinator to be blinded from the intervention activities to reduce bias during analysis and major research activities conducted on the intervention and control group. Coming across some of the participants may have influenced their decision to participate in this study. On the contrary, this familiarity may have aided in establishing rapport with the participants.

The researcher's personal experience with the IINDIAGO trial, the subject position and the relationship with the counsellors may have affected the interaction with the participants and how their subjective experience and perspective was interpreted. The researcher was constantly aware of the demographic signifiers that may affect the interactions with the participants and the research process.

3.9 Ethical Consideration

Ethical approval for the study was acquired from the University of Western Cape Biomedical Research Ethics Committee (BMREC: BM20/10/13). The University of Cape Town Chronic Disease Initiative for Africa permitted us (ANNEX 9) to use IINDIAGO data and to perform our research activities as part of the IINDIAGO process evaluation included under the IINDIAGO trial ethics approval by the University of Cape Town (HREC: 829/2016)

All interviews were conducted telephonically due to the COVID-19 lockdown regulations. Participation was voluntary amongst those who were invited to participate. The study's information sheet was read to the participants before asking for consent. The information sheet contained the details of the study, benefits, risks, and confidentiality. All participants were given an opportunity to ask questions once the researcher had read the information sheet in the participant's preferred language. When the participant had understood the information given, the researcher subsequently asked for consent to participate in the study. When the participant had given consent, the researcher requested permission to audio-record the conversation.

The collected data were de-identified by replacing participants' personal details with a study-specific identification number. Therefore, participants' personal information was not used to

record the interviews, transcripts, and analysis. Anonymised audio recorded interviews and transcripts were kept in a private and secure cloud drive.

CHAPTER 4: FINDINGS

4.1. Introduction

This chapter presents the study findings, outlining them using the COM-B model framework. The chapter begins with describing participants' demographic characteristics, followed by an outline of how the COM-B model relates to the objectives and the findings to orient the reader. All findings have been analysed using the COM-B framework and are presented through tables, figures, and quotes characterised by the components of the COM-B model. The quoted text is necessary because it adds understanding of the findings and how they relate to the chosen framework.

4.2. Demographic characteristics of participants

This study took place within the Cape Metro Health District. Seventeen women living in the Khayelitsha, Southern, Western, Klipfontein, and Mitchell's Plain sub-districts participated in the study. Eleven women were black African, and six women were of mixed ethnicities (coloured). These women were referred to an antenatal hospital from their local antenatal clinic for advanced care during pregnancy. These antenatal hospitals were Groote Schuur Hospital, Mowbray Maternity Hospital, and New Somerset Hospital. The mean age of the participants was 31.65 (SD=5.9) with the ages ranging from 23 to 40. Of the participants, ten of the women are married, six of them are single, one is widowed, and one lives with their partner. Table 1 presents the socio-demographic characteristics of the study sample, including the number of IINDIAGO intervention sessions women had participated in.

Table 1. Summary of participants' demographic characteristics

Participant ID	Age	Employment Status	Ethnicity	Marital status	Number of intervention sessions attended
S1	23	Homemaker	Black African	Married	5
S2	40	Unemployed	Black African	Widowed	6
S3	27	Homemaker	Black African	Married	4
S4	33	Employed	Coloured	Married	5
S5	32	Employed	Coloured	Cohabitating	5

S6	31	Employed	Coloured	Married	3
S7	40	Self employed	Black African	Married	5
S8	27	Employed	Black African	Single	3
S9	32	Unemployed	Black African	Married	2
S10	32	Employed	Black African	Married	6
S11	36	Homemaker	Coloured	Married	4
S12	26	Employed	Black African	Single	3
S13	32	Unemployed	Black African	Single	3
S14	25	Employed	Black African	Single	4
S15	27	Employed	Black African	Single	3
S16	38	Employed	Coloured	Married	2
S17	37	Employed	Coloured	Single	2

4.3. Data Analysis Framework

In chapter 3 (methodology), we outlined the framework of analysis and how it relates to the objectives of this study. The results are structured and outlined according to the constructs of the COM-B model to understand sources of behaviours that underpin women's experience in participating within the IINDIAGO intervention programme. The COM-B constructs are Capability (C), Opportunity (O) and Motivation (M). Behaviour is determined when one feels that they have the mental and physical capacity (C), accompanied by social and physical opportunity (O), to perform the behaviour while having the desire or a need (M) to carry out the behaviour (Michie, Stralen and West, 2019). Figure 2 below shows the different themes that emerged from the findings. These themes represent factors that influenced the experiences of women who participated in the intervention programme. It also illustrates how the themes relate to the construct of the chosen theoretical framework. Table 2 shows IINDIAGO factors that influenced the experiences of women who participated in the programme. These factors are presented in activities that occurred when women were in the intervention program. These are the factors that underpinned the activities facilitated during the intervention programme.

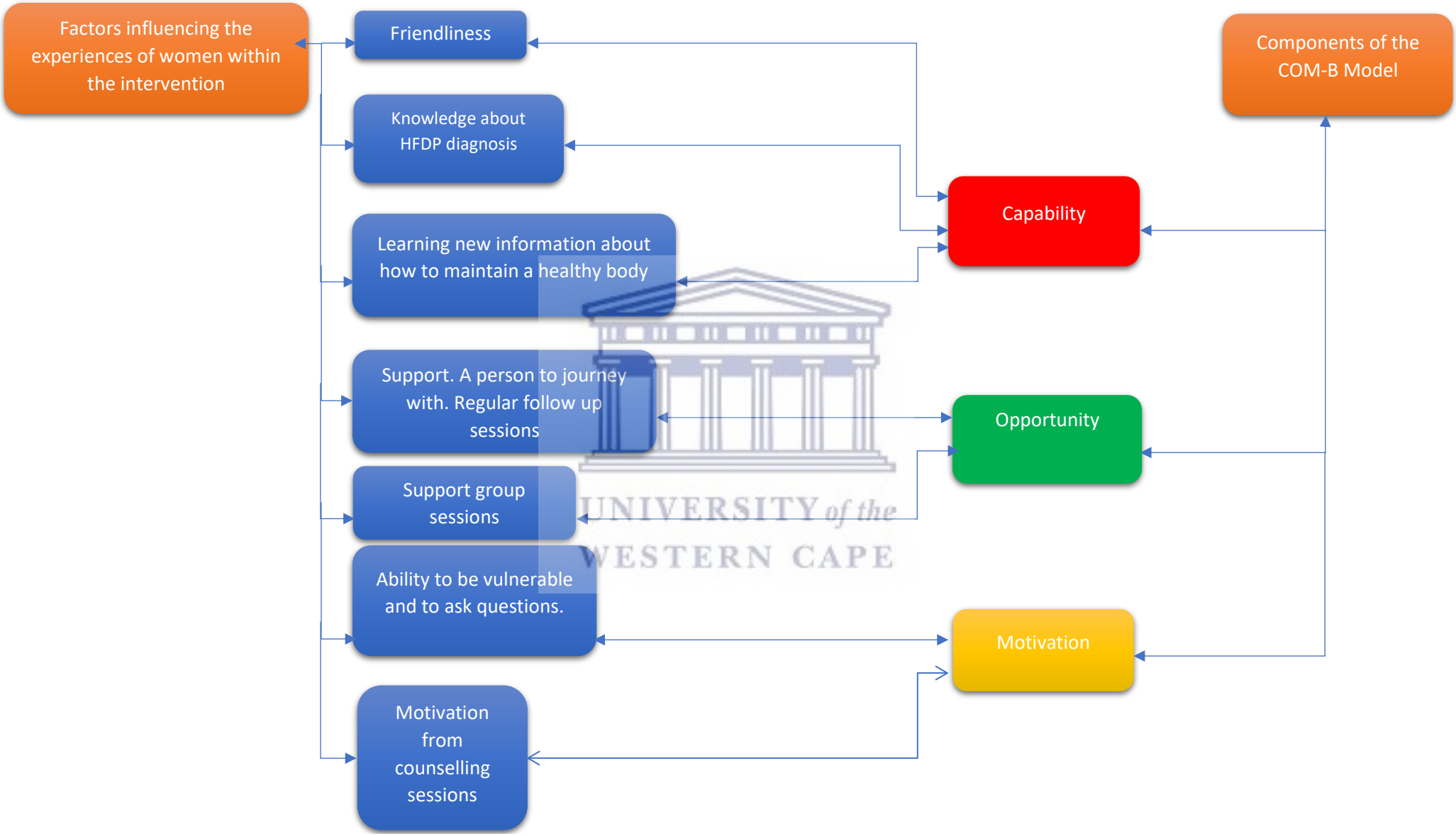


Figure 2. The relationship between factors influencing the experiences of women and the components of the COM-B

Table 2: IINDIAGO intervention programme specific factors influencing experiences of women who participated in the programme

CAPABILITY	OPPORTUNITY	MOTIVATION
PSYCHOLOGICAL • Women reported that the knowledge they received at the antenatal intervention sessions helped them understand HFDP and reduced the anxiety that came with the diagnosis. • Women reported a positive experience from the materials provided. They were able to understand and apply knowledge to change health behaviour. • Knowledge from shared personal experiences during group sessions had a positive effect. • The gain in knowledge and understanding of HFDP and a healthy lifestyle left women feeling in control of their pregnancy. • The relatability of the intervention counsellors seems to reduce the anxiety that comes with HFDP and improves a positive behaviour towards effecting healthy lifestyle change. **PHYSICAL** • Women reported gaining skills to facilitate a healthy diet through different cooking styles and knowing how to buy the right foods. • Women reported physical ability to engage in moderate physical activities through walking their kids to school, playing with kids outside the house, and intentional body exercise.	**PHYSICAL (Environmental circumstances)** • Women reported that they have time to implement a healthy lifestyle change. • The intervention provided access to resources. Women had counsellors who were always available, and they received material to help them with healthy cooking choices and physical activities. • Women reported finding ways to implement physical activities within their physical residential environment. **SOCIAL** • Women reported positive social support from families to implement healthy lifestyle changes. • Women reported that their family members did not have problems with dietary intake changes. There were no different meals amongst family members.	**REFLECTIVE** • Women reported that the HFDP diagnosis motivated them to change their lifestyles. They were intentional about changing their habits to improve their physical health. • Diet counselling by a dietitian is part of standard treatment for women with HFDP. Therefore, the added participation within the Intervention added to the intentionality of consciously deciding to lead a healthy lifestyle. • Interactions during antenatal counselling seemed to be a motivation in staying or leaving the intervention programme. **AUTOMATIC** • Psychological vulnerability is one of the factors driving women to stay within the intervention. E.g., Fear of developing T2DM.

4.4. Findings

4.1.1. Capability

We found three major themes that influenced the experiences of women during the intervention. The themes are 1) friendliness of the intervention counsellors; 2) knowledge about HFDP diagnosis for women with HFDP; 3) knowledge about maintaining a healthy body. Within these themes women gained information such as: how to control blood glucose levels, how to maintain a healthy diet, and being open about anxiety and stresses during a GDM, amongst many others. This seems to facilitate psychological and physical capabilities. Furthermore, inducing a positive experience whenever such themes appear during the intervention activities. Below, we discuss psychological and physical capabilities drawn from these themes.

Psychological Capabilities: *defined as the mental capacity to comprehend and engage with the processes necessary for behaviour change* (Michie *et al.*, 2005).

When women were interacting with the intervention activities (Counselling, guidance with educational resources), they presented capabilities to use the knowledge gathered to induce change to improve their physical health as part of treatment to HFDP.

Women reported that the knowledge they received at the antenatal intervention sessions helped them understand HFDP and reduce the anxiety that came with the diagnosis.

> *"I had a great experience with the whole programme because I was educated on what gestational diabetes is, and I got support. The programme was one of the things that I did not understand that the ladies(counsellors) worked through with me." S5*

> *"I thought the experience was great, it was also very motivational. It took away anxiousness and stress during pregnancy. I even miss those interactions." S12*

> *"I mean, I would not have known a lot of things. I would only notice that something is wrong after becoming unwell. I really would not have been good. At the hospital, I would not have received great guidance to improve my health. So, the IINDIAGO people were really taking care of us, even after giving birth, they followed us and showed care through their guidance and showing us how to do things" S13*

Women showed capabilities to comprehend and take in intervention knowledge and apply it to their daily lives to improve their physical health.

> "*I got advice about diabetic diet. I did not know what healthy food for diabetics was. I started using the advice a lot, and I saw a big change with my diabetes".* S1

> *"Because in the beginning, I did not know what gestational diabetes was, and I was not feeling well at that time, and then they explained to me what was going to happen and how they are going to help me with my health and weight. That really made me want to stay and want to find out more about the thing I was experiencing". S5*

> *" OK, the information is also very important because, like I said, I didn't know anything about blood sugar or what affects it, so yeah, they really made me wise about what's happening or what is really the reason for my gestational diabetes". S6*

Women understood how to implement physical activity in their lives, further showing their ability to comprehend the information they received from the intervention.

> *"They said we must take a lot of exercises, but not like going to the gym or big things, something like to clean around the house and walk around the neighbourhood" S1.*

> *"I thought that the exercise is mostly only through running or jogging but, even if you are doing your chores in the house, you are doing exercise. Everything that you do, you are doing exercise." S3*

> *"When I was there, they taught us how to exercise and make sure that our bodies are in the right shape" S7.*

> *"At least the exercises they showed us were a bit easy for me so, I could do one or two of them each day" S15*

Women who attended the group sessions appreciated the interactive activities they gained from such group sessions. The ability to share HFDP experiences in a group setting with other women who had HFDP seemed to reassure capability to be successful in improving physical health. In addition, they appreciated the opportunity to learn how to do exercises at home.

"*I wish it would not end because we walked together so well." S3*

"The part where I really enjoyed is the time when we got together, and the ladies would share a lot. Then you could actually learn from one another. For me, the get together was like a give and take". S5

"The experience was good; they were very supportive. We always did group gatherings. We discussed a lot of things in the gatherings to help each other, with all the other mothers that were there". S6

The women felt that they could easily relate with IINDIAGO counsellors, highlighting that the counsellors were easily approachable. This seems to improve their capacity to engage with the knowledge about leading a healthy life. Furthermore, women reported feeling less anxious and being in control of their general health and HFDP.

"First time, it was tough, and as time goes on, it was nice. Uhm, I got to experience and more so about my body. Everything was fine after." S10

"They made you feel at home, so if you want to tell them something personal about yourself, it was not so hard because they really made you feel almost like you are friends. Like I could explain my feelings and how I feel about a diet and not lie but speak openly about it because why? They Sommer [instantly] makes you feel at home man!". S4

"Even though during the lockdown, I did not see or speak to you guys. It has been a long time, but still, the information I learnt is still with me." S9

"So, I actually had a great experience. All the staff were always friendly, helpful; I could phone or message them whenever I wanted to." S6

"OK, it was nice to meet them, because all of your members are very nice. S12"

Physical Capabilities. *Physical capabilities are concerned with the physical ability required to execute the desired behaviour* (Michie *et al.*, 2005).

Women appeared to understand the positive impact of exercising (physical activity). However, they assumed that engaging in physical activity is only effective when it is done vigorously at places like gyms or sports facilities. On the contrary, they learnt how to intentionally integrate exercise within their day-to-day activities. This new skill left them feeling capable to engage in physical activities within the confines of their environment.

"I thought that the exercise is mostly only for running or jogging but, even if you are doing your job in the house, you're doing exercise. Everything that you do, you are doing exercise, because I was thinking that only running. It is the only exercise". S3

"Those sessions we had, and the guidance we received in those sessions. For example, when they ask us to try exercise, it would be nice because they would show us how to incorporate exercises during our daily activities. For example, Playing with the kids. Another example was incorporate exercises while cleaning the house." S10

"Yes! I am still exercising. I even push a truck wheel so that I can succeed in this diet thing". S2

4.1.2. Opportunity

We found two major themes influencing the creation of opportunities to lead a healthy life and navigate the GDM pregnancy and postpartum period. The themes are: 1) one on one support from the counsellors, where the counsellor provided support throughout the GDM pregnancy and the postpartum period and 2) support drawn during IINDIAGO intervention support group session, where women who had GDM shared experiences and advice amongst each other. Beyond these two themes, we found that the information embedded in the three themes influencing **Capability** played a role in influencing women to realise that there is an **opportunity** within their physical environment to engage and implement physical activity and healthier cooking options.

Physical Opportunity. *Refers* to the availability of resources, time to participate, access to resources and physical environmental barriers (Michie *et al.*, 2005).

Women reported having time to implement the skills acquired from intervention programme.. They utilised the resources they had to implement physical activity and healthier cooking options within their regular daily schedules. In addition, they were able to utilise opportunities within their environment to engage in physical exercises. For example, they reported being able to play with children on the street.

> *"I took your recipes, and I am practising doing them at home because I notice that you have nice recipes. It is healthy food, and not junk food". S7*

> *"At least the exercises that were a bit easy for me so I could do one or two of them each day" S15*

The intervention was a resource to create opportunities for women to change their lifestyles. Women appreciated the time and materials they were given to aid in the transition to healthier life choices.

> *"I got advice about the diabetic diet. I did not know what healthy food for diabetics was. I started using the advice a lot, And I saw a big change with my diabetes." S1*

> *"The ladies(counsellors) continuously followed up and checked on me. So that was quite a nice experience for me. S11"*

> *"Because I do not want to lie. Before, I used to just eat junk and do whatever I wanted. When we were there, they taught us how to exercise and make sure our bodies are in the right shape." S7*

The intervention programme was tailored for this specific demographic so that the training and activities are financially feasible to implement in real life scenarios for these women. Women appreciated being taught how to eat healthily without spending more money. They were also made aware of incorporating exercising within their normal daily activities.

"It's not so hard to follow those eating plans. It's not so hard at the end of the day. You think it's gonna be expensive, but by just cutting out some few things, man, it makes you healthier." S4

"It affected me quite well because I, after that. I lost some weight. I started walking more, started interacting more with the kids". S4

Women appreciated the ability to talk to a counsellor anytime they had a question. This seemed to increase the probability of controlling HFDP.

"I wish for every woman attending antenatal clinic at a hospital to understand the importance of participating in such an intervention programme because it is very helpful." S7

"I had a great experience participating in the intervention program because I learnt a lot about GDM, and I received a lot of support. The intervention programme clarified a lot of things I did not understand about GDM.S5".

"I actually had a great experience. All the staff members were always friendly, helpful; I could phone or message them whenever I wanted to ask any questions regarding diabetes that I had during the pregnancy" S6

Social Opportunity. *Social opportunity refers to personal beliefs, social and cultural norms, family influences and pressures* (Michie *et al.*, 2005).

Women reported that it was socially acceptable for them to implement a healthy lifestyle within their home environments. They found their families to be supportive. In addition, they expressed the desire to be health promoters, to educate women about HFDP and to equip them on how to implement healthy behaviour to maintain physical wellbeing. This desire highlighted that implementing such an intervention is not taboo but an inspiring and motivating factor within their environments.

"Yes, even at home, they joined me. My husband joined me to do the diet. It made a huge difference. Even my husband now is attending the gym at work; even when we are at home, we do exercises. Before I came to this group, I was not exercising. Even my husband was not exercising". S7

"I wish it (Intervention programme) can contribute even to others because all of us we don't know what is happening to our bodies until we will go to the hospital, and then we will notice that we've got A, B and C." S7

"I had a great experience, and today I am also a community health worker, and that what I learned there, I can actually implement today with other people." S5

Women who were interviewed did not speak about the workplace environment. However, one individual highlighted a stigma associating a healthy diet with being diabetic.

"I had conflicts with my colleagues because I changed how I ate. For example, when I drink fizzy drinks, I dilute them with water or coke Zero. They ask me if I am diabetic. I always respond that I am trying to change the way I eat, and I am also avoiding acid. I also eat plain double cream yoghurt with just cinnamon. This is how I am trying to change my habits". S8

The support group sessions were seen as an opportunity to learn from others who have had HFDP.

The part where I really enjoyed was the time when we got together, and the ladies would share and share. Then you can actually take from the other one. S5

4.1.3. Motivation

We found three major themes that influenced motivation; 1) the ability to be vulnerable 2) the ability to ask questions and 3) motivation drawn from the counselling sessions. These themes seem to indicate how women reflect on life and make better choices to lead a healthy life. In addition, women found support and accountability from the intervention programme, thus, motivating them to commit to a healthy lifestyle consistently.

Reflective Motivation. *Conscious decision-making, setting goals and plans* (Michie, Stralen and West, 2019).

Women reported that HFDP (diagnosis) motivated them to engage with the intervention. This gave them a sense of urgency to take charge of their health. They were intentional about changing their habits to improve their physical health. We also noted motivation that was facilitated by **Capability** and **Opportunity.** For example, when women realised **their physical and psychological capabilities** that were inspired and facilitated by the counsellors, they were enabled to try out physical activity and healthier cooking options which they discovered to be acceptable in their social environment. Furthermore, they discovered that their families and community were in support of their choice to lead a healthy life. This family and community support can be defined as a **social opportunity.**

"I like to dedicate myself to something, even if I do not understand. I want to know what is going on. Even more specially, something that is in my body. That is one of the things that I was afraid of insulin treated diabetes and having to use the needle thing. I was afraid." S7

"Life is important to me. That is why I stayed. As a person, you need to be reminded and kept accountable to improve your life; you cannot live life without people around you. That is the reason I am still part of this project. I also like the fact that when you have a problem with health issues, you have people who can clarify things for you." S2

"It is very important. It is so important because the impact of not eating healthy comes on without you knowing. So, constant training and guidance from them are very important to us. We gained knowledge of things we did not even know were important to us." S13

"I did not have knowledge; I do not want to die because of lack of knowledge. I would rather die knowing what is good and not good for me. I love things that are motivating in life. I love people who motivate others. I know time is difficult, but I love to learn about my health and my vitals." S12

Diet counselling by a dietitian is part of standard treatment for women with HFDP. Therefore, the added participation within the Intervention added to the intentionality of consciously deciding to lead a healthy lifestyle.

> *"I did know about diabetes and all that stuff; I did not realise how important this disease really is. But she told me a lot about it and... And how to change your lifestyle to eat well. But this helped me to realise how you are eating every day and how it can be harmful in the future" S6*

> *"Aah, yes, I saw a change from the time I started interacting with you guys. I used to suffer from swelling legs and feet; I used to sweat or have hot flushes. So, I tried following those instructions; I stopped eating a lot of starch and not to mix a lot of starchy foods on one plate, and I avoid eating starchy foods every day. I also started drinking a lot of water, especially after eating red meat. So, I really tried following their guidance. I'm not a tea-drinking person, but I also cut the quantity of sugar in tea on the occasional day that I drank tea. Honestly speaking, I saw a big change" S10*

> *"I thought it was changing my eating habits. Because I was not only diabetic, but I also had reflux...acid reflux. And since I have been changing my eating patterns. Everything changed for the better for me."* S5

Interactions during antenatal counselling seemed to be a motivation in staying or leaving the intervention programme. In addition, the initial counselling session involving background information on HFDP appeared to reduce the anxiety, fear, and worry that came with the new diagnosis. Women were able to be vulnerable and to ask questions about the HFDP. The vulnerability was facilitated by attributes of friendliness, relatability, and good manners that the counsellors presented when interacting with women.

> *"No, it was great speaking to them and communicating with them was fine. There was positive feedback, any questions I could ask, I could speak freely to them, and I'd always get positive answers." S16*

Automatic Motivation *refers to habits, reflex and impulsive behaviours triggered by external factors* (Michie, Van Stralen and West, 2011).

Psychological vulnerability is one of the factors that drove women to stay within the intervention. The thought of developing diabetes after pregnancy helped women to make conscious decisions to stay and participate in the programme.

> *"Basically, I changed everything. Maybe put the stuff in the oven or cook food out instead of frying. I changed my butter and the portion of the food I ate. I was supposed to eat less and not a lot because of the baby" S6.*

> *"I found that being part of the project influenced change in my life" S2.*

4.5. Summary of findings

Figure 3 summarises the factors that influenced women's experiences regarding the intervention programme. It illustrates the examples that led to the emerged themes influencing these experiences.

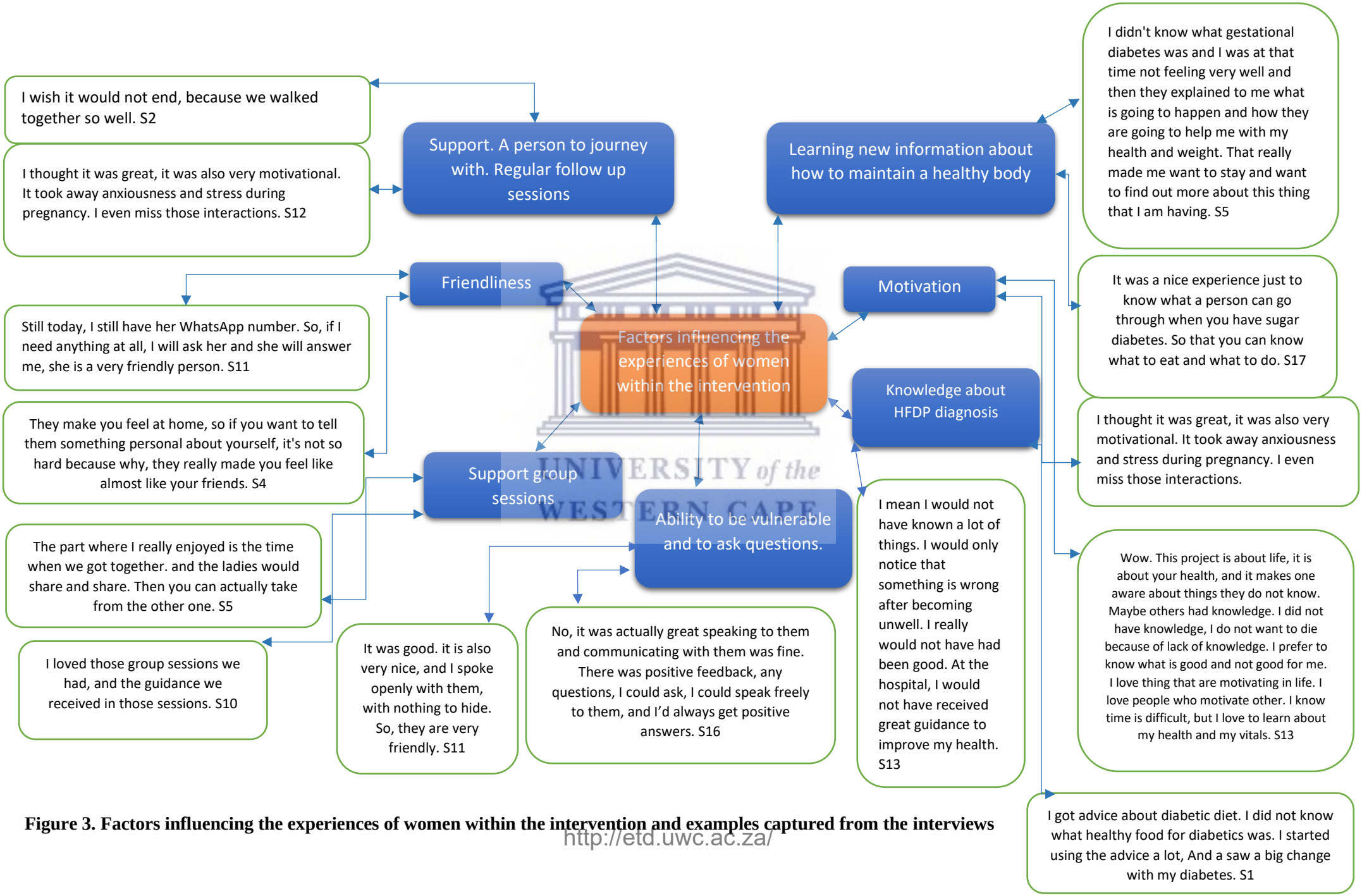


Figure 3. Factors influencing the experiences of women within the intervention and examples captured from the interviews

CHAPTER 5: DISCUSSION

5.1. Capability

We have seen several distinct themes and ideas emerging from the interviews and analysis against the COM-B framework. Several of these critical elements include friendliness, relatability, and good manners. These themes, when clustered together, can be interpreted as affability. Affability has a significant influence on how women experience the intervention programme. It was a common finding associated with women feeling capable of participating in the intervention programme. Affability incorporates social skills, cultural competence and communications skills, which are a group of behaviours and characteristics of emotional intelligence (Gregory and Austin, 2021b). Social skills refer to the ability to read and have an appropriate response to social cues. Cultural competence refers to the ability to understand, relate with, respect, and positively acknowledge cultural diversity. Communication skill refers to the ability to effectively speak with clarity, contextually and with a personal touch (Gregory and Austin, 2021a). These characteristics are evident in how women responded during the interviews. Each response seems to highlight the theme of affability. Researchers argue that when an intervention is delivered in a supportive and empathetical manner, it is more likely to have a positive effect because it allows for patients to ask questions freely and to engage with the carer on a personal level (Stage, Ronneby and Damm, 2004).

Knowledge about HFDP and how to lead a healthy life was another key factor contributing to women's experiences within the intervention. These included physical skills to carry out activities such as exercising or cooking. Gaining knowledge was consistent with their decision to remain part of the programme. When women had understood what HFDP was and how lifestyle modification can potentially alleviate the burden of disease, they appreciated the experience of participating in the intervention. In addition, they did not find the acquired knowledge to conflict with their environment, culture, or beliefs. When one of the women was asked how the participation made them feel, they responded, "*I stayed because I loved the project. Particularly during the time I was not feeling well. I would not have known all those things. More so, hearing them the way you guys delivered it" S13.* This response is consistent with recommendations from researchers regarding the impact of community targeted health education and its positive effects on lifestyle modification to prevent T2DM and improve patients' response to recommended treatments (Mekonnen, Abate and Tegegne, 2020).

Research suggests that the provision of detailed information can improve psychological capability during diagnosis (Van Ryswyk *et al.*, 2015). The intervention activities were facilitated at the antenatal hospital and during postpartum. Findings from meta-analysis studies of women with HFDP and GDM argues that health care provision that was carried out from diagnosis (antenatal) to postpartum follow-up care can yield a positive outcome amongst women who participate in T2DM prevention care after giving birth (Van Ryswyk *et al.*, 2015). This is consistent with our findings; women who participated in both IINDIAGO intervention programs (antenatal and postpartum sessions) presented a positive desire to continue participating in such programmes aimed at reducing the risk of progressing into T2DM.

5.2. Opportunity

The social and emotional support that women experienced during one-on-one sessions and focus group sessions created an opportunity for women to engage, learn and draw support from one another. Social and emotional support are key factors in facilitating a successful behaviour change (Kaiser, Razurel and Jeannot, 2013). The intervention programme created opportunities such as learning to use their home and surrounding as a safe space for physical activities and how to maintain a healthy diet in an affordable way, amongst many other recommendations. During HFDP pregnancy, women and their families tend to focus on ensuring that the pregnancy goes well. This is accompanied by directing all finances to the pregnancy at the cost of all other family members (Stage, Ronneby and Damm, 2004). The opportunities that were created by the intervention programme seemed to lessen this burden, therefore directing women to feel more positive, which contributed to their overall experience. In addition, women presented a positive attitude towards implementing the newfound knowledge in their daily lives. Although some acknowledged that lifestyle behaviour change is hard, they showed courage and were free to discuss their shortfalls in these sessions. None of the women reported a clash between the knowledge received and cultural norms or beliefs (Van Ryswyk *et al.*, 2015). Women appreciated the opportunity to meet with the IINDIAGO counsellors alongside their well-baby clinic appointments. This was seen as a time saver because women did not need to allocate different timeslots or find other avenues for postpartum screening of T2DM and ongoing diet counselling. This is consistent with the recommendations of preventing progression to T2DM for women who had HFDP (Martis *et al.*, 2018).

5.3. Motivation

Participating in the intervention programme reduced the overwhelming distress that comes with the new diagnosis of HFDP. The ability to be vulnerable with the counsellors and being able to find support and clarity at a time of diagnosis contributed to a positive experience of the participants. Studies have shown that support is crucial after HFDP diagnosis, and it helps reduce overwhelming distress that comes with HFPD pregnancy (Kaiser, Razurel and Jeannot, 2013). Although psychological vulnerability might have influenced some women to participate, it did not seem to motivate them to stay within the intervention programme. The different components that contributed to them realising that they have capabilities and opportunities to lead a healthy life resulted in women feeling motivated. In addition, they reported that the counsellors were motivating and relatable enough for them to be vulnerable. Women's psychological motivation is achieved when they have received targeted psychological interventions, including providing necessary information to facilitate behaviour change (Parsons *et al.*, 2018). In summary, the combination of all the intervention activities motivated women to commit to their participation within the intervention programme.

CHAPTER 6: CONCLUSION

The current study was inspired by the IINDIAGO intervention programme to learn more about the experiences of women who participated in the programme. This chapter draws conclusions from the findings and what they mean to the researcher. We will describe the experiences of women who participated in the programme, how they made meaning of it, and how it affected their beliefs and attitudes about behaviour change.

6.1. Conclusion

Using the COM-B theoretical framework enabled us to elicit behaviour that influenced women's experiences during their intervention programme. Major influences were centred around capability, with knowledge gained and truly mastered by women and affability of the counsellors as the driving factors. The findings suggest that most activities that the IINDIAGO counsellors facilitated were delivered with excellent social skills, cultural competence and communications skills that influenced a positive response from the participants. Women found the knowledge acceptable, not offensive, nor clashing with who they are. In addition, they appreciated the opportunities created by participating in the programme. They were interested in learning new information, and the results suggest that they had a positive experience while engaging with the information. The desire to engage and learn more information contributed to their decision to stay in the intervention programme. Opportunities to learn new information and draw support during HFDP and at postpartum, including the motivation women received from the counsellors and other intervention activities, influenced the experiences of women during their participation. This resulted in women finding time to engage with activities and the desire to incorporate them into their daily lives.

In summary, the intervention activities assisted women in realising their capability to change their behaviour and to lead a healthy lifestyle. It provided women with opportunities to learn, engage and draw support during their pregnancy and postpartum. This resulted in women feeling motivated, thereby resulting in an overall positive experience.

6.2. Significance

This study contributes to the process evaluation of the IINDIAGO trial. It evaluates the process of implementing the behavioural prevention intervention by counsellors to women and how the implementation of the intervention may affect the routine functioning of the health services and systems in which it is meant to be integrated.

6.3. Limitations

The nature of this study (qualitative research design) does not allow for generalisability. We were unable to conduct the research until saturation because of the limited sample size recommended by the University of Western Cape for a mini-thesis. However, the inability to reach saturation is common in qualitative descriptive research studies. We employed purposive sampling methods to allow for an equal representation of all women who participated in the IINDIAGO trial. However, despite our extensive efforts, we could not reach women who had minimal interaction with the intervention activities or those who dropped out. Therefore, our findings may omit negative feedback from those who dropped out.

The COVID-19 lockdown regulations prevented us from having face to face contact with our participants, limiting us to conducting interviews via telephone calls. In addition, this affected the availability of a research fieldworker who was going to assist with Afrikaans when needed, co-facilitation of interviews and helped bridge the gap between me (a male researcher) and our participants who are females. Therefore, we acknowledge that we may have missed face-to-face nuances that may have aided in collecting more information during our interviews and nuances due to language barriers. The intervention programme was concluded in January 2020; therefore, we may have experienced recall bias, where participants omit or inaccurately recall their experiences during the intervention programme.

6.4 Recommendations

This evaluation has provided us with insight on the effectiveness of the IINDIAGO intervention programme and the impact it had on women who participated in the study. Therefore, we recommend the following to strengthen the findings of the INDIAGO Trial and measurement outcomes.

6.4.1 The importance of each intervention activity within the IINDIAGO intervention program

- The IINDIAGO team should assess the effectiveness of each intervention activity and milestone. Although participants had different exposures to the intervention activities, they presented with; common positive experiences and gain in knowledge about leading a healthy lifestyle. This implies that there are certain activities that were significant in achieving a positive response and outcome from the participant. In addition, this may enhance the practicality of implementing such an intervention in the public health sector.

6.4.2 Education and Counselling for women with GDM

The findings in this study highlighted the importance of educating women about GDM, including motivational counselling to women with GDM.

- The IINDIAGO team should explore avenues of educating women without having to physically meet women in the community or the hospital. This can enhance reach to those who may not have the time or resources to access the day hospital or are working long shifts. For example, to incorporate readings and counselling tips within maternity case record books. An additional example would be to utilise social media platforms such as TikTok to educate people about GDM.

6.4.3 Recommendations for further research studies.

- A similar trial to IINDIAGO should be carried out in rural arears to obtain; a holistic picture of the state of care and education received by women with GDM in antenatal public hospital and clinics; and to assess if the IINDIAGO intervention programme can be adopted in a different region within South Africa.

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8. Apendices

Appendix 1. Interview guide

1. Can you please tell me about your experiences in participating in the IINDIAGO study?
    - How did you experience the interactions with the counsellors?
    - How did the interaction impact your lifestyle choices?
    - What was the highlight of being part of the study?
2. Do you think being part of the study affected your experience of having GDM
    - Please explain in what way? How? Or why?
3. What do you think about the guidance you received?
    - What conflicts did the guidance have on your culture or any of your beliefs?
    - What knowledge did you gain?
4. How did participating in the study affect your life?
    - How did it affect you daily activities?
5. What motivated you to remain part of the programme for this long (this can refer to an early drop out or a participant who completed the 12 months follow up)
6. What parts of the programme would you change for it to be more helpful for women like you?

Appendix 2. Information sheet

UNIVERSITY OF THE WESTERN CAPE

Private Bag X 17, Bellville 7535, South Africa
Tel: +27 21-959 2809, Fax: 27 21-959 2872
E-mail: soph-comm@uwc.ac.za

Project Title: Exploring the experiences of women participating in a lifestyle intervention programme who had Hyperglycaemia First Detected in Pregnancy

Participant information sheet

INTRODUCTION

My Name is Takalani Tshikovhi. I am a student from the University of Western Cape in South Africa. I am conducting a research study amongst women who participated in a lifestyle intervention programme for women with high blood sugar level first detected in pregnancy – a specific type of diabetes in pregnancy. This research is a requirement and forms part of the training for the completion of my master's degree. I am inviting you to participate in this research project because you participated in the lifestyle intervention programme. In this study we would like to explore the lived experiences of women who participated in the lifestyle intervention programme. By participating in the study, you will contribute knowledge that will help the researcher to improve the lifestyle intervention programme to best support women in maintaining a healthy lifestyle and blood glucose management after pregnancy

ANSWERS TO QUESTIONS YOU MAY HAVE

Who is being invited to participate?

I am inviting women who participated in the IINDIAGO lifestyle intervention programme.

Who has given permission for the study?

I have permission for the study from the Human Research Ethics Committee of the University of Western Cape. This special committee is set up to review proposals for research

studies to make sure that they meet the required ethical standards, for example, in the way they treat study participants.

What will participation involve?

If you agree to be part of the study, I call you at your convenience to conduct a simple interview. The interview will only be conducted once and will not last longer than one hour. We will have an open discussion about your experience as a participant of the IINDIAGO lifestyle intervention programme. The interview will be audio recorded with your permission. The recording will assist the researcher to listen to the interview in case they forgot some of the details you shared.

What about confidentiality?

After the interview, you will be allocated a study ID number and your name will no longer be used on records of our interview and transcript. No names will be used in the write up of any of the research findings. I will be the only one working with the information you provide. Only the researcher will have access to your consent form, and this will be kept separate to the information you have given me in the interview.

Are there any risks involved in taking part in this research?

Our interaction and talking about your experience of participating in the IINDIAGO lifestyle programme should not carry any risk to you. Should you experience any psychological distress during the study, or discomfort, an appropriate referral will be made to a social worker at your nearest day hospital, or a lay councillor from the University of Cape Town. At any point during the interview session you have the right to refuse to answer questions you are not comfortable with, and you may stop participating in the study at any point without giving reasons. As already mentioned, your name and personal details will be kept strictly confidential and will not be given to anyone outside of the research team.

What if one does not agree to take part?

Your participation in the study is entirely voluntary. You are free to withdraw from the study at any point, even if you have already agreed to take part.

What are the benefits of this research?

This research is not designed to help you personally. However, the results will help the researchers improve the lifestyle intervention programme to best support women with high

blood glucose (sugar) first detected in pregnancy. The overall results can be used to argue for the Department of Health to implement it as part of their routine healthcare services for women with high blood glucose (sugar) first detected in pregnancy. Your participation will not cost you anything, except your time.

What if I have questions?

This research is being conducted by Takalani Tshikovhi from the School of Public Health at the University of the Western Cape. If you have any questions about the research study itself, please contact Takalani at**: 073 048 6555, tshikovhitk@mail.com**

Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

Prof U Lehmann
Head of Department: School of Public Health
University of the Western Cape
Private Bag X17
Bellville 7535
ulehmann@uwc.ac.za

Prof Anthea Rhoda
Dean: Faculty of Community and Health Sciences
University of the Western Cape
Private Bag X17
Bellville 7535
chs-deansoffice@uwc.ac.za

This research has been approved by the University of the Western Cape's Biomedical Research Ethics Committee.

Biomedical Research Ethics Committee
University of the Western Cape
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7535
Tel: 021 959 4111
e-mail: research-ethics@uwc.ac.za

Appendix 3. Informed Consent Form

UNIVERSITY OF THE WESTERN CAPE

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Tel: +27 21-959 2809, Fax: 27 21-959 2872
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Project Title: Exploring the experiences of women participating in a lifestyle intervention programme who had Hyperglycaemia First Detected in Pregnancy

INFORMED CONSENT

By signing this document, I confirm that I have read the above information and understand it. I also confirm that the purpose of this study has been explained to me, that I have had an opportunity to ask questions and I am satisfied with the answers and explanations that have been given to me.

If I agree to participate in this study, I understand that:

1. My participation in this study is entirely voluntary and I am free to withdraw at any time without having to give a reason.
2. All information will be treated with the strictest confidentiality and my identity will not be included in the results of the study.

Please tick one of the boxes below:

- YES, I would like to take part in this study ☐ NO, I do not wish to take part in this study

PARTICIPANT:

Printed Name	Signature/Mark or Thumbprint	Date & Time

RESEARCHER:

Printed Name	Signature/Mark or Thumbprint	Date & Time

Biomedical Research Ethics Committee

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Appendix 4. IsiXhosa information sheet

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Project Title: Exploring the experiences of women participating in a lifestyle intervention programme who had Hyperglycaemia First Detected in Pregnancy

Iphepha lolwazi labathabathi nxaxheba.

Intshayelelo

Igama lam ndingu Takalani Tshikovhi, ndingu mfundi kwi Dyunivesiti yaseNtshona Koloni apha eMzantsi Afrika. Ndenza uphando kubantu ababhinqileyo, ababe thabathe inxaxhebe kuphando iLifestyle intervention ebantwini abane qondo lweswekile eliphezulu (hyperglycaemia), ethi yona ufumaneke xa umntu ekhulelwe (luhlobo lwe Swekile ethi ifumane amanina xa ekhulelwe). Ndiyakumema uba ubeyingxalenye yoluphando kuba wawuthabathe inxaxheba kuphando iLifestyle Inteverntion Programme, ngokwenza njalo uyakusinceda sikwazi ukhangela amava kwabasetyhini ababeyinxalenye ye projekti yase kuqaleni. Ngokuthatha inxaxheba kolu phando, uya kufa'isandla kulwazi oluza kunceda umphandi ukuba aphucule inkubo yokungrnelela kwindlela yokuxhasa ngokufanelekileyo abasetyhini ekugcineni indlela yokuphila esempilweni kunye nalawulo lweswekile yegazi emva kokukhulelwa.

Uphendula imibuzo onoba nayo

Ngubani omenywayo?

Simema abantu basetyhini ababe yingxalenye ye projekti iLifestyle Interevention.

Ngubani onike imvume yalu phando?

Ndinemvume yalemfundo kwiKomiti yeeNqobo ezseSikweni yaphando lwabantu kwiDyunivesithi yaseNtshona Koloni. Le komiti ekhethekileyo yenzelwe ukuba iphonononge

izindululo zezifundo zophandoukuze ziqiniseke ukuba ziyahlangabezana nemilinganiselo yokuziphatha efanelekileyo, umzekelo, kwindlela abaphatha ngayo abathathinxaxheba.

Ukuthatha inxaxheba kubandakanya ntoni?

Ukuba uyavuma kuba yinxalenye yoluphando, ndikubiza ngexesha elilungele wena ukwenza udliwano ndlebe olu lula. Udliwano ndlebe lenziwa kube kanye, kwaye alidluli kaphezulu kwe yure. Siza kuba nengxoxo evulelekileyo malunga namava akho njengomthathi nxaxheba kwinkqubo ye Iindiago yokuphila. Udliwanondlebe luya kurekhodwa ngemvume yakho. Lonto iyakunceda umphandi kuba aphinde amamele enkcukacha zonke.

Imfihlelo yona?

Emva kodliwano ndlebe, uzonikwa inombolo kwaye ne gama lako alisetyenziswa kuphando. Akukho magama aya kusetyenziswa xa kubuya iziphumo. Ngabaphandi bodwa abazokwazi amagama abantu kwaye nabo baqeqeshiwe uba bagcine imfihlelo.

Ingaba ikhona imingcipheko ekhoyo xa uthe wathabatha inxaxheba kuphando?

Ukudibana kwakunye nokuthetha ngamava akho okuthatha inxaxheba kwinkqubo yendlela yeINDIAGO inokuthwala umngcipheko othile. Ukuba kungathi ngelithuba uthatha inxaxheba kuphando uzive uphathwa luxinizeleko lwengqondo okanye ukungakhululeki uyakudityaniswa nonontlalontle kwisibhedlele sasemini esikufuphi kuwe okanye udityaniswe umncebisi kwi Dyunivesiti yaseKapa . Nanini na ngexesha lo dliwano ndlebe uyakwazi uyeka uphendula nangeliphi ixesha unganikezi isizathu.

Kwenzeka ntoni umntu xa engafuni uthatha inxaxheba?

Ukuthatha inxaxheba kwakho kuphando kukuzithandela. Ukhululekile uba ungayeka nangaliphi ixesha noba ubuvumile ngapha mbili. Ukunga vumi ubayinxalenye yophondo okanye uyeka kwakho phakathi uphando, akusoze kuchaphazele indlela uzophathwa ngayo ekliniki okanye nakwesiphi isibhedlele

Ungafunda ntoni ngothatha inxaxheba kolu phando?

Olu phando alenzelwanga unkunceda wena. Nangona kunjalo, iziphumo ziya kunceda abaphandi baphucule inkqubo yokungenelela yobomi ukuxhasa ngcono abasetyhini abane glucose ephezulu(iswekile) ufumaneka xa umntu ekhulelwe. Iziphumo zizonke

zingancedisana ne sebe lezeMpilo ukuyisebenzisa njegenxalenye yeenkonzo zabo zokunakekelwa kwempilo kwabasetyhini abane glucose (swekile) ebona xa bekhulelwe.

Ukuba ndine mibuzo?

Olu phando lenziwa ngu Takalani Tshikovhi okwi skolo sePublic Health kwiDyunivesithi yaseNtshona Koloni, xa unemibuzo ungaqhakamshelana naye kule nombolo: **073 048 6555, tshikovhitk@mail.com**. Ukuba unayo imibuzo malunga nolu phando kunye nama lungelo akho njenngomthathi nxaxheba wophando okanye ufuna ukuxela naziphi iingxaki ozifumeneye ezingxulumene nophando nceda unxulumane apha:

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Prof Anthea Rhoda
Dean: Faculty of Community and Health Sciences
University of the Western Cape
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Oluphando lupasiswe sisigqeba sekomiti yophando lYunivesithi yaseNtshona Koloni kunye nekomiti yezemigomo Biomedical.

Biomedical Research Ethics Committee
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Appendix 5 IsiXhosa informed consent form

UNIVERSITY OF THE WESTERN CAPE

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Project Title: Exploring the experiences of women participating in a lifestyle intervention programme who had Hyperglycaemia First Detected in Pregnancy

Imvume eyazisiweyo

Ngoku tyikitya apha kweli phepha ndiyagqina ukuba ndiyifundile ingcaciso ingentla kwaye ndiyayiqonda. Ndiyangqina ukuba injongo yoluphando ndiyichazelwe, ndibenethuba lokubuza inibuzo kwaye ndonelisekile ngeempendulo neenkcaciso endizinikiweyo.

Kuba ndiyavuma uthatha inxaxheba kolu phando, ndiyakwazi oku:

1. Ukuthatha inxaxheba kwam kolu phando kukuzithandela ngokupheleleyo kwaye ndikhululekile ukurhoxa nangaliphi ixesha ngaphandle kwesizathu.
2. Lonke ulwazi luya kunyangwa ngemfihlo engqongqo kwaye isazisi sam asizo kufakwa kwiziphumo zesifundo

Khetha enye kwezi zilandelayo:

- Ewe ndiyavuma ubayinxalenye yolu phando

- Hayi andifuni ubayinxalenye yolu phando

Participant:

Igama **Tyikitya** **Umhla**

Reseacher:

Igama **Tyikitya** **Umhla**

Biomedical Research Ethics Committee

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Appendix 6. Afrikaans information sheet

UNIVERSITY OF THE WESTERN CAPE

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Tel: +27 21-959 2809, Fax: 27 21-959 2872
E-mail: soph-comm@uwc.ac.za

Study Title: Exploring the experiences of women participating in a lifestyle intervention programme who had Hyperglycaemia First Detected in Pregnancy

Inligtingsblad vir deelname

INLEIDING

My naam is Takalani Tshikovhi.Ek is 'n student aan die Universiteit van Wes-Kaapland in Suid-Afrika. Ek doen ‘n navorsing studie onder vroue wat aan lewenstyl intervensieprogrammedeelgeneem het vir vroue met hiperglukemie wat die eerste keer tydens swangerskap opgespoor is –‘n spesifike tipe diabetes tydens swangerskap. Hierdie navorsing is ‘n vereiste en vorm deel van die opleiding vir die voltooiing van my Meestersgraad. Ek nooi U uit aan hierdie navorsingsprojek deel te neem omdat U aan die leefstylintervesieprogrammedeelgeneem het. In hierdie studie wil ons die lewendige ervarings van vroue wat aan die leefstylintervensieprogrammedeelneem, ondersoek. Deur aan die studie deel te neem, dra by wat die navoser kan help om die lewensstylintervensieprogrammete verbeter en ondersteun vroue die beste om ‘n gesonde leefstyl en bloedglukosebeheer na swangerskap te handhaaf

ANTWOORDE OP VRAE WAT U MAG HET

Wie word genooi om deel te neem?

Ek nooi vroue uit om deel te neem aan die IINDIAGO –leefstylintervensieprogram.

Wie het toestemming gegee vir die studie?

Ek het toestemming vir die studie van Die Etiese Komitee vir Menslike Navorsing van die Universiteit van Kaapstad. Hierdie spesiale komotie is saamgestel om voorstelle vir

hersieningstudies te hersien om seker te maak dat dit aaan die vereiste etiese standaarde voldoen, byvoorbeeld aan die manier waarop hulle deelnemers behandel.

Wat sal deelname inhou?

As U instem om deel te neem aan die studie, skakel ek U op U gemak om'n eenvoudige onderhoud te voer. Die onderhoud sal slegs een keer gevoer word en sal nie langer as een uur duur nie. Ons asl 'n oop gessprek voer oor U ervaring as deelnemer aan die IINDIAGO leefstylintervensieprogram. Die ondehoud sal met U toestemming deur klank opgeneem word. Die opname sal die navorser help om na die onderhoud te luister as hulle 'n paar besonderhede vergeet wat U gedeel het.

Wat van vertroulikheid?

Na afloop van die onderhoud kry U 'n studie ID nommer u naam sal nie meer gebruik word op rekords van onderhoude en transkripsies nie. Geen name sal gebruik word by the opstel van navorsingsbevindinge nie Ek sal die enigste wat sal werk met die inligting wat U verskaf het. Slegs die navorser het toeegang tot U toestemmingsvorm. Dit sal apart gehou word met die inligting wat U in die onderhoud aan my gegee het.

Is daar risiko's verbonde aan die ddelname aan hierdie onderhoud?

Ons interaksie en praat oor U ervaring van deelname aan die IINDIAGO-leefstylintervensieprogrammekan 'n mate van risiko inhou. As U enige sielkundige probleme tydens die studie ervaar, of as U ongemaklik is, sal toespaslike verwysing na 'n maatskaplike werker in U naaste hospital of 'n lekelid van die Universiteit van Kaapstad gerig word. Op enige punt tydens die onderhoudsessie het U die reg om te weier om vrae te beantwoord waarmee U nie gemaklik is nie, en U kan op enige stadium ophou om aan die studie deel te neem sonder om enige redes daarvoor te gee. Soos reeds genoem, sal U naam en persoonlike besonderhede streng vertroulik gehou word en sal nie aan iemand buite die navorsingspan gegee word nie.

Se nou mens stem nie in om deel te neem nie?

U deelname is heeltemal vrywillig. U kan op enige studium van die studie onttrek, selfs as u reeds ingestem het om deel te neem.

Wat is die voordele van hierdie navorsing?

Hierdie navorsing is nie ontwerp om U persoonlik te help nie. Die resultaat sal egter die navorsers help om die lewensstylintervensieprogrammete verbeter om vroue met hoe bloedglukose (suiker) die beste te ondersteun die eerste keer tydens swangerskap ogespoor was. U deelname sal u niks kosnie, behalwe U tyd.

Wat as ek vrae het?

Hierdie ondersoek word gedoen deur Takalani Tshikovhi van die Skool van Openbare Gesondheid aan die Universiteit vad Wes-Kaapland. As U vrae het oor die navorsingstudie self, kontak asseblief Takalani by: 073 048 6555.

As U enige vrae het oor hirdie studie en Uregte as navorsingsdeelnemer, o as U enige probleme wat U ondervind het met betrkking tot die studie, wil rapporteer, kontak asseblief:

Prof U Lehmann
Head of Department: School of Public Health
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ulehmann@uwc.ac.za

Prof Anthea Rhoda
Dean: Faculty of Community and Health Sciences
University of the Western Cape
Private Bag X17
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Hierdie navorsing is goedgekeur deur die Universiteit van Wes-Kaapland se Biomediese Navorsingsetiekkomitee.

Biomediese Navorsingsetiekkomitee
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Appendix 7 Afrikaans informed consent

UNIVERSITY OF THE WESTERN CAPE

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Study Title: Exploring the experiences of women participating in a lifestyle intervention programme who had Hyperglycaemia First Detected in Pregnancy

INLIGTINGSTEMMING

Deur hirdie dokument te onderteken, beaam ek dit ek het bogenoemde inligting gelees en dit verstaan. Ek bevestig ook dat dit doel van hierdie studie aan my verduidelik is, dat ek die geleentheid gehad om vrae te stel en ek is tevrede met die antwoorde en die verduideliking wat aan my gegee is.

As ek instem om ann hierdie studie deel te neem, verstaan ek dat:

1. My delname in hierdie studie is geheel en al vrywillig en dit is my vry om te eniger tyd te onttrek sonder om 'n rede daarvoor te gee.
2. Alle inligting sal met die strengste vertroulikheid hanteer word en my idenititeit sal nie by die resultate van die studie ingesluit word nie.

Merk'n onderstaande blokkie asseblief:

☐ Ja, ek wil graag aan hierdie studie deelneem. ☐ Nee, ek wil nie aan hierdie studie deelneem nie.

DEELNEEMER:

Gedrukte Naam	**Handtekening/Merk of Duimafdruk**	**Datum & Tyd**

NAVORSER:

Gedrukte Naam	Handtekening/Merk of Duimafdruk	Datum & Tyd

Biomedical Research Ethics Committee

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Appendix 8. Request to use IINDIAGO DATA.

UNIVERSITY OF THE WESTERN CAPE

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Dr Katherine Murphy

Chronic Initiative for Africa (CDIA)

University of Cape Town

Re: Request to undertake data collection as part of IINDIAGO process evaluation

I am currently pursuing a master's degree in public health at the University of Western Cape. I am required to complete a mini thesis to graduate in this programme. As an employee of the CDIA, I have grown a significant interest in the IINDIAGO research study. I want to conduct a research study aimed at exploring the experiences of women who participated in the intervention programme. This research study can be used as part of the process evaluation that is stipulated in the IINDIAGO protocol, and it will be ideal for me to fulfil my mini thesis requirements to complete my degree.

I would like to request permission to use the IINDIAGO data to complete this research study. I trust that you will find this valuable.

Yours sincerely

Mr Takalani Tshikovhi

Appendix 9.Approval for use of IINDIAGO data.

Chronic Disease Initiative for Africa

Postal Address: c/o Department of Medicine · Faculty of Health Science
University of Cape Town · Private Bag x3 · Observatory ·7935
Physical Address: J47 Room 86 · Old Groote Schuur Hospital Building · Observatory ·7935
Telephone: +27 21 650 5228
Email: Directorate: Naomi.Levitt@uct.ac.za
Senior Secretary: Chantal.stuart@uct.ac.za
http://www.health.uct.ac.za/fhs/research/groupings/cdia/about

29 September 2020

To whom it may concern

Re: Public Health Masters student: Mr Takalani Tshikovhi

As one of the principal investigators on the IINDIAGO trial, I would hereby like to confirm that Takalani Tshikovhi has our full permission to undertake data collection under the auspices of our project and to use the contact information of trial participants to sample respondents. The individual qualitative interviews he is planning to conduct with study participants were specified in the original trial protocol and will form part of the ongoing process evaluation.

This work has the approval of the human sciences research ethics committee at UCT (HREC reference 829/2016: IINDIAGO: an integrated health system intervention aimed at reducing type 2 diabetes risk in disadvantaged women after gestational diabetes in South Africa).

Takalani's master's mini thesis project is regarded by the IINDIAGO investigators as a valuable contribution to the greater study. We offer him our full support and would like to thank him for choosing this topic for this master's thesis.

Yours sincerely

Dr Katherine Murphy

UNIVERSITY of the WESTERN CAPE

60 YEARS of hope, action & knowledge

11 December 2020

Mr T Tshikovhi
School of Public Health
Faculty of Community and Health Sciences

Ethics Reference Number: BM20/10/13

Project Title: Exploring the experiences of women participating in a lifestyle intervention programme (IINDIAGO) who had Hyperglycaemia First Detected in Pregnancy

Approval Period: 11 December 2020 – 11 December 2023

I hereby certify that the Biomedical Science Research Ethics Committee of the University of the Western Cape approved the scientific methodology and ethics of the above mentioned research project.

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

Please remember to submit a progress report annually by 30 November for the duration of the project.

Permission to conduct the study must be submitted to BMREC for record-keeping.

The Committee must be informed of any serious adverse event and/or termination of the study.

Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape

Director: Research Development
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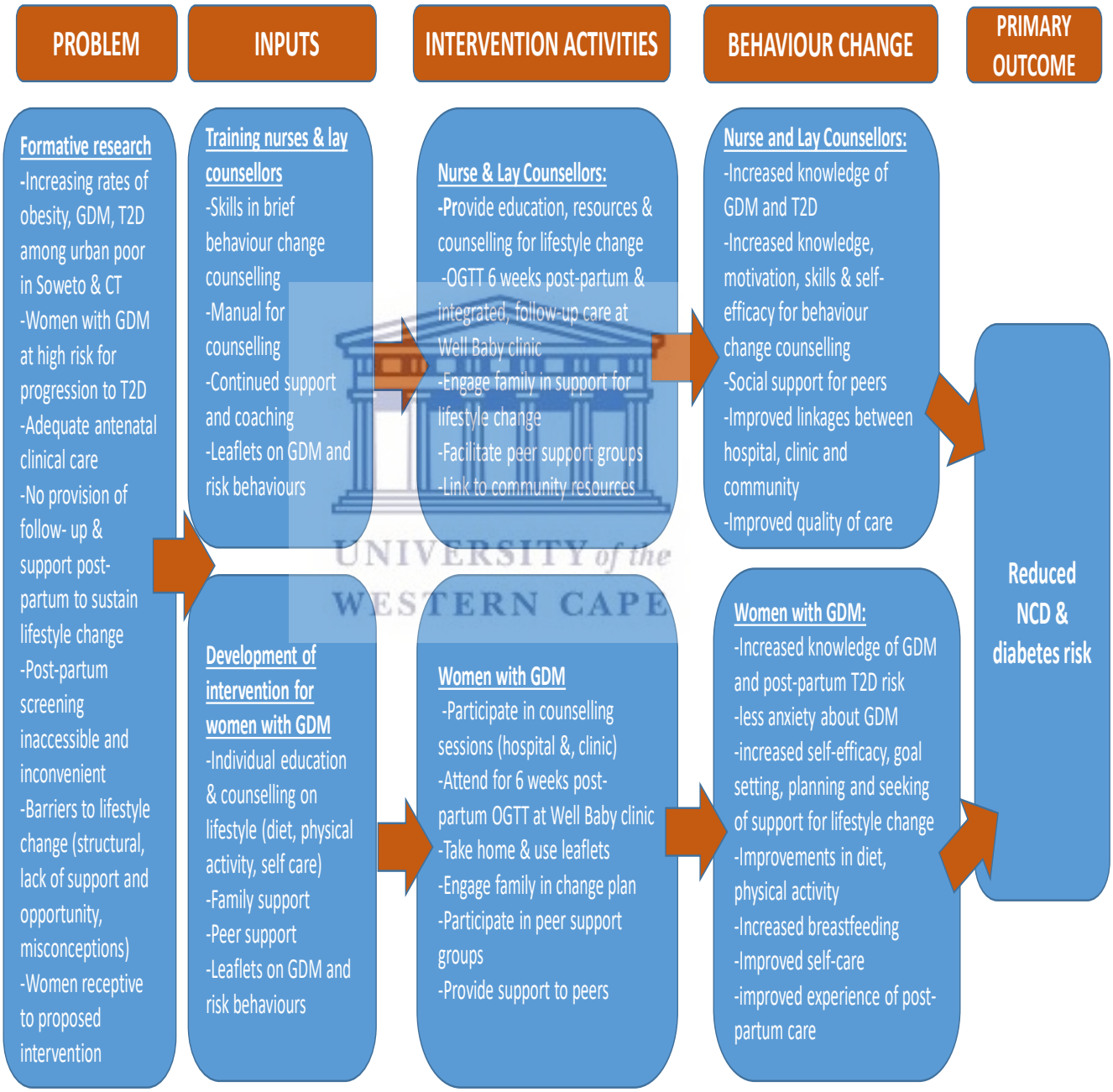
NHREC Registration Number: BMREC-130416-050

Appendix 11. The description of the IINDIAGO Intervention programme

The intervention components were informed by the logic model developed from both published data and formative research. The intervention will take place in the hospital, clinic and community setting delivered by nurses and lay counsellors (who will be of the same profile as either the existing health promoters or the HIV lay counsellors employed in the public-sector health service



Hospital based antenatal intervention: Women recruited into the intervention arm at 29-33 week's gestation will be eligible to receive two face-to-face, individual counselling sessions from an IINDIAGO lay counsellor at the hospital where they are receiving their routine

antenatal GDM care. These sessions will focus on the nature of GDM, the risks to both the mother and baby and the importance of a healthy lifestyle, not just for the pregnancy, but for the long term. It will be emphasised that the GDM diagnosis provides an opportunity and cue for the woman, as well as her family, to review their current lifestyle and take measures to prevent T2DM and other non-communicable disease. The benefits of breastfeeding and how to cope with stress and anxiety will also be raised as topics for discussion. The first session will take place as soon as possible after recruitment and the second, any time before delivery.

Post-partum clinic-based intervention: All women in the intervention group will receive a point of care OGTT at the Well Baby clinic during the routine 6-week post-partum visit, scheduled for the mother to bring the infant to the clinic for immunisation. The participants will have a fasting, finger prick blood sample drawn. They will then be asked to drink 75g glucose in 250ml water and a second finger prick sample with be drawn 120 min later. This test will be performed by the lay counsellor employed by IINDIAGO. XXX device will be utilised that has been shown to provide accurate assessments compared to laboratory methods. Participants will be contacted in the week prior to the appointment and another reminder SMS will be sent the day before the appointment to reinforce the need for fasting. The IINDIAGO lay counsellor will liaise with the clinic staff to facilitate completion of the routine 6-week baby visit.

Behaviour changes counselling: Women in the intervention arm will be offered a total of four brief, individual, face-to-face counselling sessions at the Well Baby clinic with the IINDIAGO lay counsellor at each of the routine visits for immunisation i.e., 6, 10, 14 and 36 -weeks post-partum. These sessions will focus on supporting the woman to achieve and maintain healthy lifestyle changes in the post-partum period. From the outset, the counsellor will negotiate with the woman which target behaviours will be prioritised in the four sessions. These may include diet, physical activity, weight loss, smoking, alcohol use, breastfeeding and stress or anxiety, depending on a brief risk assessment and the woman's expressed needs and readiness to change. The counsellor will actively engage the woman in setting behaviour change goals and developing a personalised risk reduction plan appropriate to her circumstances, resources, and preferences.

As previous GDM interventions report lack of social support as a significant constraint, the counsellor will prompt the woman to seek the support of a close family member or friend in the behaviour change plan. This person will be welcome to accompany the woman during follow up visits. Follow up counselling will be offered by the same counsellor and focus on enhancing self-efficacy, positively reinforcing progress, problem solving and dealing constructively with relapse. The counsellor will keep contact with study participants via mobile phone messaging and follow up any women who do not attend for their scheduled clinic visits. This will communicate continued social support and caring, in addition to reducing potential drop out from the study.

Community based intervention: In between the counselling sessions at the clinic, women may receive a discretionary home visit by the same lay counsellor, with whom she has built up a relationship during the Well Baby clinic counselling sessions. These visits could take place at around 8, 12 and 16-weeks post-partum and will focus on assisting the family (and/or other members of the household) engage with healthy lifestyle change. The lay counsellor will also organise at three peer support group sessions, once there are enough women in the intervention arm living in the same general residential area. These will take place at an agreed local venue or at one of the women's homes if preferred and at a time agreed upon by participants. Women will be encouraged to bring along their support person or buddy. The group sessions will be tailored to the expressed needs of each group, and will focus on sharing experiences, problem solving common barriers to lifestyle modification and exploring how to access available community resources and opportunities. They will also involve practical activities such as demonstrations on how to prepare healthy meals and how to shop for healthier products, as well as physical activity classes. It is envisaged that these sessions would last several hours at a time. The lay counsellor will encourage the formation of WhatsApp groups among women for additional social support and will discuss how the peer support groups could possibly be sustained beyond the study.

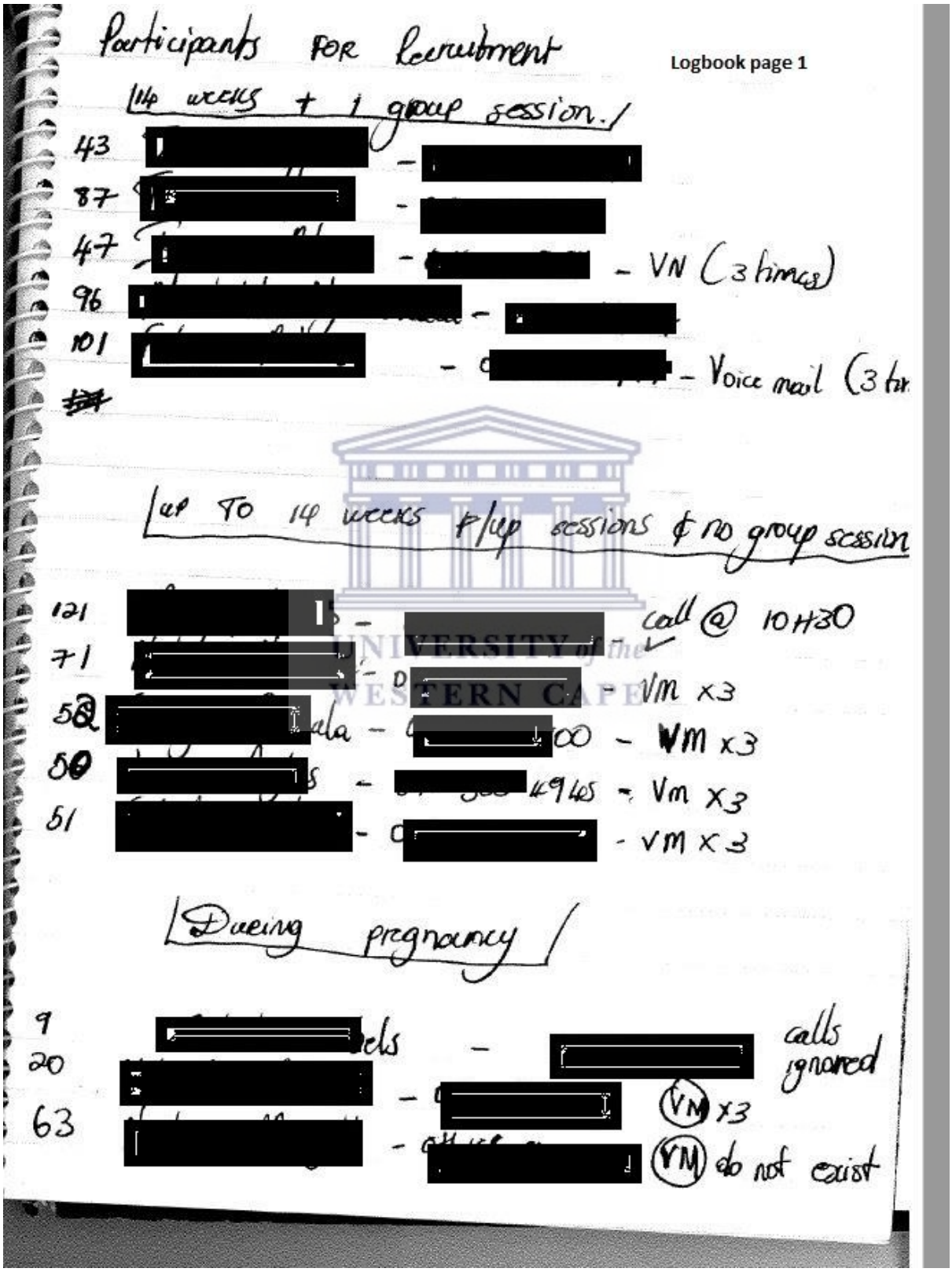
Health literacy resources: During the counselling sessions, participants will be offered education/self-help materials that will provide further information on lifestyle change and teach behaviour change skills. CDIA has already researched and developed such tools on physical activity, diet, alcohol use and smoking (see www.ichangeforhealth.co.za). These will be made available for this intervention. These materials include real-life testimonials from

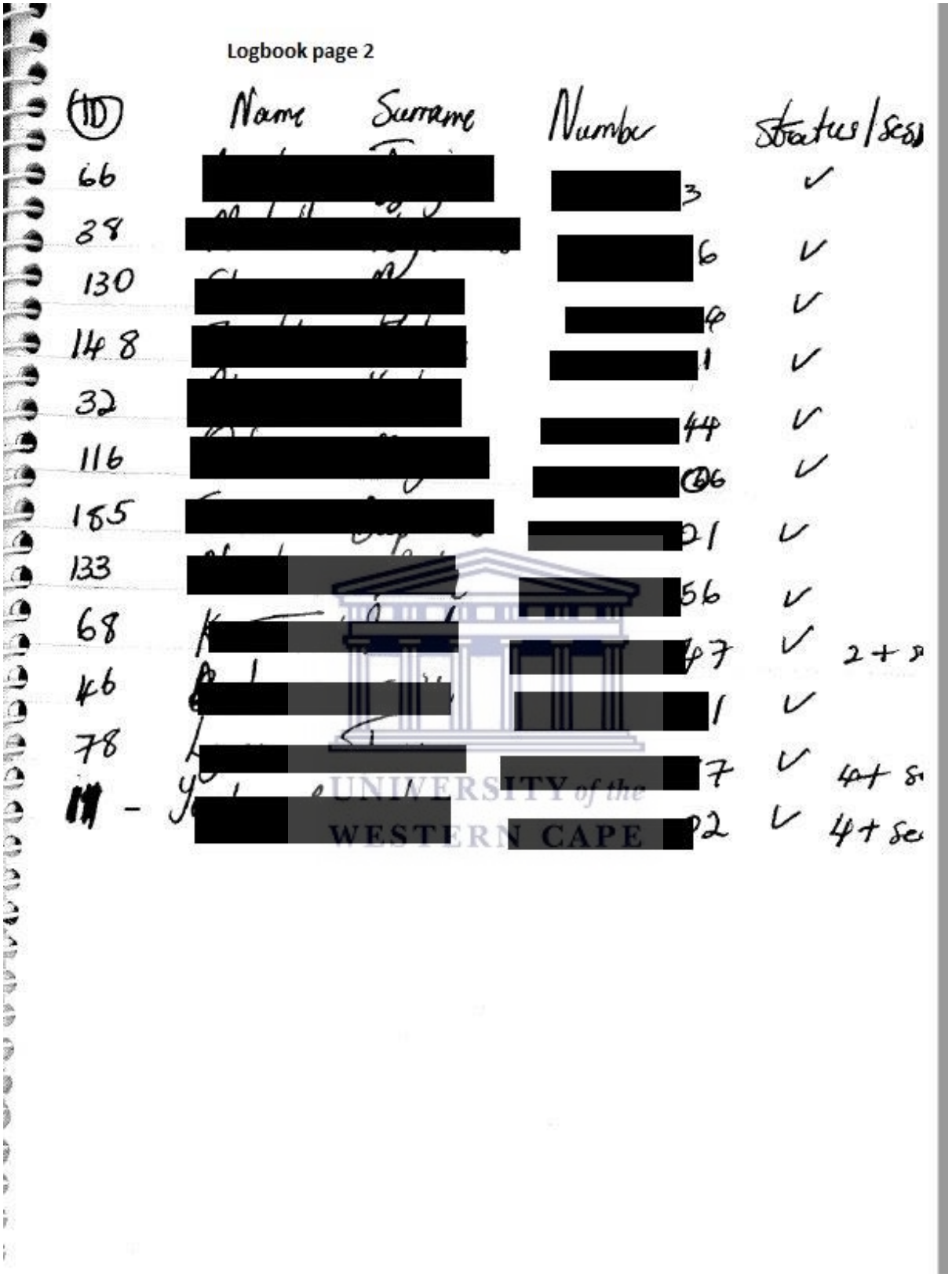
the same target community who model successful lifestyle change, despite facing many of the barriers to achieving change experienced by people of low socio-economic status. Further complementary resources will include leaflets on GDM & T2DM, post-natal depression and breastfeeding.

Training and approach: The IINDIAGO lay counsellors will be trained in a patient-centred counselling method blended from three evidence-based methods: (i) Motivational Interviewing (Rollnick et al, 2002), (ii) the 5As Best Practice Guidelines (Witlock et al, 2002) and (iii) "Healthy Conversations", (Barker et al 2011). During the training they will learn how to: approach behaviour change; ask open, discovery questions to better understand a woman's context and perspective; and support women to identify opportunities for change and set goals that are realistic and feasible in their circumstances. The training will also include content knowledge on the nature of GDM and T2DM and the relevant behavioural risk factors. The blended method is congruent with empowerment models for self-management of chronic disease and the "guiding style" of Motivational Interviewing, which aims to actively engage patients in a conversation about behaviour change, evoke their own motivations to change, promote autonomy in decision making and enhance self-efficacy.

The training will consist of three intensive training sessions, plus individual follow up coaching by the trainer and intervention team support sessions every month. Knowledge of and competency in the method will be evaluated before and after the training. The intervention team will be required to reach a level of acceptable competency before they are tasked with implementing the intervention. The trainer will provide at least one session of follow up observation and coaching in the real life, clinic setting before the intervention starts. The intervention team will be provided with a comprehensive resource package containing guidelines on the counselling method and information on GDM, T2DM and their behavioural risk factors.

Appendix 12: Logbook





Appendix 13: Analysis Chart

Analysis Chart and themes

Identified Theme	Description
Knowledge	Knowledge. Not knowing of Risk. Awareness about diabetes. Finding it easy to lead a healthy and affordable diet life. Remembering advice about exercising. COM-B
Intervention programme as part of public care	Should be part of government care. Or rather we expect PHC to recommend
Feeling uncared for in the hospital	Services not offered by day hospital
Experiences within the intervention	Great Experience or Any experience, The get together experience. Someone available to talk to. Openness
Relatability of counsellors	Relatability to IINDIAGO counsellors and ability to be vulnerable
Lifestyle Change due to intervention	Lifestyle change.Positive effects like losing weight, blood sugar levels becoming normal. "My life changed to the better", Making the pregnancy better
Effects on beliefs	Culture/traditions/religion not affected by counsellor's advice COM-B
Desire to share knowledge	The need to share the knowledge with others by participants. Participants becoming a CHW
Motivation	What motivated the staying or leaving the project COM-B
Challenges in implementing recommended activities	The difficulty to uphold the lifestyle highlighted
Feedback from Participants	Recommendations from participants