FACTORS INFLUENCING ATTRITION FROM A ONE-YEAR POSTPARTUM LIFESTYLE INTERVENTION FOR WOMEN EXPERIENCING DIABETES IN PREGNANCY

This master's research contributes to the process evaluation of the IINDIAGO trial:

A RANDOMIZED CONTROLLED TRIAL OF AN INTEGRATED HEALTH SYSTEM INTERVENTION AIMED AT REDUCING TYPE 2 DIABETES RISK IN WOMEN AFTER GESTATIONAL DIABETES IN SOUTH AFRICA (IINDIAGO)

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A Dissertation Submitted to the Faculty of Health Sciences, University of the Witwatersrand, in fulfillment of the requirements for the degree Master of Science in Medicine

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1. DECLARATION

DECLARATION

I, Irene Masuluke, student number [1970313], declare that this dissertation is my work and that I contributed adequately towards research findings published in the article stated below which are included in my Dissertation.

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Agreement by co-authors: By signing this declaration, the co-authors listed below agree to the use of the article by the student as part of her Dissertation. In cases where the student is not the 1st author of a published article, the primary supervisor must explain (under comments) why the student is entitled to use the paper for her degree purposes.

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Submitted to The South African Medical Journal.

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DEDICATION

In memory of my Son

Mikhongelo

2020 – 2020

PUBLICATIONS

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ABSTRACT

Gestational diabetes mellitus (GDM) is a glucose tolerance disorder detected during pregnancy and has risks for both the mother and fetus. GDM prevalence in South Africa is estimated to be as high as 26%. Women with GDM are at high risk of developing type 2 diabetes mellitus (T2DM) though this risk can be managed by healthy lifestyle interventions. However, attrition from such intervention programmes is still a challenge. Therefore, this study aimed to assess factors affecting women's attrition from a one-year randomized controlled lifestyle intervention. This was a cross-sectional descriptive-analytic qualitative study nested within an ongoing pilot trial IINDIAGO (Integrated health system intervention aimed at reducing T2DM risk in women after gestational diabetes) in Soweto. Women were recruited from the intervention arm of IINDIAGO using extreme case sampling to create two groups: Group A - "retained women" who received at least 40% of the intervention sessions; Group B - "disengaged women" who received less than 30% of the intervention sessions. Twenty-eight interviews were conducted using a semi-structured topic guide, with transcripts thematically analysed using inductive and deductive approaches. Facilitating factors for retention were the perceived benefits received i.e. friendliness, kindness, and education, the and perceived risk of GDM and T2DM interventions. In comparison, disengaged women reported challenges related to their personal situation (work commitments, schedule conflicts, relocation, illness, childcare, travel costs); communication challenges with the intervention team; and fear/anxiety related to medical procedures to the COVID-19 pandemic as reasons for attrition.

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LIST OF ABBREVIATIONS

DPS:	Diabetes prevention study
DPP:	Diabetes prevention program
IINDIAGO:	Integrated health system intervention aimed at reducing type 2 diabetes risk in women after gestational diabetes in South Africa: a randomized controlled trial
GDM:	Gestational diabetes mellitus
OGTT:	Oral Glucose Tolerance Test

CHAPTER 1 - INTRODUCTION

1.1 Brief background and problem

Gestational diabetes (GDM) is a glucose tolerance disorder that is first diagnosed during pregnancy(1,2). GDM is a growing public health problem with short- and long-term consequences for both the fetus and the mother. With a lack of a coherent framework, a constant vocabulary, and an agreement about social changes, public health assembles, by political analysts, economists, social and behavioural analysts, health systems analysts, and a range of medical practitioners. This anthropologist suggests that only if there is an agreement amongst every practitioner involved in health global challenges can be solved by applying the biosocial approach(76,77). GDM is reported to affect 14% of pregnancies globally (1, 3). Although data are scarce, the prevalence of GDM in South Africa has been estimated to be as high as 26% (3, 4). Without appropriate glucose management, both women with GDM and their offspring have an increased risk of developing Type 2 Diabetes Mellitus (T2DM) as well as other metabolic conditions later in life (3, 5, 6).

However, evidence shows that there are ways to reduce the risk of T2DM in those at higher risk including pregnancy-related risks like GDM (7–9). Lifestyle interventions, primarily diet and physical activity modification with weight management, may help prevent the progression to T2DM in individuals identified high-as risks (10). South African guidelines recommend that women diagnosed with GDM be immediately referred to their health facility or management including counselling and health education from health care practitioners (11). Evidence shows that lifestyle interventions have a health benefit for high-risk individual (6,12). Findings from the RADIEL Study established that postpartum lifestyle intervention for those with a history of GDM seem to have some beneficial effects in reducing progression to T2DM, however, an intervention initiated during pregnancy and continued during the first postpartum year might be even more effective (13). Meanwhile, the Finnish Diabetes Prevention Study (DPS) found that an intensive lifestyle intervention produced long-term beneficial changes in diet, physical activity, and clinical and reduced diabetes risk. Furthermore, in the Finland study, lifestyle intervention was additionally effective in decreasing the excessive birth weight of infants born to mothers at risk for GDM (12,13). Studies have found a reduction of 58% in the incidence of

diabetes mellitus in high-risk individuals (with impaired glucose tolerance) after an average of three years of lifestyle intervention focusing on diet and physical activity (14).

This type of intervention is a feasible option to prevent T2DM and can be implemented in the primary health care system (15). In South Africa, despite overburdened health systems, examples exist of combined services that have had success integrating primary healthcare (PHC) and engaging clinic users, for example, the prevention of mother-to-child transmission of HIV (PMTCT) (16). As such, integration of lifestyle intervention programs within 'usual' health-service appointments for women with GDM during and after pregnancy may lessen the burden and increase participation and engagement. One benefit of a lifestyle intervention soon after the diagnosis of GDM is greater awareness of future perceived T2DM risk. When women are aware of the risk they might want to continue or stay in the trials and less attrition might be encountered (17,18).

While much effort is placed on enhancing the health and well-being of the participants through lifestyle intervention, there is often less focus on the retention of participants in these intervention programmes (19). Considering the resources invested in the planning and structuring of lifestyle intervention programmes, it is imperative to understand why people choose to engage with or disengage from such initiatives to inform program effectiveness (15,20).

Evidence shows that women may have various reasons to disengage or remain engaged (21). For example, women with GDM may participate in interventions primarily because they are concerned about their infant's successful delivery and increased risk of adverse health outcomes, which could motivate engagement and the adoption of preventive behaviours during pregnancy (11). After the delivery of the baby, however, perceptions of risk may change, and the study may see a decrease in participation. Additionally, even though individuals may decide to seek help and comply with the recommended lifestyle interventions or education offered, various issues related to the healthcare system may also influence their behaviour. For example, a conflict between participants' work schedules and their time of clinic attendance is a frequently cited reason for attrition (15, 22,23).

In addition to retention in clinical or public health interventions, the need to formulate strategies to retain participants in trials has been recognized (24). Understanding the factors that influence

attrition is important to help future researchers in understanding their participant's behaviour and how best to support participants to minimize attrition. Good retention is necessary to provide sound evidence to inform policy and practice: complications in participant recruitment, retention, and attrition have been recognized as serious challenges that potentially threaten the success of clinical trials (25,26). For example, high attrition can reduce the statistical power and threatens the internal validity of a study (15,27). To address participant attrition, few studies have investigated issues related to the attrition of individuals in clinical trials and observational studies with a very little data available (28,29). Findings show that irrespective of the benefits associated with the lifestyle intervention program, the challenge of attrition persists (9,29). The challenges of attrition and retention in trials, therefore, can be similar to the challenges of attrition and retention in interventions outside of a clinical trial setting.

Therefore, the aim of this study was to explore retention and attrition in women with GDM recruited to a pregnancy and post-partum health system-integrated lifestyle intervention being evaluated in the pilot study: Integrated Intervention for Diabetes Risk after Gestational diabetes (IINDIAGO).

1.2 Study aims and objectives

The overall aim of this study was to explore factors related to attrition and retention in women recruited to the intervention arm of IINDIAGO. The specific objectives were:

I. To investigate participants' perspectives on attrition and retention in this diabetes prevention lifestyle intervention after gestational diabetes.
II. To explore facilitators and barriers experienced by women in receiving the intervention counselling sessions.

1.3 Dissertation layout

This dissertation consists of four chapters. Chapter 1 includes a brief introduction to GDM, the importance of retention and attrition, and the research aim and objectives. Chapter 2 presents a literature review introducing GDM, how to manage it, and attrition challenges associated with interventions that focus on reducing the risks associated with GDM. It also presents what other researchers have reported related to factors associated with retention and attrition and

introduces the IINDIAGO trial in which this project was embedded, including the conceptual framework guiding IINDIAGO and this study. Chapter 3 presents the major findings of the study in the form of a manuscript submitted to The South African Medical Journal. Chapter 4 is the overall discussion.

CHAPTER 2 – LITERATURE REVIEW

This chapter outlines the importance of GDM as a public health problem and presents the existing literature and theories on retention and attrition in healthy lifestyle interventions aiming to reduce the postnatal risks associated with GDM. It also introduces the study in which this master's project was nested, the IINDIAGO project, together with the conceptual frameworks guiding IINDIAGO and this master's project.

2.1 Gestational Diabetes Mellitus prevalence and management

Gestational diabetes mellitus (GDM) is any degree of impaired glucose tolerance first detected during pregnancy (30,31). It has been reported that GDM affects 14% of all pregnancies globally and that its incidence has been steadily rising (23,32). However, there is a lack of data on the global prevalence of GDM (15). Furthermore, there is a lack of consensus and uniformity in the screening standards, definition, and diagnosis criteria for GDM, limiting comparative assessment of the GDM prevalence across countries and regions.

GDM is regarded as the seventh leading cause of morbidity and mortality worldwide for both the mother and infant (3). It is evident that there are risk factors associated with the risk factors of developing GDM which include advanced and advancing maternal age (i.e., age > 35 years) (33), family history of diabetes, and high pre-pregnancy weight as reported by body mass index (BMI) (34). GDM has been related to significant short- and long-term adverse health outcomes such as premature birth, macrosomia, and stillbirths (31). GDM is associated with adverse pregnancy outcomes and an increased risk of future metabolic conditions in mothers and their offspring, further contributing to the growing burden of non-communicable diseases (28). The long-term consequences for the mother include developing T2DM, and for the child, increasing risks over the first 20 years of their life being overweight/obese, glucose, intolerant, and with elevated blood pressure. It has been shown that patients with T2DM are more likely to develop

macro-vascular diseases, as T2DM is known to cause severe damage to the kidneys, eyes, and heart, as well as the vascular health system more generally (23,35,36).

The increasing prevalence of GDM worldwide may reflect advanced childbearing age and increased maternal obesity (3). This is particularly concerning, as South African women are considered among the most overweight globally (37). In South Africa, the prevalence of GDM is estimated to be as high as 26% with diagnosis based on various screening and various strategies employed, however, data on prevalence is limited (3). One study conducted in 2007 in rural settings in Limpopo South Africa reported a GDM prevalence of 8.8% (5,20). In 2017, another study conducted in Johannesburg reported an extremely high GDM prevalence of 25.8% amongst 554 black women using the International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria (4). However, another screening systematic study of GDM prevalence conducted in African countries indicates that South Africa has seen an increase in GDM since 2007 (now estimated at 25%) (3,6). Despite variations in estimates, experts agree that the prevalence of GDM is rapidly increasing in SA and is becoming a major public health concern. This increase is concerning also for the burden of GDM management within the healthcare system. The more the GDM prevalence increases, the more there is a need for well-understood interventions to manage the burden on health care systems.

However, both GDM and T2DM can be impacted by intensive lifestyle change interventions offered to high-risk people (17,27). Due to its significant risk for the mother of developing T2DM later in life, GDM has gained public health attention to understand not only the global burden but to find ways to intervene successfully (7). Lifestyle interventions with a focus on diet and physical activity may help prevent the progression to T2DM in individuals identified as high risk or subsequently aid in the management of T2DM in individuals already diagnosed (3,6,9). Different countries such as the United Kingdom (UK) and Netherlands have adopted healthy lifestyle interventions to reduce the risk of T2DM for women who had GDM (17, 38,39). Studies and systematic reviews have shown that lifestyle interventions for women with a history of GDM are effective in reducing their risk of developing T2DM and improving health outcomes for both the mother and baby, through improving diet and increasing exercise (40). The Finnish Diabetes Prevention Study and the Diabetes Prevention Program both showed a reduction of 58% in the incidence of T2DM in women with GDM after an average of 3 years of lifestyle interventions focusing primarily on diet and physical activity (38,41). Other research indicates that GDM requires lifelong self-management with regular health

professional support and supervision (11,33,42). Recommendations around GDM management indicate that it is critical to develop behaviour change interventions to reduce this risk (26,43). Diabetes self-management education (DSME) is a critical component of diabetes care (43). However few studies have addressed professional support and follow-up supervision while trying to understand the views of women who experience GDM.

2.2 IINDIAGO: A South African initiative to support women with GDM in behaviour change to decrease T2DM risk

According to South African guidelines, women diagnosed with GDM are to be immediately referred to their nearest health facility for management, including counselling and health education from health care practitioners (11). In practice, however, follow-up is poor (44). Due to the increasing GDM prevalence and burden on the South African health system, effective interventions and accurate up-to-date information are required to inform successful GDM management programs during the antenatal and postnatal care periods (17,45). In response to this need, a complex intervention study including an ongoing randomized controlled trial aiming to lower T2DM risk for women with GDM known as "*The Integrated health system intervention aimed at reducing type 2 diabetes risk in women after Gestati**o**nal diabetes"* (IINDIAGO) was initiated in Gauteng and the Western Cape in South Africa (46).

The IINDIAGO trial intervention included a hospital-based antenatal intervention and a primary healthcare well-baby clinic postnatal intervention. During the antenatal period, women received two face-to-face counselling sessions from the IINDIAGO nurse at the hospital where they were receiving their routine antennal GDM care. The GDM session focused on the nature of the GDM, the risks to both the mother and baby, and the importance of a healthy lifestyle, not only for the pregnancy but for the long term, with the sessions starting right after recruitment and the second offered any time before women delivered. The postnatal clinic-based intervention was delivered during routine well-baby clinic visits at 6 weeks post-partum and included an oral glucose tolerance test (OGTT) scheduled for the mother when bringing the infant to the clinic for immunization.

The IINDIAGO trial intervention continued behaviour change counselling, with women offered four brief face-to-face counselling sessions at the well-baby clinic by a lay counselor at each of the routine visits for immunization., 6-, 10-, 14, and 36-weeks post-partum. These

sessions focused on supporting the women to achieve and maintain healthy lifestyle changes in the postnatal period. The healthy lifestyle sessions included changes to 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 counsellors were actively engaging the woman in setting behaviour change goals and developing a personalised risk reduction plan appropriate to their circumstances, resources, and preferences. In between the counselling sessions at the clinic, women could receive a flexible home visit by the same lay counsellor, with whom she built up a relationship during the well-baby clinic counselling sessions. These visits took place at around 8, 12, and16 weekss post-partum and focused on assisting the family (and/or other members of the household) to engage with healthy lifestyle change. Figure 2.1 presents the logic framework for the IINDIAGO trial. This framework informed the qualitative study reported here.

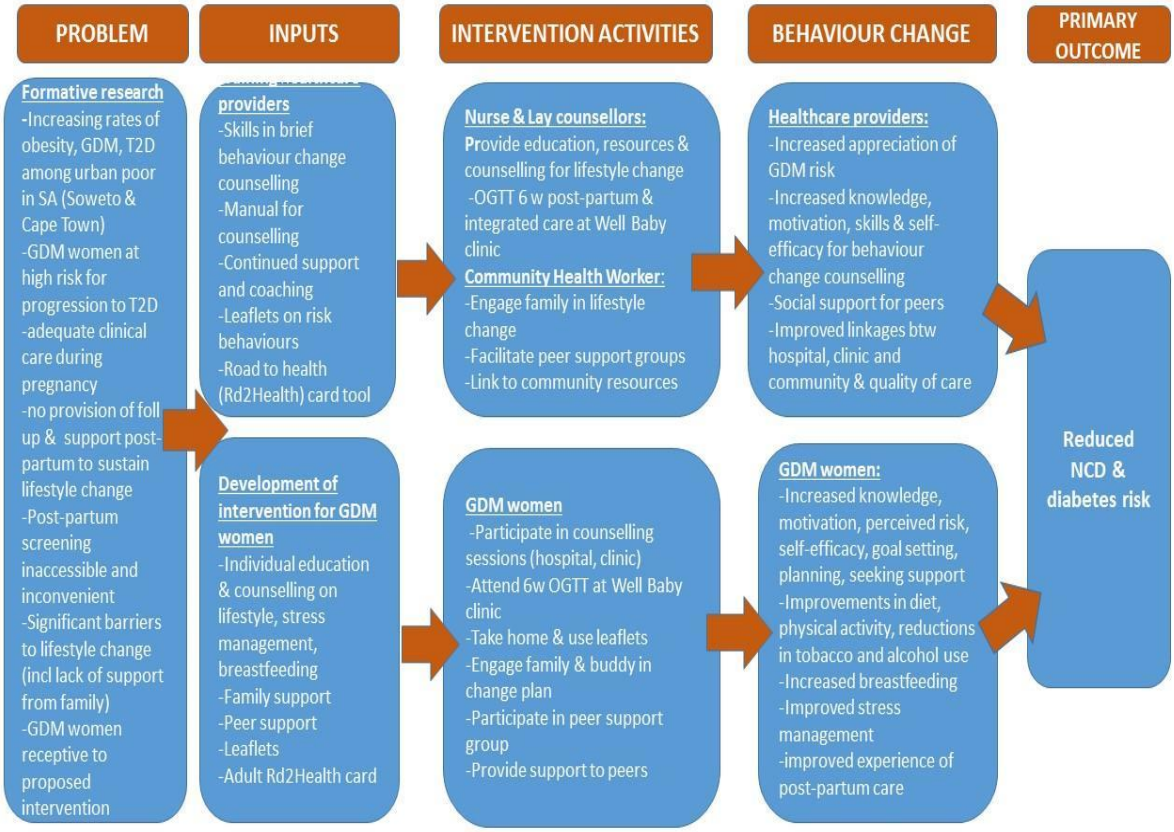


Figure 2.1. The IINDIAGO logic framework reproduced with permission from the publication by Norris et al. 2022 (ref 46) is currently under review).

The overall aim of the IINDIAGO trial was to develop and evaluate an innovative health system intervention to reduce the succeeding risk of developing T2DM among women with recent GDM during its implementation. Its methods were developed around the design which focused

on evaluating the intervention and identifying opportunities and barriers to subsequent scale-up and sustainability within routine, community-based primary healthcare services. The overall study design was a convergent parallel mixed methods study comprising formative research to develop the intervention; an exploratory, individually randomized, trial evaluating the uptake and outcomes of the intervention (postpartum screening and ante-and postpartum T2DM prevention counseling integrated into routine infant care visits among women with recent GDM), and concurrent qualitative and quantitative process evaluation of the implementation and economic evaluation of the intervention.

IINDIAGO further adapted the COM-B behavioural change model (**Figure 2.2)** (11,47), which also became relevant to this master's project as this model has aided the study to understand the factors influencing attrition behaviour within the IINDAGO project. The COM-B model and the Behaviour Change Wheel pay attention to the Capability, Opportunity, and Motivation to change behaviour, within broader personal and social contexts (Figure 2.3 Applying the COM-B model and the Behaviour Change Wheel led to more contextually relevant and acceptable design of the IINDIAGO interventions (47,48) As this Master's study was based on two groups within the intervention arm of IINDIAGO, this model has allowed us to understand the experience of the IINDIAGO participants during their participation from their motivation and ability to participate, the motivation, capability,y and opportunities influencing retention and also allow to those who have disengaged from the trial to be able to share their reasons for attrition. The reasons why women were interested in participating also reflect the COM-B dimensions: as will be reported in Chapter 3, most if not all women indicated that they felt that they would be provided with an opportunity to learn new ways of conducting themselves to take care of their health (behavioural change). In summary, a conceptual framework including the COM-B and Behaviour Change Wheels models was adopted in this study based on existing theories and evidence, and to help us in exploring the underlying factors that were influencing attrition.

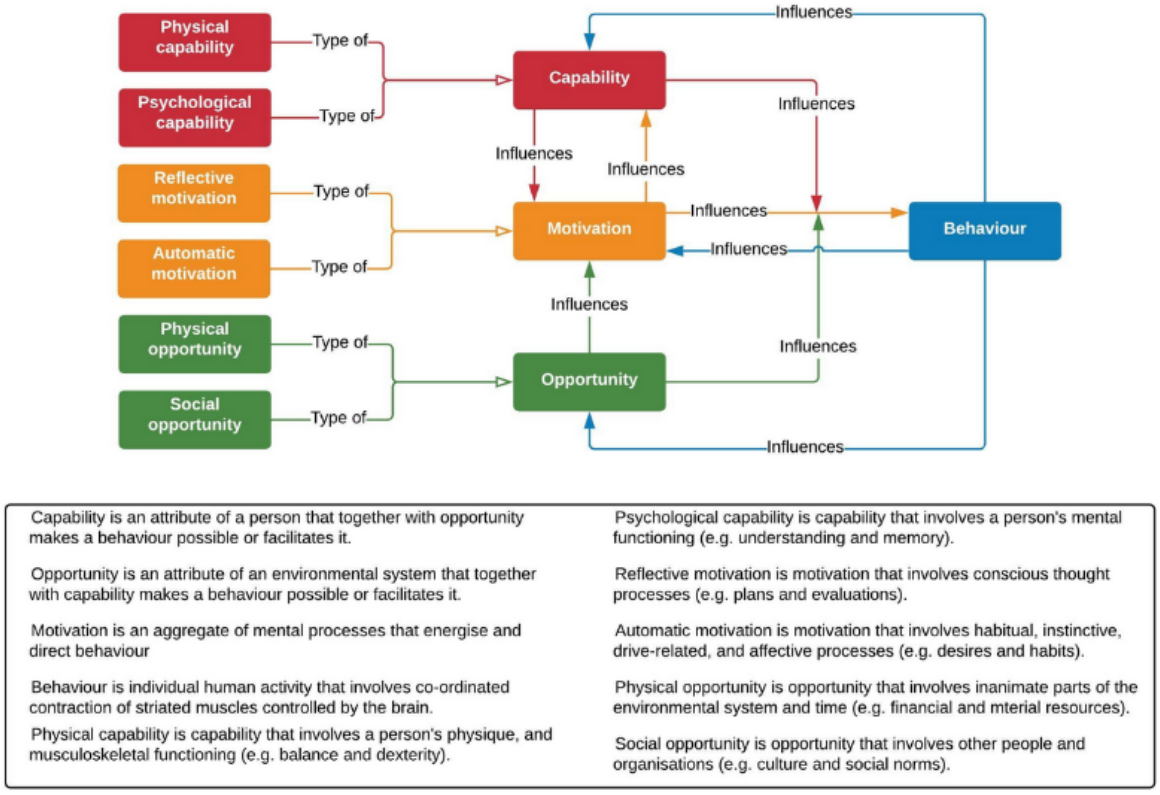


Figure 2.2. The COM-B model, a framework for understanding behaviour (reproduced from the publication by West & Michie, 2020 (57) published under a CC-BY 4.0 Licence).

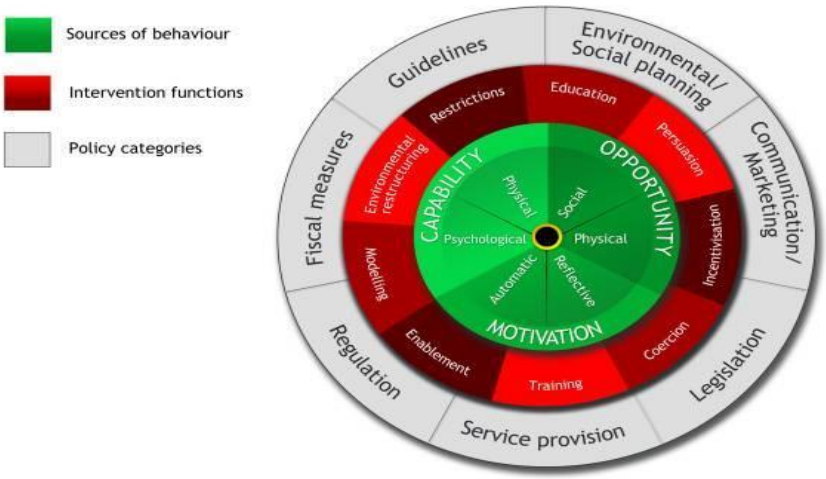


Figure 2.3. Behavioural change wheel (BCW; reproduced from the publication by Michie et al. 2011 (47) published under a CC-BY 4.0 Licence).

Thus, healthy lifestyle intervention programmes aiming at postpartum women with a history of GDM give a unique opportunity for preventing T2DM and other disease burdens (9). As discussed above, evidence is increasingly showing that lifestyle interventions are beneficial when it comes to reducing the risk of developing T2DM. Furthermore, findings show that lifestyle interventions that start during pregnancy and continue postpartum may prevent weight retention and help overweight women lose weight (49).

2.3 Attrition and retention in clinical research and management

Irrespective of the benefits associated with adopting healthy lifestyle interventions there is still the challenge of patient participation and attrition. Despite worldwide efforts to develop diabetes healthy lifestyle interventions programs (including the IINDIAGO intervention), high attrition rates are often reported in clinical practice and in trials focusing on reducing the risk associated with GDM (43). Even though it is now well recognized that success or failure of any intervention lifestyle program may depend on individuals' initial availability, attitudes, or beliefs and that the individuals themselves are an important resource in better understanding attrition behaviour, these perspectives are seldom represented in the literature (25,42,50).

Attrition is defined as a loss to follow-up or disengagement by participants, i.e participants do not participate through until the end of the study or programme (51). Many factors influence

attrition within healthy lifestyle interventions. Among the most cited reasons are death, illness, time commitments, travel issues, work commitments, and pregnancy issues such as tiredness while others reported dissatisfaction with the treatment allocation (50,52). These factors indicate it is important to understand when to introduce a healthy lifestyle intervention. For the greatest effect, women's readiness to engage also may need to be aligned to when such interventions may have the greatest clinical benefit e.g., be immediately GDM diagnosis with intervention postpartum (53), as evidence shows interventions introduced after birth and continued post-partum have clinical benefits to both the mother and the fetus (12,54).

Although studies have examined attrition in developed countries, very little information is presented from resource-constrained environments such as developing countries, including South Africa (55). Evidence from studies conducted in Africa also shows that experiences and strategies from western longitudinal studies cannot be adopted directly and without adaptation to local contexts in developing countries as many factors related to a country's social and economic development status can influence attrition (56). For example, in low-income countries, there may be, higher loss of vulnerable groups (disadvantaged or low socio-economic status social classes, minority or racialized groups, and substance users) (58). Meanwhile in other contexts, attrition may be linked to urban-circular migration or people from higher socioeconomic classes being reluctant to participate due to inconvenience (59).

"Social aspects i.e., a broader understanding of social aspects could guide culturally relevant treatments and educational initiatives to enhance self-control. In one study conducted in South Africa, it was identified or linked that in difficult social situations, many pregnant women would visit their antenatal clinic without eating a sufficient breakfast, as evidenced by their identical random and fasting glucose levels (62,77)".We face a double burden of disease due to malnutrition, poverty, and communicable diseases, as well as a middle-to-low-income country, while obesity and lifestyle-related non-communicable diseases are on the rise. However, if risk factor-based screening is something we want to examine, we'll need to establish what is appropriate and can be easily implemented.

Additionally, although panel study attrition has received a lot of coverage in developing countries, evidence from situations with limited resources, and poor structural development, such is scarce. Indeed, due to the challenges involved in contacting and locating participants in most trials, the experiences and approaches from Western longitudinal research may not be suitable for developing nations.

Through the centuries, human participants' research has led to numerous breakthroughs in medicine, which were often accelerated with technological advances. However, concerns about the ethics of research involving human participants have a long history. “In relation to Crane’s writings, the study team for this trial were all South African researchers but I acknowledge the greater need to understand the pressures on women and how this impacts their decisions to take part in the research. Through the centuries, human participants' research has led to numerous breakthroughs in medicine, which were often accelerated with technological advances. However, concerns about the ethics of research involving human participants have a long history. In the past half-century, the level of oversight on human participants’ research has exploded from almost none to what is now an exhaustive system of protections. However, there is still a need to understand patients’ motives for engaging in research and to ensure that vulnerabilities of all kinds are considered in such interactions”. (77-78).
Barriers and facilitators are circumstances that may influence the participants’ completion of health research trials (54,60).

These can be categorized as either psychological (including emotional support) or socio-ecological (physical or social environmental) conditions (60). Despite being aware of the benefits associated with adopting and maintaining healthy lifestyle programs, women may still have barriers that lead them to disengage from these trials or have competing priorities that create challenges to staying engaged (54). In a study conducted in Finland (FIN-D2D) in women with GDM, such barriers include lack of motivation, financial and time constraints, childcare duties, or work-related obstacles (12,50). One important and worrying reason cited is that women may not perceive themselves as being at high risk for T2DM after delivery (34,49,61). Other studies note logistical and administrative barriers: findings from a trial in Canada found that several participants were struggling to honour their appointments because they were not reminded of their upcoming appointment or because they were not able to locate the centre (43). Similar barriers may be reported for intervention adherence as for attrition as shown in a lifestyle intervention trial conducted with Australian women who had GDM: women outlined their challenges to intervention adherence as time pressure, physical and social constraints as well as comprehension difficulties (62).

However, when it comes to facilitators for engagement, evidence has shown that women can have different motives or reasons for why they stay engaged with healthy lifestyle interventions. The unethical exploitation of races owing to their living situations, yet there is

less information regarding the motivations behind research trial participation. Some of the participants in this thesis are motivated by a desire to learn more about health, while others are motivated by incentives they get, which all come down to race, class, education, and unfavourable living situations. One study conducted in South Africa found that most pregnant participants joined interventions because they were concerned about the health of their unborn baby, which facilitated adherence to lifestyle modification during pregnancy (41). Other studies found that willingness from participants and social support for participants were important for retention in trials (45,50). Social support can play a vital role in women's ability to adapt or likelihood to disengage from the healthy lifestyle intervention programmes. According to the study conducted in Australia, social support provided by family members and friends can motivate participants in adapting well to the programs (50,63).

In a nutshell understanding the factors that drive attrition may inform the viability of similar interventions in the future (50,54). Evidence is limited regarding the attrition factors that may affect the effectiveness of the healthy lifestyle interventions for women who had GDM during their pregnancy. Thus, it is relevant to investigate the factors influencing attrition in the IINDIAGO trial, to contribute to understanding of attrition and retention in both trials and lifestyle interventions in countries such as South Africa. This Master's study sought to contribute to deepening such an understanding, in the context of a lifestyle intervention trial with women who had GDM in their most recent pregnancy. The following chapter below is the paper that was written from all the study's data.

3. CHAPTER 3 – MANUSCRIPT

Factors influencing attrition from a one-year postpartum lifestyle intervention for women experiencing diabetes in pregnancy

The manuscript was submitted to the South African Medical Journal.

Masuluke I.M, Kolkenbeck-Ruh A., Zarowsky C., Mutabazi J.C and Ware L.J. (2022).

3.1 Abstract

Background Lifestyle interventions have positive health benefits for women with gestational diabetes (GDM) and their offspring. However, these interventions may be hampered by poor retention.

Main objective: This study aimed to assess and understand the factors affecting women's attrition from a post-GDM intervention program in South Africa.

Methods: Cross-sectional descriptive-analytic qualitative study design was employed. Participants were recruited from IINDIAGO (Integrated Health System Intervention aimed at reducing Type 2 Diabetes risk in women after Gestational diabetes) in Soweto. 28 women from two groups were telephonically interviewed using a semi-structured interview guide: Group A (n=11), those retained and who received more than 40% of the intervention sessions, Group B (n=17), those who disengaged and received less than 30% of the sessions. Interviews were conducted in English or the preferred language of the participant and were audio recorded, transcribed and analysed with both inductive and deductive coding using ATLAS TI.

Results: Group A reported that they did not face any attrition challenges. Facilitating factors for retention were benefits received; friendliness and kindness (hospitality) and relationship with the study team, education about GDM, T2DM interventions, and perceived risk. In comparison, group B reported challenges related to their personal situation, COVID-19 pandemic and travel costs as reasons for attrition.

Conclusions: For successful GDM interventions women must be convinced of the benefits of healthy lifestyle interventions. Communication by intervention teams is critical: both practical information sharing as well as a willingness to listen. Personal situations and work commitments vary; hence interventions should be tailored to possible circumstances.

Keywords: Gestational diabetes mellitus, attrition, type 2 diabetes mellitus, lifestyle intervention, and Health behaviour.

Trial registration: The trial is registered with the PAN African Clinical Trials Registry (https://pactr.samrc.ac.za); Identifier PACTR20180500333617

3.2 Introduction

Gestational diabetes mellitus (GDM) is reported to affect 14% of pregnancies globally (1,3). In South Africa, estimates suggest GDM affects up to 25.8% of pregnant women (3,4). GDM results from a glucose tolerance disorder that occurs or is diagnosed for the first-time during pregnancy (1,2). GDM is a major public health problem that has short- and long-term consequences for the foetus and the mother. Without appropriate glucose management, both women with GDM and their offspring have an increased risk of developing type 2 diabetes mellitus (T2DM) as well as other metabolic conditions later in life (3,5,6).

However, GDM is manageable, and evidence shows that there are ways to reduce the risk of T2DM in those who have experienced GDM during pregnancy (7–9). Lifestyle interventions, primarily diet and physical activity modification with weight management, have been reported to prevent the progression to T2DM in high-risk individuals (10). Furthermore, diagnosis of GDM also leads to greater awareness of future T2DM risk (17,64). In South Africa, women diagnosed with GDM are to be immediately referred to their nearest health facility for management with counselling and health education from health care practitioners; however, in practice, follow-up is poor (11).

A study conducted in Finland showed that lifestyle interventions during pregnancy among women with GDM generated behaviour change, reduced the risk of birth defects and contributed to good fetal brain development (12,13). The Finnish Diabetes Prevention Study and the Diabetes Prevention Program both showed a 58% lower incidence of diabetes mellitus in high-risk individuals after an average of 3 years of intervention focusing on diet and physical activity (13). However, while much effort is invested in the delivery of lifestyle interventions, less research is focused on the retention of participants in the intervention or trial (19). Globally, high attrition rates are often reported in clinical practice (43). Evidence shows that women with GDM may be concerned about their infant's increased risk of adverse health outcomes, which could motivate the adoption of lifestyle interventions and preventive behaviours during pregnancy (5,41). After the delivery of the baby, however, perceptions of risk may change and engagement with the intervention decrease. Considering the resources invested in the planning and structuring of lifestyle interventions including self-management education programmes, it is important to understand why people choose to engage with or disengage from such initiatives to inform programme effectiveness (43,65). Thus, this study

aimed to identify factors associated with attrition and explore why some women remain engaged with a lifestyle intervention integrated into primary care in the post-partum period for women with GDM during pregnancy.

3.3 Methods

3.3.1 Study sites and population

This was a cross-sectional, descriptive qualitative study that was nested within an ongoing study: IINDIAGO (Integrated Intervention for Diabetes Risk after Gestational Diabetes) in South Africa. A cross-sectional study looks at data at a single point in time. The participants in this type of study are selected based on variables of interest. Cross-sectional studies are often used in developmental psychology, but this method is also used in many other areas, including social science and education. "Qualitative cross-sectional studies are often used in developmental psychology, but this method is also used in many other areas, including social science and education. Cross-sectional studies typically allow researchers to collect a great deal of information quickly. Data is often obtained through focus groups or in-depth interviews. Although researchers cannot use cross-sectional studies to determine causal relationships, this method has helped in this study by providing useful indications to inform further research." (66,79). Because we were looking at post-partum healthy lifestyle intervention, it helps us to understand that certain behaviour might be linked to a particular the challenges of poor retention. Pregnant women with GDM were recruited from antenatal clinics in Soweto at the Chris Hani Baragwaneth Academic Hospital. Women were randomly assigned to either the control or intervention group. The control group continued with their standard care. The intervention group received two counselling support sessions during late pregnancy and sessions to support behaviour change up to 36 weeks postpartum with a lay counsellor, known as a healthy living coach. We randomly selected women from the IINDIAGO intervention arm and then used extreme case sampling (66) to create two groups: group A - women who attended 3 or more counselling sessions (over 40% of the intervention) and had not disengaged from the study i.e. had completed or were still completing sessions and visits; and group B - women who attended less than 3 counselling sessions (received less than 30% of the intervention) and had disengaged from the study i.e. stopped attending intervention sessions and measurement visits. Participants were only recruited if they were willing to give their informed consent and

to voluntarily participate in the interviews. Ethical approval for the study was granted by the University of Witwatersrand Human Research Ethics Committee (Medical) [Reference M210435].

3.3.2 Data collection

A semi-structured topic guide (**Table 3.1**) was used during in-depth interviews with women to gather information about their experiences related to the intervention, including what they learned and how they thought retention could be improved, with particular focus on the barriers and facilitating factors related to attrition and retention. All interviews were conducted by telephone due to COVID-19 restrictions. A multilingual interviewer conducted all interviews in the South African language in which participants felt most comfortable. Interviews were audio recorded then translated into English and transcribed. Translated transcripts were cross-checked by two masters' graduates trained in transcription and speaking local languages. Out of the 28 interviews, more than half were conducted in isiZulu (53%), 29% were conducted in English, 7% in Xitsonga, and one each in Setswana, Sepedi, and Sesotho.

Table 3.1. Interview Topic Guide

1. Please can you tell me about how you got involved in the study? Where were you and who talked to you first about the study? What did you think? What attracted you to take part in the IINDIAGO study at that time?
2. When you were pregnant, what did you think of what the study team were asking you to do (diet, exercise, etc.)? What about after you had delivered, how did this change what you thought?
3. How would you describe your social support structure in terms of adapting to this lifestyle behavioural change?
4. How many times have you seen or talked to staff from the study since that first time?
5. Please describe your experience in the study What have you talked to the study staff about? What has made it easier or harder for you to have these conversations or to meet with or chat to study staff?
6. What have you learned from participating in the trial? What has been helpful? What has not been so helpful?
7. Was there a period where you did not want to continue being a part of the study? If yes, can you tell me about it, what happened?
8. What do you think would help you to have more sessions with a nurse or somebody who supports these kinds of health changes? What do you think could make it easier for women like you to engage with or to make more of these lifestyle changes? What do you think making these changes do for you?
9. What has been your favourite bit of being part of the IINDIAGO study? What has been your least favourite bit?

3.3.3 Data Analysis

Interview transcripts were imported into qualitative analysis software ATLAS TI V9 (Scientific Software Development GmbH, Berlin, Germany) for management and to support analysis. Transcripts were first read and reread to become familiar with the data, noting impressions, emerging ideas, and developing codes and categories. A joint deductive and inductive thematic content analysis approach was used for analysis (66,67). Deductive analysis was guided by an initial thematic coding framework developed from the interview topic guide. An inductive approach was used to identify additional themes from the transcripts. The code book and extracts of the transcripts were then checked by all authors, with a discussion between authors to resolve differences of opinion in the coding, thematic content analysis, or interpretation. The analysis sought to identify facilitators and barriers that could be practically addressed across a range of conceptual and substantive frameworks, rather than to develop or test theory. The items of the consolidated criteria for reporting qualitative research (COREQ) guided the development of this research and reporting of the findings (68).

3.4 Results

Of the 69 women who had been assigned to the IINDIAGO intervention arm at the time of data collection we randomly contacted 40 participants in total. Of these 40 women, 12 could either not be contacted or did not want to participate, resulting in 28 who agreed to be interviewed (Group A n=11; Group B n=17). All the interviewees in both groups were female, within the age range of 28 to 43 years (mean age 33 years for group A; mean age 35 years for group B) and currently residing in Soweto.

We identified 20 themes from 86 codes from the transcripts. From these themes, 6 combined categories were developed, namely: why women agreed to take part initially, factors related to staying engaged, factors related to attrition, participant's recollections about study aims, outcomes of taking part, and participant recommendations, as shown in **Table 3.2**.

Table 3.2. Outline of themes

Why women agree to take part initially	Health concerns Need for information

Factors related to staying engaged	Benefits and Hospitality Communication Education Perceived risk Personal effort
Factors related to attrition	Personal situation Communication Fear Pandemic (Lockdown) Cost
Participant's recollections about study aims	Communication about the study aim.
Outcomes of taking part	Access to information Health behaviour change Support/hospitality
Recommendations from participants	Location and timing of sessions Clarification of benefits Healthcare system change Use of technology

In this section, we begin by describing the reasons that women gave for why they were first attracted to participate in the study. Next, we review why women remained engaged in the study, and then why other women disengaged after initially agreeing to participate. These findings about women's reasons for joining, remaining, or disengaging may be relevant to health interventions and also to intervention studies and trials more broadly. After presenting these findings, we return to the women's recollections of the aims of the study and what they reported being gained from taking part, as these may provide insights to help encourage engagement and retention in other research-based interventions. Finally, we present the women's recommendations to this – and other – teams of intervention researchers.

Category 1: *Why women agreed to take part initially*

Almost all the narratives included the reason for deciding to join the study within the response to the question inviting them to describe their recollection of the first meeting. Women reported various reasons to participate in the study. Some women indicated that when they were introduced to the study, during the recruitment process occurring while women were still pregnant, they were concerned about their recent diagnosis of GDM - a relatively new concept to them - and realized that they lacked knowledge of the risk involved with the way they were living their life. They decided to be part of the study so that they could acquire new knowledge about diabetes during pregnancy and understand what was happening to them better.

Because I felt like the study will help me understand my situation differently. Because it was for the first time, I was diagnosed with GDM and I was admitted to the hospital I did not understand what is happening to me, by me participating in this study I'm keen to learn about the GDM. Excerpt 6: 35y - group B

I was also keen to know why I had suddenly gotten diabetes. Since it was something, I never had. It only started when I was pregnant. Excerpt 8: 28y - group B

Some indicated that they participated in the trial as they had high blood glucose, and they hoped the study would help them manage their condition better. Women were concerned about their health, but they were predominantly worried about their baby's wellbeing and risks associated with GDM: fear about the baby's health was the most frequently cited reason for participating in the trial. These women indicated that through participating in the study, they hoped to deliver healthy babies. Some explained that they were fearful for their babies' wellbeing as they had miscarriages before, hence the fear of losing the babies was at the front of their minds. This motivated them to participate in the study.

I just told myself that since I want the baby to come out healthy and for myself to be well then, I will have to do as they said and change my diet and follow through with everything, they told me to do because we both had to live; me and the baby. Excerpt 9: 39y - group A

The fear of losing my baby was the first thing coming to my mind. Since I lost the baby once the fear was just hovering in my mind. Excerpt 10: 40y - group B

The women had different reasons to stay engaged or disengage from the IINDIAGO Trial as shown in **Table 3.3**.

Table 3.3. Themes associated with disengagement versus continued engagement with the intervention

Continued engagement:	Disengagement:
Benefits (transport, health) and hospitality Education (GDM knowledge, conversations about health) Communication (reminders by the study team) Perceived risks (awareness) Personal effort (willingness)	Personal situation (work commitments, weekend/inconvenient appointments, schedule conflicts, relocated, illness, childcare) Communication challenges (change of contact details, trust, and hospitality) Instilled fear by health care personnel (health care system) Fear of pain (OGTT procedure needles) COVID-19 Pandemic (lockdown) Transport costs (distance)

Category 2. *Factors related to staying engaged*

With the fear of harm to the baby during pregnancy a major cited motivational force, many women remained engaged until childbirth - only 2 of the 17 women in Group B disengaged before giving birth.

I just told myself that since I want the baby to come out healthy and for myself to be well then, I will have to do as they said and change my diet and follow through with everything, they told me to do because we both had to live; me and the baby. Excerpt 9: 39y - group A

Well, because I had quite a few miscarriages and a stillborn, that's what encouraged me to continue with the diet. I wanted what was best for my baby. Excerpt 12: 28y - group B.

However, after giving birth, differences were observed between the groups. Women in both groups reported an opportunity to learn (education) as a benefit of the study and women in Group A who were aware of or perceived a future risk associated with having had GDM

decided to stay in the study so they could decrease their future risk. Women in Group A also felt the study team members were taking care of them, and they believed the study would improve their health. Education and relationship with the study team appeared as the most cited reasons why women continued with the study, rather than perceived risk. All women in the study (intervention and control) were given a gift (a small baby towel and hygiene product) at birth but those in Group A mentioned this as contributing to building this relationship.

And their hospitality (generosity and kindness) was great because they provided us with transport then they took us back where the study was taking place. They gave us food. They were talking to us like they were… very… their hospitality was very great. Excerpt 39: 31y - group A

You offer the best services. So… I really do not know but you are doing your best as far as I can see. I even got my gift, that towel. Excerpt 38: 31y - group A

Communication was also a factor enabling some of the women to stay actively engaged with the intervention. Women reported that both the practical reminders of their appointment and frequent communication in general, alongside the perception that it was safe to communicate openly with the study team, including about their problems, were important.

They made me feel like I am part of a family, at least. Because even if you forget your clinic dates, they will call me and remind me. Excerpt 39.1: 40y – group A

Women in group A also cited their own effort among the reasons they continued with the trial. Some women noted that they were satisfied with how the study was structured and with the intervention, however, they felt that women themselves should be proactive and responsible by putting more effort in to honour appointments. They said that if women communicate any challenges or changes and show interest in the study then it will be much easier for the implementation.

They could reach me when they called me. And if they could not reach me at the time, whenever I saw their missed calls, I made follow-ups and called them back because I now knew their number. Then they would tell me that they needed me then I would make sure that if I had somewhere to go but it was not that important, then I would not go, just like today, I was supposed to go out and sell some things, but I made sure to avail myself here instead. Excerpt: 37.2: 30y - group A

It is our responsibility as patients. If you know that say for instance that I have an appointment for OGTT and I found that I have GDM. So, the decision should come from me, to know that I

must honour my appointments because the study already informed me that my next appointment is such on this date and all I must be there at such a time. So, it's not like they phone me today or they tell me 'Today, you must come tomorrow.' I have time and if it' is important to me then I would know and I understand that I need to make time and I have to be there because like I'm saying, it's my health, it's my baby's health. […] You, yourself must acknowledge that it's important and invest your time in it. Because all women want to be healthy, and all women want their children to be healthy why would I skip an appointment? If I cannot, it must be something very important. But then, not making it, phone in, let them know that 'this is happening now at this moment, I can'- It must be urgent. It doesn't have to be, just because I see now, I don't have petrol fare, I don't have transport money to come, no. I would say that this is irresponsible from the patient's side. It's like I can go anytime, they will help me – no. So, it comes from us as the patients, we need to be more responsible. And we need to know that our health and our baby's health come first. Excerpt 37. 1: 41y - group A.

Category 3: *Factors related to attrition*

Like other interventions and studies, the IINDIAGO study faced challenges of attrition. The following section outlines the reasons why women disengaged from the trial. This section explores why some women, the participants in group B, did not continue with the study despite enrolling and participating in at least some of the intervention activities. The women in group A faced similar challenges but they reported that the intervention was important to them, and that they were able to circumvent these challenges to prioritise carrying on with the intervention.

The following factors were identified by women who were not able to continue the study: personal situations (work commitments and schedule conflicts, relocated, illness, childcare), communication challenges (change of contact details, trust, and hospitality), fear instilled by health care personnel, fear of pain (OGTT procedure needles), pandemic (lockdown and fear of contracting Covid 19) and lastly transport costs (distance and time).

Women in group B reported different personal situations that had played various roles in their continuing with study, with work commitments being the most cited reason for disengaging from the trial. Women reported that after they delivered their baby, they needed to return to work thereby changing their availability for other commitments. More women in group B were in paid employment (47%) than in group A (18%).

Also, some women further reported that their working conditions did not allow them to use cell phones and communicate with the team and that this made telephone counselling sessions difficult. Others had to make up for the time they took during their pregnancy, including days

they had to take before official maternity leave for clinic visits. In addition, women reported that their work demanded their time during weekdays so that over weekends, they needed to complete duties at home, such that no time was left for other commitments.

Well, as I said, I was back at work. Things got hectic because nobody was filling in my gap here as well, so I had to come back and start my work. Do you know? So, I had to catch up on the work that is the reason I had left [the study]. Excerpt 56: 28y - group B

Some women reported that they were willing to meet with the team members, but the times that were proposed to meet were unreasonable. For example, women reported that the counsellors wanted to meet with them after their clinic appointments, but (with long clinic wait times) they were tired by then as they had already spent half of their day at the GDM clinic. By this time, all they wanted was to go home and rest. As a result, sessions with after the clinic visits were also less productive as women were tired, could not concentrate, and were distracted. Often the counselling sessions were held in an open space near to the antenatal GDM clinic as there was no private space available for use. Women noted that they were not comfortable meeting with the counsellors in these open spaces to have a private counselling session.

*You find that by the time you go to the diabetic clinic it is already past one (*13:00) so you are already irritated, and you have already been there at seven (*07:00) so you have not eaten because you don't know what the procedure is, well if I leave this queue, who will take my spot, so you are just irritated. But […] with my mind being at home I will not concentrate on the session. Excerpt 42.1: 38y - group B*

Remember I was pregnant, and I would spend half days at the clinic and the research team members wanted to see me after my consultation, at that time I'm tired, I'm only looking forward to going home nothing else and very impatient with spending more time at hospital after my GDM/ANC routine. Excerpt 40: 36y - group B

Other women from group B indicated that they disengaged from the study because they had to relocate from Soweto (Gauteng) to different provinces. Most reported that their move was unplanned, hence they had to discontinue the study despite having been willing to continue. The reasons for relocating included job losses for some, new opportunities for others, and unstated reasons for yet others. However, some women who disengaged from the study reported that they did not stop what the intervention taught them - they continued with the activities.

It just happened unexpectedly because my husband no longer works in Johannesburg. He lost his job, so we were forced to move back to Limpopo. Excerpt 43: 30y - group B

Even though I am not going to the study anymore, I continued with the diet tips that I was given and a bit of exercise. Though I am a little bit lazy, but at least there is something that I am doing to ensure that I stay healthy. Excerpt 43.1: 36y - group B

Several women in group B indicated that communication challenges were an obstacle to being able to continue with the study - either poor communication, discontinued communication with no stated reason or complete break in communication between some women and the study team members, resulting in a loss to follow-up. Some women described a communication breakdown resulting in a team member leaving a participant waiting, while others decided not to communicate changes in contact information with the research team. One participant described that there was no clarity on their appointments and at some point, the communication between the research team members and participant stopped with no stated reasons and with no future appointment details communicated.

We had some (sessions) - well, she did call me when I was done, I guess there was some break in communication. Excerpt 45: 34y - group B

The last time someone contacted me by telephone is when they told me I must call this number to tell them when I am in labour. Excerpt 47: 34y - group B

The reasons they were struggling to get hold of me is because that I lost my phone, and I was not able to do sim swap because the person who picked up my phone was using my number so when the team members called he was not picking up and would block any number that was calling my phone. I even tried to call him. Until this one time, he stopped using my phone then I was able to do a sim swap. Excerpt 48: 40y - group B

Some participants reported that the health care personnel's behaviour towards them was the reason they disengaged from the research. These women reported that the nurse made them feel that GDM can kill them and that they should be more afraid, and in fact this did instil fear in the participants.

The nurses made it scarier; you know. Excerpt no 49.1: 36y - group B

With the nurses as well. I felt that they should be more comforting rather than putting it like it is a death sentence. Excerpt no 49.2: 36y - group B

For me, it was the first encounter with the nurses. You know, the first encounter is important so my first encounter with them I – you know when you are at Bara, right, you are scared […] and being ill-treated because of the lack of good treatment there. Excerpt no 49.3: 36y - group B

Some women in Group B indicated that the reason they could not continue being part of the study is that they feared medical procedures such as drawing blood for OGTT as they were

afraid of needles and associated the study site with the procedures experienced during pregnancy. Women assumed that the same procedures done to them during pregnancy would be repeated after pregnancy.

So, the problem is that we as women who had GDM after giving birth it becomes difficult for us to come back to Baragwanath because we think you are going to draw blood from us again so when one thinks of the pain of the injections, we become scared to come. Excerpt 49.4: 40y - group B.

Women recruited and still enrolled in the trial during the pandemic (March 2020- end 2021) reported being hesitant to come to the research site situated in a hospital as they worried that they might contract Covid-19. Others stated that they missed their appointment(s) due to South Africa's national lockdown restrictions.

For me, number one – the main thing is… is the pandemic itself… has made one to be scared to even come to the hospital because you know corona is there now. Excerpt 60: 38y - group B

Finally, some women reported that they disengaged from the study because the hospital was far from where they stayed. For some, transport costs and the complexity of travel were prohibitive. Others felt the distance was too much for them, even though transport to the site was offered.

Yes. There was such a time because I felt like it was too far; I could not come to Bara. Excerpt 50: 39y - group B

Category 4: *Participants' recollections about study aims*

The recruitment process is very important in interventions as it may affect the results. During this process, it is important to ensure that communication is well established during the introduction by the intervention or research team members and study participants, including clarity about what is expected from the participant and the potential benefits. The findings under this category present the women's narratives and recollections of their initial encounters with the research team members recruiting participants into the study, and their understanding of what the intervention study is about based on the recollections of these initial encounters.

While many women could accurately reflect on the aims and purpose of the study, this was not always the case. Most of the women from group B noted that the details about the study were communicated to them before they were recruited and allocated into the intervention. For these women, it seems that their initial interest in the study was based on the health benefits of the intervention. In contrast, most women from group A reported remembering the OGTT services that will be offered to them by the study: these women, who stayed in the study, were more

interested in being able to access very practical, specific, medical benefits, and this led them to decide whether they would take part in the study or not.

Most women from group B reported that after their first encounter with the team member they now understood their condition better and understood the purpose of the study and that they were willing to participate in the study. Many remembered what they thought was important to them at the time and their narratives show that they opted to participate into the study because they perceived the aims and benefits of the study.

Based on the information shared by the recruiter, women decided to participate in the study to have the opportunity to change their behaviour in ways that would improve their health or the health of their children.

When she explains she made me realize that I and my baby are both in danger. Because of the benefits of this program explained to me I felt like there is a need for me to participate in this study because I felt like the study will help me understand my situation differently. Excerpt 1 35y - group B

Category 5: *Outcomes of taking part*

Participants from both groups reflected on what they had learned during their participation in this intervention study overall. Women in both groups reported that, from the support and guidance they received from the counsellors during their interactions, they had managed to understand their health better. They also felt it was important to share the knowledge and experiences that they acquired with other women from their local areas who are not part of the study but had GDM, and with family as well. Finally, they reported learning that conducting research is not about researchers aiming to get money but to bring awareness and prevent deaths.

Other women indicated that their experience during their participation in the trial was mostly about changing their lifestyle. They stated that their recent pregnancy was different from their previous pregnancies as the study had assisted them to be prepared mentally and they were ready to adopt a healthy lifestyle due to the knowledge they acquired. Some women reported that their participation in the study provided them with an opportunity to share personal problems and challenges, to change their lifestyle and learn how to deal with personal difficulties, learning to open up and share personal challenges or problems that they came across.

I have learned that when a person follows instruction from the experts it helps even though you still do not understand why it is happening. It did help me only even the people that are close to you, and when I meet someone who is having GDM and is ignorant I share my experiences

with them. So, I tell them I have been in the same situation, and I have seen people losing babies because of denial and ignorant of GDM hence I try and motivate other people. I have further learned that people who are doing research are just after money, but no you guys are saving lives. I remember I used to compare. I am from Limpopo, I will compare here and Limpopo and say why do not we have this at home? You guys are just after money maybe you benefit from this until I realize GDM is real and is dangerous, and I only knew about type 1 and Type 2, it was the first time I learned about GDM. As I was participating, I realise that even my first pregnancy maybe I had GDM, but I was not diagnosed. Excerpt 22: 35y - group B

It was not like the other pregnancy when I knew I could have chocolates or fruits or what-what every other day. Yeah, so you just knew how to eat, how to go about eating and your state of mind would change because now you knew that… you don't have to stress about everything, you can't handle everything on your own, you need to speak up. If you go through something, you need to speak up. That's what I've learned, I've learned a lot from the study. So at least now it's a little bit better. Excerpt 25: 41y - group A

Category 6: *Recommendations from the study participants*

Women expressed a sense of satisfaction about how the study was structured and delivered. Even though these women were content with the study and its intervention services, knowledge acquired and research team members' hospitality, they made some recommendations on how best to accommodate women who had difficulties in attending their appointments.

I can't say anything that is not helpful. Because I have been through the situation whatever I did has helped me. From what they've told me and what I've done, it has helped, and it has changed a lot because, in the beginning, I was sceptical. I thought I was going to lose the baby due to this diabetes and the high-risk patient I was. Excerpt 63: 28y - group B

Women in Group A had a range of recommendations for how to support continued engagement. Some suggested that for those who were having challenges making it to their appointment for different reasons, telephones should be used in the future to avoid travel. The use of this technology seemed to be the most recommended method to accommodate more women including the use of communication platforms such as WhatsApp, email, etc. While some women preferred to avoid weekend appointments, women recommended that for those who were not available on weekdays, weekend appointments and/or extending the study to include home visits should be considered. Some women found weekend appointments preferable.

You can create a WhatsApp group whereby you can interact with the ladies who are not available and communicate with them. Excerpt 67: 41y - group A

Women felt that the intervention was important not only to women with GDM in the hospital but that it should be extended to local clinics and integrated within the current healthcare system by training clinic nurses around GDM awareness. Other women went as far as to suggest school campaigns and community outreach to raise awareness, and to support women staying further away from the hospital. They indicated that when you meet other people who are in the same situation as you, it was encouraging.

I do not know. I am not sure. But perhaps in the clinics, there should be a dedicated space for diabetic people. Then they would know that on certain days, they come through and meet with other people. When you meet other people who are in the same situation as you, you get that encouragement that you are not alone, you see? Excerpt 73: 37y - group A

What I think you can do is you can teach all the nurses in the local clinics to makes sure that women who are facing challenges can go and attend in their free time and be able to get equal information with the ones that are attending with the study full time. And for us who stay far away from the hospital is a challenge. If it is offered in the local clinic, it will be better. Excerpt 70: 30y - group A

3.5 Discussion

This study was designed to explore the experiences of women who had remained engaged with or disengaged from a lifestyle intervention to reduce T2DM risk in women with GDM in late pregnancy and the postpartum period. We learned that women in both groups found the IINDIAGO trial beneficial, and some stressed that it improved their health, and they gained knowledge about GDM and the potential future risks. However, despite these benefits attrition still occurred. The barriers leading to withdrawing from healthy lifestyle interventions may differ across individuals, with work commitments and inconvenient timing or schedule conflicts of the appointment being the most cited reasons why women disengaged from the IINDIAGO trial. Many factors such as personal situations and low perceived seriousness of T2DM risk after pregnancy contributed to attrition. In studies from high income countries (HICs) and low-income countries (LICs), the conflict between participants' work schedules and their time of attendance is a frequently cited reason for attrition in the literature (18,43,69). Our study found that women who disengaged faced a wide range of challenges; the recommendations from women in Group A would respond to some of the challenges faced by

some women, but no single intervention (e.g., using telephones for communication, or scheduling on weekends) would meet all needs. Tailoring to the specific details and contexts of "conflicts in schedules" or "work (or family) commitments" is essential.

Additionally, even though individuals may decide to seek help and comply with the recommended lifestyle interventions or education offered, various facets within the healthcare system may influence their behaviour. In South Africa, health systems are overburdened but examples exist of combined services that have had success in integrating services into primary healthcare (16). If lifestyle intervention programmes are integrated with women's usual antenatal care visit and/or routine well-baby clinic visits, attrition may be less (69,70).

Finally, communication and establishing and maintaining a good relationship with the intervention team are crucial. The findings of a Kenyan study which emphasised how relationship was built through SMS messages and phone call reminders (71).

Understanding the reasons behind attrition is very important as it provides both trials and non-trial interventions with an opportunity to understand their participants' behaviour and how best to deal with it. Complications in participant recruitment, retention, and attrition have been recognized as serious challenges that potentially threaten the success of many clinical trials (25,26). Attrition can reduce the statistical power and threaten the internal validity of a study (27,72). To address the problems of participant attrition, a few studies have investigated factors related to the attrition of individuals in clinical trials and observational studies (51,72). Findings show that irrespective of the benefits associated with lifestyle intervention programmes, the challenge of attrition persists (9,29). Therefore, there is a need for more studies to be conducted or integrated into intervention programmes in order to understand why attrition persists within healthy lifestyle intervention trials and initiatives.

3.5.1 Strengths and limitations

One strength of this study was that the researcher was able to reach and engage with many women who had disengaged and/or had been lost to follow up from the trial. Another related strength of this study was that it was conducted by the first author who had previously worked for the IINDIAGO project. This helped the participants feel at ease as most of them already knew the researcher. This has also allowed the researcher to understand and interpret the data with a deeper contextual knowledge. One limitation was that half of the interviews were conducted in vernacular other than English, and during translation of the data there might be a

potential loss of rich meanings. Another limitation of the study was that the study was conducted among African women living in urban centres, and experiences and barriers may be different in rural settings.

This study provided both women who decided to disengage and those still engaged in the trial with the opportunity to share perspectives on why some women were not able to continue with their participation. The findings could help clinicians and similar future interventions and trials to be aware of what might unfold and how to approach possible solutions.

3.6 Recommendation

For successful GDM interventions women must be convinced of the benefits and feasibility of healthy lifestyle interventions and not only of the risks to their health. Communication by and with intervention teams is critical – both practical information sharing as well as a willingness to listen and to show friendliness and kindness, referred to by participants as "hospitality". Personal situations and work commitments vary; hence interventions should be tailored to a range of circumstances where possible. Finally, it is up to the participants to stay engaged or to disengage with the intervention, thus, not all disengagement reflects dissatisfaction or lack of interest. What interveners can do is to ask, listen, and attempt to adapt interventions to the realities lived by the participants.

CHAPTER 4 – DISCUSSION AND CONCLUSIONS

The purpose of this study was to explore factors related to attrition and retention in women recruited to the intervention arm of IINDIAGO. Like other interventions, the IINDIAGO trial was indeed facing the challenge of attrition, hence we explored participants' perspectives on attrition and retention in this diabetes prevention lifestyle intervention after gestational diabetes. Our findings show that there are many factors influencing attrition within the IINDIAGO trial. Women with GDM in this trial have reported different reasons as to why some stayed engaged and others disengaged from the trial. Even though the study aimed to understand attrition, we were also interested in the reasons for retention, as it is important to explore retention when tackling attrition (21).

To explore facilitators and barriers experienced by women in receiving the intervention counselling sessions, we thematically analysed the qualitative data on the barriers outlined by the women in the IINDIAGO intervention arm. We discovered that the main source of IINDIAGO participants' attrition was related to personal commitments and challenges, including work commitments, weekend/inconvenient appointments, schedule conflicts, relocation, illness, and childcare. In addition, transport costs, communication challenges (change of contact details, trust, and hospitality), instilled fear by health care personnel (health care system), fear of pain (OGTT procedure needles), and COVID-19 Pandemic (lockdown) were also cited as reasons. These findings show that there is a need to understand the locally relevant competing factors that may affect participants' engagement in future trials, and there is also a need to emphasise the benefits associated with this healthy lifestyle intervention and not only the risks of GDM and T2DM.

Throughout the study, the women were able to communicate clearly about the different kinds of attrition challenges that they were facing during their participation in the study as well as to share why they stayed in the study. In contrast with the disengaged women, retained women were influenced by their experiences during their time in the study. The findings among retained women have shown that women's experiences of trust, kindness, good communication and good understanding of the outcome of the trial - notably the future risk associated with disengaging from a health trial - can influence participant's retention. This indicates that clear information sharing and a good relationship between the research team members and

participants can motivate participants to stay within a healthy lifestyle intervention. Our findings also show that there were different views with respect to perceptions of T2DM future risk between the disengaged and retained women. These differences may have assisted us in understanding the timing of factors associated with attrition and retention, particularly with most women in group B, the "disengaged" women, disengaging right after giving birth to a healthy child. If this is the case, program managers need to take it this into account when implementing strategies to retain women with GDM in future healthy life intervention, varying their approaches over time.

The IINDIAGO study intervention was developed around the COM-B (Figure 2.2) and Behaviour Change Wheel (Figure 2.3) model. These models have proven to be useful. For example, the COM-B model has also allowed us to see that the intervention enabled some women to feel more capable to maintain their diet without being monitored or being followed up. This could mean that the more women feel that they have the ability, the more they feel motivated, and it becomes easier for them to stay in the intervention. One common outcome from women in both groups A and B was that women reported that they have learned and benefited from new ways of managing their diet, physical activity, and other behaviours (behavioural change). They reported learning new diet tips during their participation in the study and gained knowledge about GDM. But new knowledge is not enough: we found that most women who were primarily interested in gaining knowledge about diet decided to disengage from the study after delivery. For both groups, the motivation was there in the beginning of the study as women have indicated that they were all interested to take part initially despite having different motives, however that changed over time. Women who were retained reported that they are motivated to continue and do not face significant challenges, while women who disengaged faced challenges that decreased both their motivation and their ability (capability) as well as decreased opportunities (related to work or home constraints on using cell phones, travelling to appointments and so forth) to continue with the intervention, and led to them disengage.

Evidence has shown that creative use of the COM-B framework when applied in a socio-ecological context can identify the difficulties and challenges inherent in interventions (73). The literature further shows that for behavioural change models to be effective for participants, they need to show some capabilities in terms of wanting to learn more, psychological readiness including belief in their capacity to implement change in their lives and motivation to adopt

the services offered to them by the interventions (74). Women also need to understand the availability of support structures and be able to get support for them to stay motivated: this reflects both capability and opportunities. But the initiative and ownership by women themselves is very important: in this study, personal effort was also identified as one theme in the retention group, where women suggest that it is the responsibility not only of the intervention team and the health system but of the participants as well, to invest energy to receive the services offered (70).

The COM-B model has helped us to identify that it is important to understand the personal situation of the women from the beginning when they agree to participate, and to find out if their situations change with time. These changing personal situations affect all elements: capability, opportunity, and motivation, and then behaviour. Integration of healthy lifestyle interventions into regular routines, such as regular healthcare, is important as women with conflicting demands may still prioritise their infant's health routine check-ups and postpartum visits. Hence the emphasis should be put on the awareness of not only the perceived risk but also the possibility (both opportunity and capability) of positive change, both after during and after pregnancy. To support this, clear and supportive information sharing by the research team members is essential. Our findings show that there is a need to integrate the GDM interventions with the normal routine clinics for the women facing attrition challenges, because the most competing factors with interventions sessions were not mentioned when women were supposed to go for their scheduled clinic appointments, but only with respect to the intervention component that had been added to the routine visits – and made these visits longer and more complex.

Conclusions

The findings from this study suggest that to accommodate challenges that lead to attrition i.e., moving house, going back to work etc. we need to develop and implement strategies that can be open to change over time, in this case from the antenatal period to the postpartum period where the competing factors are starting to challenge the motivation and perceived opportunities and capabilities of participants.

Recommendations

To support the person-centred COM-B approach, it is important to listen to participants' suggestions. In this study, women suggested school campaigns as well as community outreach by themselves and by the intervention team, to bring the awareness of GDM and its future risk to the broader community. Others recommended the use of technology to be able to accommodate the women for whom work commitments and change of dwelling become a

competing factor after they have delivered (post-partum), but for some women the use of cell phones during work hours was forbidden and thus posed an important barrier. Nevertheless, the recommendation is an example of creative thinking by women to listen to and respond to challenges faced by others. It is a good example for intervention teams to follow.

4. APPENDICES

Appendix A. Ethics certificates

IINDIAGO Main Study Ethics Certificate

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Dr L Ware

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M170228

NAME: (Principal Investigator)	Dr L Ware
DEPARTMENT:	School of Clinical Medicine Department of Paediatrics and Child Health Developmental Pathways for Health Research Unit Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	An integrated health system intervention aimed at reducing Type 2 Diabetes risk in women after gestational diabetes in South Africa (IINDIAGO): a randomised controlled trial
DATE CONSIDERED:	24/02/2017
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Professor SA Norris
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	30/10/2018

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on 3rd floor, Phillip V Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.
I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date of the meeting when the study was initially reviewed. In this case, the study was initially reviewed in **February** and will therefore reports and re-certification will be due early in the month of **February** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Masters Research Ethics Certificate

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R49 Ms I Masuluke

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M210435

NAME: (Principal Investigator)	Ms I Masuluke
DEPARTMENT:	School of Clinical Medicine Department of Paediatrics and Child Health Developmental Pathways for Health Research Unit Medical School University
PROJECT TITLE:	*An integrated health system intervention aimed at reducing Type 2 Diabetes risk in women after gestational diabetes in South Africa (IINDIAGO): A randomized controlled trial*
DATE CONSIDERED:	2021/04/30
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Drs L Ware & A Kolkenbeck-Ruh; Prof C Zarowsky
APPROVED BY:	CB Penny Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2021/07/09

This Clearance Certificate is valid for 5 years from the date of approval. An extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office secretariat on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **April** and therefore reports and re-certification will be due in the month of **April** each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Masuluke
Signature of Principal Investigator

11/08/2021
Date

Appendix B: Participant quotes

Theme & subtheme: **Recruitment and reflections about study aims -** Women's recollections about the study aim
Quotes: *"And then I meet this lady she explained the study to me that they are looking for pregnant women who have had gestational diabetes, she said to me their aim is to assist the pregnant women who have been diagnosed with GDM to change their diet to be prevented from getting type 2 diabetes." Excerpt 1: 35y – group B* *"The day I signed the consent form with the IINDIAGO ladies I was at the hospital attending my GDM routine visits. So, they explained what GDM is and indicated that women get GDM or have high blood and I was not fully understanding and then they told me that GDM goes away after pregnancy and sometimes it does not go away, and they told me about the risk involved including the baby's risk." Excerpt 2:40y group B* *"I meet this lady who explained the study and then my interest was on the diet when she recruits me because since I am diagnosed with GDM I needed to change my diet that was the most important thing that attracted me." Excerpt 3:36y group B.* *"Ok. They told us about the … gestational sugar diabetes which affects women who are pregnant, so they talked about the study that they want to know like what causes it and what makes it go away and what makes it go to stage 2." Excerpt 4:31y group A)*
Theme & subtheme: **Attraction/reasons for participating -** GDM knowledge / general health concerns
Quotes: *''What attracted me was I wanted to know more about diabetic (GDM), and the healthy lifestyle so I realise I was living a wrong life, so I wanted to know that is why I joined the study because /I also wanted to find out about my health and how I was living my life things like that''. Excerpt 5: 28y Group A*

"Because I felt like the study will help me understand by situation differently. Because the first time I was diagnosed with GDM and I was admitted at hospital I did not understand was happening to me, by me participating in this study am keen to learn about the GDM." Excerpt 6:35y Group B. *And I wanted to know more about it. How does it work? Who does it affect?' Excerpt 7 :35y Group B* *"I was also keen to know why I had suddenly gotten diabetes. Since it was something, I never had. It only started when I was pregnant" Excerpt 8:28y group B*
Theme & subtheme: **Attraction/reasons for participating -** Protect the baby
Quotes: *"I just told myself that since I want the baby to come out healthy and for myself to be well then, I will have to do as they said and change my diet and follow through with everything, they told me to do because we both had to live; me and the baby." Excerpt 9:39y group A* *"The fear of losing my baby it was the first thing coming to my mind. Since I lost the baby once the fear was just hovering in my mind? Excerpt 10:40y group B.* *"When she explains she made me realise that me and my baby we are both in danger. Because of the benefits of this program explained to me I felt like there is a need for me to participate in this study, because I felt like the study will help me understand my situation differently. Because the first time I had GDM." Excerpt 11:35y Group B* *"Well, because I had quite a few miscarriages and a stillborn, that's what encouraged me to continue with the diet. Obviously, I wanted what was best for my baby." Excerpt 12:28y group B*
Theme & subtheme: **Attraction/reasons for participating –** Diet
Quotes: *"she said they will be teaching about the importance of diet and exercise to women who were GDM during and after pregnancy" Excerpt 13:36y group A* *"she said to me their aim is to assist the pregnant women who have been diagnosed with GDM To change their diet in order prevented from getting type 2 diabetes "Excerpt 14: 35y Group B*

"I was also keen to know why I had suddenly gotten diabetes. Since it was something, I never had. It only started when I was pregnant" Excerpt 8:28y group B *"And then my interest was on the diet when she recruits me" Excerpt 15:36y group B*
Theme & subtheme: **Experiences, learnings and lessons** - Adapting to the healthy lifestyle
Quotes: *"It was difficult because during the pregnancy you do not think about diets, especially dieting". Excerpt 16:39y group B* *"The diet part was difficult but with exercising I never had problems, I was ok with it". Excerpt 17:3y9 group B* *"They suggested the plan on how I can I slowly change my diet e.g. with exercise on how to start daily by walking and the one was the part where they explained to me what is GDM during pregnancy and how it can affect you after pregnancy if you don't stick to your diet or you don't control what you eat, They said you might have type 2 diabetes if you don't stick to the diet. I am not sure if I covered everything" Excerpt 18 :28y Group A*
Theme & subtheme: **Experiences, learnings and lessons**
Quotes: *Everything was… when they said the diet, I knew it is an expensive thing because even when you go to the shops, when you look at your low-fat things or anything like that with fat because anything that triggers sugar, you would know. So, when you look at the bread verses the bread you would buy in a tuck shop or a shop, it is more expensive." Excerpt 19:38y group B* *"Because I felt like the study will help me understand by situation differently. Because the first time I was diagnosed with GDM and I was admitted at hospital I did not understand was happening to me, by me participating in this study am keen to learn about the GDM." Excerpt 6:35y Group B.* *"I have learned that when a person follows instruction from the experts it helps even though you still do not understand why it is happening. It did not inly help me but the people that are close to me, and when I meet someone who is having GDM and ignorant I share my experiences with them. So, I tell them I have been in the same situation, and I have seen people losing babies because of denial and ignorant of GDM hence I try and motivate other people. I have further learned that people who are doing research are just after'' Excerpt 20: Excerpt 1:35 Group B*

. *"she said to me their aim is to assist the pregnant women who have been diagnosed with GDM To change their diet in order prevented from getting type 2 diabetes " Excerpt 14: 35y Group B.* *"The fear of losing my baby it was the first thing coming to my mind. Since I lost the baby once the fear was just hovering in my mind? Excerpt 10:40y group B* *"And I wanted to know more about it. How does it work? Who does it affect?' Excerpt 7 :35y Group B* *''My favourite part is the knowledge that was shared with me that has made it easy to follow the instructions of doctors and nurses, so maybe if I did not meet the IINDIAGO team maybe now my diabetic status will be worse' Excerpt 10:40y group B* *"And then my interest was on the diet when she recruits me" Excerpt 15:36y group B* *"And then I meet this lady she explained the study to me that they are looking for pregnant women who have had gestational diabetes, she said to me their aim is to assist the pregnant women who have been diagnosed with GDM to change their diet to be prevented from getting type 2 diabetes. When she explains she made me realise that me and my baby we are both in danger. Because of the benefits of this program explained to me I felt like there is a need for me to participate in this study, because I felt like the study wil l help me understand my situation differently. Because the first time I had GDM." Excerpt 11:35y Group B* *I was also keen to know why I had suddenly gotten diabetes. Since it was something, I never had. It only started when I was pregnant. Excerpt 8:28y group B*
Theme & subtheme: Adapting to the healthy lifestyle (Diet and Knowledge)

Quotes: *"It was not like the other pregnancy when I knew I could have chocolates or fruits or what-what every other day, so you just knew how to eat, how to go about eating and your state of mind would change because now you knew that… you don't have to stress about everything, you can't handle everything on your own, you need to speak up. If you go through something, you need to speak up. That's what I've learnt, I've learnt a lot from the study. So at least now it's a little bit better''. Excerpt 25: 41y group A* *"They suggested the plan on how I can I slowly change my diet e.g. with exercise on how to start daily by walking and the one was the part where they explained to me what is GDM during pregnancy and how it can affect you after pregnancy if you don't stick to your diet or you don't control what you eat, They said you might have type 2 diabetes if you don't stick to the diet. I am not sure if I covered everything. Excerpt 18:28y Group A* *"She said to me their aim is to assist the pregnant women who have been diagnosed with GDM To change their diet in order prevented from getting type 2 diabetes. "Excerpt 14: 35y Group B* *"And then I meet this lady she explained the study to me that they are looking for pregnant women who have had gestational diabetes, she said to me their aim is to assist the pregnant women who have been diagnosed with GDM to change their diet to be prevented from getting type 2 diabetes. When she explains she made me realise that me and my baby we are both in danger. Because of the benefits of this program explained to me I felt like there is a need for me to participate in this study, because I felt like the study will help me understand my situation differently. Because the first time I had GDM." Excerpt 11:35y Group B.* *"It was difficult because during the pregnancy you do not think about diets, especially dieting". Excerpt 16:39y group B* *"The diet part was difficult but with exercising I never had problems, I was ok with it". Excerpt 17:3y9 group B.* *"She said they will be teaching about the importance of diet and exercise to women who were GDM during and after pregnancy" Excerpt 13:36y group A*
Theme & subtheme: Combination of practical and social support

Quotes: *"Ok. Firstly, it was my husband. My husband is a… person who love vegetables so we researched about it that what a pregnant woman needs to eat for this kind of diabetes so that it can go away. I also had high blood and it also went away after the pregnancy. So, I made sure that I was eating healthy so my husband would always buy vegetables and fruits for me and relevant ones because we know that even… veggies and fruits are healthy but there are ones that we are not supposed to eat. I do not even remember which ones we are not supposed to eat but um… we researched about it and bought the relevant food that I needed to eat. And I did not eat too much of them because you know that too much of a thing is not right. So, I would eat different kinds of fruits that would help my immune system and help the baby to grow healthy''. Excerpt 26:31y group A.*

"My family, my husband, my friends. I had a lot of support because at home they started eating what I was eating''. Excerpt 27:30y group B

"At home they supported me a lot, you know, because they also stopped eating salty foods. We all started steaming the food and eating healthier''. Excerpt 28:37 group B

"I had support from my partner since we are living together, He made the diet changes with me, Going back home was my mother and my sister who were very supportive we even created an eating plan with my sister that will assist everyone in the house to reduce unhealthy food that we were eating to eat bit healthier food it was much better since I had people who were very supportive''. Excerpt 29:28y Group A

"They were asking how I was going to do it since I love food so much. They wondered if I was going to make it'' Excerpt 30: women with GDM aged 34 group B

"Everyone; my sister and everybody else. They were really discouraging me. Excerpt 31:34y group B Everything was… when they said the diet, I knew it is an expensive thing because even when you go to the shops, when you look at your low-fat things or anything like that with fat because anything that triggers sugar, you would know. So, when you look at the bread verses the bread you would buy in a tuck shop or a shop, it is more expensive." Excerpt 19:38y group B

" and then my interest was on the diet when she recruits me" Excerpt 15:36y group B

"Well, because I had quite a few miscarriages and a stillborn, that's what encouraged me to continue with the diet. Obviously, I wanted what was best for my baby." Excerpt 12:28y group B
Theme & subtheme: Retention Reasons (Perceived Risk, Communication and Hospitality)

***Quotes*: "I** *am continuing with that because they then explained to me that there is a possibility that you might be stage something if you do not adhere to the rules or anything like that'' Excerpt 33:36y group B.*

''I continued doing them. All the things that they said I should do, I did them even when I was alone. I was not cheating because when you take bloods, the results tell the truth more than your claims''. Excerpt 34:40y group A. ''Because I regarded as the people who were willing to help me managing my condition I, would listen to them and comply''. Excerpt 23: Excerpt 15:36y group B. Everything was… when they said the diet, I knew it is an expensive thing because even when you go to the shops, when you look at your low-fat things or anything like that with fat because anything that triggers sugar, you would know. So, when you look at the bread verses the bread you would buy in a tuck shop or a shop, it is more expensive." Excerpt 19:38y group B.

"Diet specifically, hence I see it fit to continue with the study and the importance of exercise even though now I have not gone back to my excessing schedule since I gave birth'' Excerpt 35: Excerpt 13:36y group A.

"My baby was positioned badly by the placenta so if I won't listen to how I am supposed to eat and reduce- he was too big ''Excerpt 24: 40y group A.

"It was not like the other pregnancy when I knew I could have chocolates or fruits or what-what every other day, so you just knew how to eat, how to go about eating and your state of mind would change because now you knew that… you don't have to stress about everything, you can't handle everything on your own, you need to speak up. If you go through something, you need to speak up. That's what I've learnt, I've learnt a lot from the study. So at least now it's a little bit better''. Excerpt 25: 41y group A.

"You offer the best services. So… I really do not know but you are doing your best as far as I can see. So… no… if you were to do anything more, I do not know. I even got my gift, that towel and''. Excerpt 38:31 group A.

"It was not like the other pregnancy when I knew I could have chocolates or fruits or what-what every other day, so you just knew how to eat, how

to go about eating and your state of mind would change because now you knew that… you don't have to stress about everything, you can't handle everything on your own, you need to speak up. If you go through something, you need to speak up. That's what I've learnt, I've learnt a lot from the study. So at least now it's a little bit better''. Excerpt 25: 41y group A "They made me feel like I am part of a family, at least. Because even if you forget your clinic dates, they will call me and remind me Excerpt 39.1:40y group A. "Diet specifically, hence I see it fit to continue with the study and the importance of exercise even though now I have not gone back to my excessing schedule since I gave birth'' Excerpt 35: Excerpt 13:36y group A
Theme & subtheme: Withdrawal Reasons (Personal situation - work commitments, schedule conflicts, relocation, illness, childcare, travel costs; communication)
Quotes: *" I have already mention that timing of the counselling was not working for me, I have already said that I spent half of the day at hospital and in the afternoon, I was supposed to meet with the team, but I could not I will go home instead. Imagine I arrive at hospital in the morning, and I finish at 14:00 and meet a counsellor I could not because pregnancy is tiring and exhausting''. Excerpt 42:3y6 group B.* *"You find that by the time you go to the diabetic clinic it is already past one (*13:00) so you are already irritated, and you have already been there at seven (*07:00) so you have not eaten because you don't know what the procedure is, well if I leave this queue, who will take my spot, so you are just irritated. But how (*08: 33 – 08:35 is inaudible) engage more with them with my mind being at home I will not concentrate on the session". Excerpt 42.1:38y group B* *"The reason I have pulled out from the study is because I had no time, after my consultation I wanted to go home not to meet with the study team'' Excerpt 41: 36 group B.* *"Then, the conversation stopped there''. Excerpt 46: 36Y group B.* *"It just happened unexpectedly because my husband no longer works in Johannesburg. He lost his job, so we were forced to move back to Limpopo." Excerpt 43:30Y group B.*

"Was home in the Eastern Cape and they said they would like to see me; I told them that I would not be able to because I am in the Eastern Cape''. Excerpt 44:30Y group B.

"It just happened unexpectedly because my husband no longer works in Johannesburg. He lost his job, so we were forced to move back to Limpopo". Excerpt 43:30Y group B.

"We had some- well, she did call me when I was done, I guess there was some break in communication''. Excerpt 45: 34y group B

The last time someone contacted me by telephone is when they told me I must call this number to tell them when I am in labour''. Excerpt 47: 36Y group B.

"The reasons they were struggling to get hold of me is because that I lost my phone, and I was not able to do sim swap because the person who picked up my phone was using my number so when the team members called he was not picking up and would block any number that was calling my phone I even tried to call him .Until this one time He stopped using my phone then I was able to do sim swap''. Excerpt 48:40Y group B. "The reason I have pulled out from the study is because I had no time, after my consultation I wanted to go home not to meet with the study team''. Excerpt 41: 36 group B

"The nurses made it scarier; you know. For me, it was like... it is like a…, what can I say? How do I put it? 'Excerpt no 49.1:36y group B. nurses as well. I felt that they should be more comforting rather than putting it like it is a death sentence''. Excerpt no: 49.2:36y group B

"Yes, there was such a time because I felt like it was too far; I could not come to Bara''. Excerpt 50: 39y group B

"For me it was far. Remember coming from Orange Farm to Bara now and then''. Excerpt 51: 39y group B. "Then, the conversation stopped there''. Excerpt 46: 36Y group B

"Yes, there was such a time because I felt like it was too far; I could not come to Bara''. Excerpt 50: 39y group B.

"Because I took a lot of time out while I was admitted at Bara, I did not have enough leave days. But once I accumulate enough days, I will go back and avail myself to them." Excerpt 53: 37y group B.

"My challenge is that when I am at work, I do not have time for the phone''. Excerpt 54: 30y group A ''I never had a problem I waited for their call''. Excerpt 49: 40Y group B

"I said I did not want to get into trouble; I had been absent too many times''. Excerpt 55:34y group B

"Well, like I said, I was back at work. Things got hectic because there was nobody to filling in my gap here as well, so I had to come back and start my work. You know? So, I had to catch up the work that is "the reason I had left''. Excerpt 56: 28Y group B

"I work Monday to Friday''. Excerpt 58:39y Group B

"Saturday and Sunday I want to do house chores because I hardly do during the week, laundry, and the other things''. Excerpt 59:39y Group B.

Subtheme: Lockdown

"For me, number one – the main thing is… is the pandemic itself… has made one to be scared to even come to the hospital because you know corona is there now''. Excerpt 60: 38y group B "Yes, there was such a time because I felt like it was too far; I could not come to Bara''. Excerpt 50: 39y group B.

"The reasons they were struggling to get hold of me is because that I lost my phone, and I was not able to do sim swap because the person who picked up my phone was using my number so when the team members called he was not picking up and would block any number that was calling my phone I even tried to call him .Until this one time He stopped using my phone then I was able to do sim swap''. Excerpt 48:40Y group B.

"Now, one gets scared… I will be honest with you, I was like very paranoid and said Yho… you know going to the hospital, I'll catch this thing there." So, one gets very paranoid that you are meeting… more than… more than, you know, the people that you should see a day or something – I do not even know what is the… the number of people you should see a day. But all I'm saying is that I felt it would be easier if you communicated maybe through the phone like we are doing now''. Excerpt 61:38y group B.

"Now, one gets scared… I will be honest with you, I was like very paranoid and said "Yho… you know going to the hospital, I'll catch this thing there." So, one gets very paranoid that you are meeting… more than… more than, you know, the people that you should see a day or something – I do not even know what is the… the number of people you should see a day. But all I'm saying is that I felt it would be easier if you communicated maybe through the phone like we are doing now''. Excerpt 61: 38y group B.

Subtheme: Personal Effort

"From my… from my perspective, I would say that I don't think anything needs to change. You know, it' is our responsibility as the patients. If you really know that say for instance that I have an appointment for OGTT and I found that I have GDM So the decision should come from the me, to know that I must honour my appointments because the study already informed me that my next appointment is such on his date and all I must be there at such a time. So, it's not like they phone me today or they tell me 'Today, you must come tomorrow.' I have time and if it' is important to me then I would know and I understand that I need to make time and I have to be there because like I'm saying, it's my health, it's my baby's health. So, these people already tried their best to help me, so I must – I, myself must also try to help myself and my baby. So, it's important for us to know that it's not only the hospital or the person that's helping you that they need to force you.' You, yourself must acknowledge that it's important and invest your time on it. Because all women want to be healthy, and all women want their child to be healthy so why would I skip an appointment. If I cannot, it has to be something very important. But then, not making it, phone in, let them know that 'this is happening now at this moment, I can'- It must be urgent. It doesn't have to be, just because I see now, I don't have petrol fare, I don't have transport money to come, no. I would say that this is irresponsible from the patient's side. It's like I can go anytime, they will help me – no. So, it comes from us as the patients, we need to be more responsible. And we need to know that our health and our baby's health comes first''. Excerpt 37. 1:41y group A.

"and if it' is important to me then I would know and I understand that, I need to make time and I have to be there because like I'm saying, it's my health, it's my baby's health. So these people already tried their best to help me, so I must – I, myself must also try to help myself and my baby. So it's important for us to know that it's not only the hospital or the person that's helping you that they needs to force you.' You, yourself

have to acknowledge that it's important and invest your time on it. Because all women want to be healthy, and all women want their child to be healthy so why would I skip an appointment. If I cannot, it has to be something very important. But then, not making it, phone in, let them know that 'this is happening now at this moment, I can'- It has to be urgent. It doesn't have to be, just because I see now, I don't have petrol fare, I don't have transport money to come, no. I would say that this is irresponsible from the patient's side. It's like I can go anytime, they will help me – no. So it comes from us as the patients, we need to be more responsible. And we need to know that our health and our baby's health comes first''. Excerpt 37. 1:41y group A.

" I have already mention that timing of the counselling was not working for me, I have already said that I spent half of the day at hospital and in the afternoon, I was supposed to meet with the team, but I could not I will go home instead. Imagine I arrive at hospital in the morning, and I finish at 14:00 and meet a counsellor I could not because pregnancy is tiring and exhausting''. Excerpt 42:3y6 group B.

*"You find that by the time you go to the diabetic clinic it is already past one (*13:00) so you are already irritated, and you have already been there at seven (*07:00) so you have not eaten because you don't know what the procedure is, well if I leave this queue, who will take my spot, so you are just irritated. But how (*08: 33 – 08:35 is inaudible) engage more with them with my mind being at home I will not concentrate on the session". Excerpt 42.1:38y group B*

"The reason I have pulled out from the study is because I had no time, after my consultation I wanted to go home not to meet with the study team'' Excerpt 41: 36 group B.

"Then, the conversation stopped there''. Excerpt 46: 36Y group B.

"It just happened unexpectedly because my husband no longer works in Johannesburg. He lost his job, so we were forced to move back to Limpopo." Excerpt 43:30Y group B.

"Was home in the Eastern Cape and they said they would like to see me; I told them that I would not be able to because I am in the Eastern Cape''. Excerpt 44:30Y group B.

"It just happened unexpectedly because my husband no longer works in Johannesburg. He lost his job, so we were forced to move back to Limpopo". Excerpt 43:30Y group B. *"We had some- well, she did call me when I was done, I guess there was some break in communication''. Excerpt 45: 34y group B* *The last time someone contacted me by telephone is when they told me I must call this number to tell them when I am in labour''. Excerpt 47: 36Y group B.* *"The reasons they were struggling to get hold of me is because that I lost my phone, and I was not able to do sim swap because the person who picked up my phone was using my number so when the team members called he was not picking up and would block any number that was calling my phone I even tried to call him .Until this one time He stopped using my phone then I was able to do sim swap''. Excerpt 48:40Y group B.* *"The reason I have pulled out from the study is because I had no time, after my consultation I wanted to go home not to meet with the study team''. Excerpt 41: 36 group B* *"The nurses made it scarier; you know. For me, it was like... it is like a…, what can I say? How do I put it?''Excerpt no 49.1:36y group B.*
Theme & subtheme: Satisfaction and Fear instilled by health care personnel and fear of pain from needle prick during OGTT

Quotes: *"For me, nothing. For me it was 100%, there's nothing that I can say- oh I regret going there''. Excerpt 62:41y group A. "well, like I said, I was back at work. Things got hectic because there was nobody to filling in my gap here as well, so I had to come back and start my work. You know? So, I had to catch up the work that is the reason I had left''. Excerpt 56: 28Y group B.* *"With the nurses as well. I felt that they should be more comforting rather than putting it like it is a death sentence''. Excerpt no:49.2:36y group B* *For me, it was like. , It is like a…, what can I say? How do I put it?''. Excerpt no 49.1 :36y group B* *. "With the nurses as well. I felt that they should be more comforting rather than putting it like it is a death sentence''. Excerpt no: 49.2:36y group B* *"For me it was the first encounter. You know, first encounter is important so my first encounter with them I – you know when you are at Bara, right, you are really scared what do you call it? (* 08:10 – 08:12 is inaudible) and being ill-treated because of the lack of good treatment there''. Excerpt no 49.3:36y group B.* *"Like I said, there is nothing that I can say, that I can complain and say, no this was-they didn't do this right, they didn't do that right… With me… how they treated me, and with others, I don't know. But what I've seen, they were very concerned about the people. They took good care of us. They took good care of the mother and the baby. So, for me it was, it was excellent joining this study because it was nice, and I enjoyed it. It was an excellence group and I have no complaints''. Excerpt 64:41y group A*
Theme & subtheme: Use of technology, Local clinic /campaigns

Quotes: *"Something like that, because you do get 5-minute breaks where you can go onto your phone and you check, you can go on to that link''. Excerpt 65:28y group B.*

"Saturday and Sunday I want to do house chores because I hardly do during the week, laundry, and the other things''. Excerpt 59:39y Group B.

"Maybe have them nearer. Yes, maybe the induction can be at Bara''. Excerpt 71:39Y group B.

"So, if you try to go to the clinics and introduce it because some of the patients in the clinics end up giving birth in the clinic itself, so they know nothing about this thing''. Excerpt 75:35y Group B. "But all I'm saying is that I felt it would be easier if you communicated maybe through the phone, like we are doing now''. Excerpt 69:38y group B.

"Something like that, because you do get 5-minute breaks where you can go onto your phone and you check, you can go on to that link''. Excerpt 65:28y group B

"Like campaigns, identify your targets I am not sure if campaigning in schools can work because of Covid that is where you can spread more information'' Excerpt 77:36Y group A ''I do not know. I am not sure. But perhaps in the clinics, they should be a dedicated space for diabetic people. Then they would know that on certain days, they come through and meet with other people. When you meet other people who are in the same situation as you, you get that encouragement that you are not alone, you see''? Excerpt 73:37Y group A.

"What I think you can do is you can teach all the nurses in the local clinics to makes sure that women who are facing challenges are able to go and attend at their free time and be able to get equal information with the ones that are attending with the study full time. And for us who stay far away from the hospital is a challenge if it is Offered in the local clinic, it will be better''. Excerpt 70:30y group A.

"It would be better because you can walk to the clinic''. Excerpt 72: 39Y group B.

"If you just add clinics because most people in clinics do not know anything about diabetes'' Excerpt 74:35y Group B.

"I do not know. I am not sure. But perhaps in the clinics, they should be a dedicated space for diabetic people. Then they would know that on certain days, they come through and meet with other people. When you meet other people who are in the same situation as you, you get that

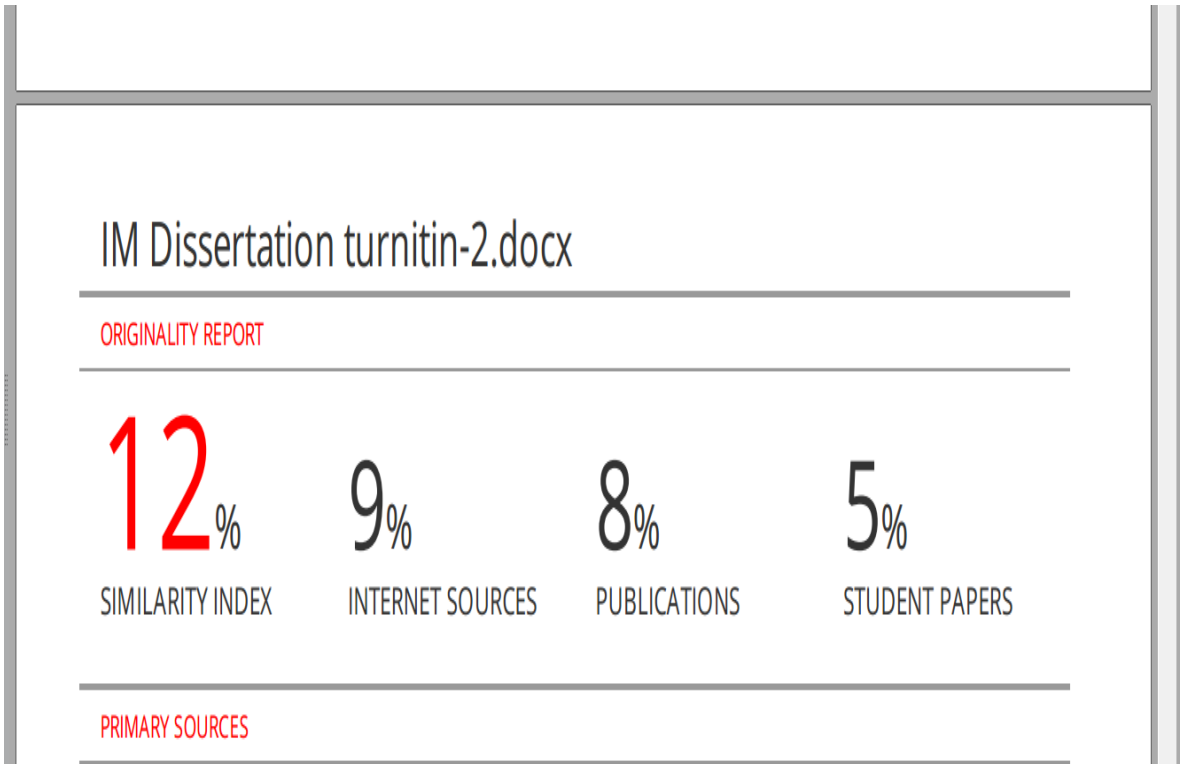
encouragement that you are not alone, you see''? Excerpt 73:37Y group A. "Like maybe do them via WhatsApp or maybe create a group or something so when they get time they join''. Excerpt 67:41y group A

"Or email for instance''. Excerpt 66:28y group B

"Like maybe do them via WhatsApp or maybe create a group or something so when they get time they join''. Excerpt 67:41y group A. "You know I do not have time at all, but I like to be part for this study but honestly, I do not have time''. Excerpt 57:39y Group B

"What I think you can do is you can teach all the nurses in the local clinics to makes sure that women who are facing challenges are able to go and attend at their free time and be able to get equal information with the ones that are attending with the study full time. And for us who stay far away from the hospital is a challenge if it is Offered in the local clinic, it will be better''. Excerpt 70:30y group A

Appendix C: Turn-it-in report



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ORIGINALITY REPORT

12%	9%	8%	5%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

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