

**The home environment and play: The co-creation of an intervention aimed at
increasing participation in infant play in a low- income community in
Johannesburg, South Africa.**

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A thesis submitted to the Faculty of Health Sciences

School of Clinical Medicine

Department of Paediatrics and Child Health

University of the Witwatersrand

in fulfilment of the requirements for the degree of

Doctor of Philosophy

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DECLARATION

I, Fiona Alison Bennin, declare that this thesis is my own, original work. It is being submitted for the degree of Doctor of Philosophy at the University of the Witwatersrand, Johannesburg, South Africa. It has not been submitted before for any degree or examination at any other university or institution.



Date: 11 August 2025

DEDICATION

I dedicate this thesis to my children and to all the children who I have had the pleasure of meeting that don't have the same opportunities as my own, only because of where they were born. You have inspired me to work towards making the world a healthier, safer and more equitable place for all who live in it.

ACKNOWLEDGEMENTS

I so appreciate the support of my supervisors, Dr Alessandra Prioreshi and Professor Shane Norris in guiding me in this journey towards completing this PhD. You have both gently guided me in developing the skills and the knowledge required to complete the PhD and encouraged me to continue with the journey despite numerous personal, financial and geographical constraints along the way. I will forever be grateful for the support of my fellow PhD students – Helene, Sarah (and Dumsile) in getting through the highs and lows of our project, I am not sure how I would have gotten through some of the more trying times without you. This study would not have been possible without the amazing PLAY study research team – Zama, Ngomeni, Dudu, Ngoyi and Kgomotso, you were the absolute best to work with and your passion for the project and participants was inspirational. Of course, this study could not be possible without the mothers and infants of Soweto who volunteered their time and shared so much of their personal lives over these two years – your stories will remain with me and inspire me to work harder to see better support given to postpartum mothers in South Africa. I cannot thank my family, friends and colleagues at DTHF enough for the numerous pep talks, hearing my endless complaints about my stats, provision of childcare when writing up my thesis, etc. (the list goes on) – it really does take a village, and I am so thankful for your support in getting me to the finish line. Lastly, I would like to thank my husband, Kweku, for his unconditional support, sacrifice and belief in what I can achieve, often at his own expense. I thank God for His grace and provision during this time and for the opportunity to pursue this degree.

FUNDING AND AWARDS

The PLAY study was supported by the National Institute for Health Research (NIHR) (using the UK's Official Development Assistance (ODA) Funding) and Wellcome [222007/Z/20/Z] under the NIHR-Wellcome Partnership for Global Health Research. This funding contributed to the development and implementation of the PLAY study intervention, which my thesis study was part of. However, personally, I received the following awards:

1. Wits Postgraduate Merit Award (PMA) 2022-2024 – A merit award covering tuition fees and provision of a termly stipend while assisting the Department of Paediatrics with set duties each term
2. International Society for Behavioural Nutrition and Physical Activity (ISBNPA) 2024 Pioneers scholarship - \$1500 award given towards the completion of a study or part of a study, in view of submitting an abstract and presenting at ISBNPA conference 2025

PUBLICATIONS AND PRESENTATIONS

Peer Reviewed Publications arising from this PhD:

First author:

Paper 1 (Chapter 3)

1. **Bennin F**, Theunissen H, Norris S, Prioreshi A. Determining the perceived acceptability of an intervention designed to improve health literacy around developmentally appropriate play during infancy, with a community advisory group of mothers, in Soweto, South Africa. *PLOS Global Public Health*: 4(8): e0002233. <https://doi.org/10.1371/journal.pgph.0002233> (Appendix Q)

Paper 2 (Chapter 4)

2. **Bennin F**, Norris SA, Prioreschi A. The feasibility and acceptability of an app-based intervention aimed at improving maternal health literacy around infant play and development: A mixed methods study. *JMIR Form Res* (forthcoming) doi:10.2196/76517

Co-author:

3. Prioreschi A, Pearson R, Richter L, **Bennin F**, Theunissen H, Cantrell SJ, Maduna D, Lawlor D, Norris SA. Protocol for the PLAY Study: a randomised controlled trial of an intervention to improve infant development by encouraging maternal self-efficacy using behavioural feedback. *BMJ Open* **13**:e064976. <https://doi.org/10.1136/bmjopen-2022-064976>.
4. Theunissen H, **Bennin F**, Cantrell S, Dennis C-L, Prioreschi A. Formative research to co-create and determine the acceptability of intervention content designed to improve breastfeeding self-efficacy and outcomes in Soweto, South Africa. *Pilot and feasibility studies: Breaking Barriers: Shaping Global Health Futures with Pilot and Feasibility Initiatives. (Currently in Review)*
5. Stuart L, Hart C, Desai R, Norris SA, **Bennin F**, Theunissen H, Prioreschi A. Examining maternal health literacy as a mediator of the relationship between social vulnerability and caregiving practices for improving infant development. *BMC Public Health (Currently in Review)*

Conference Proceedings arising from this PhD:

1. **International Society for Behavioural Nutrition and Physical Activity (ISBNPA): Omaha, USA, 20-23 May 2024. Oral Presentation.** Determining the perceived acceptability of an intervention designed to improve health literacy around developmentally appropriate play during infancy, with a community advisory group of mothers, in Soweto, South Africa.

2. **International Society for Behavioural Nutrition and Physical Activity (ISBNPA): Auckland, New Zealand, 11-14 June 2025. Poster Presentation (accepted, still to attend).** Opportunities for active play: Determining the effect of a 12 month intervention aimed at improving maternal health literacy around infant play and development in a low-income community in Johannesburg, South Africa.

Thesis Material and Contributions

Together with my supervisors I contributed to the conceptualization of my topic and study methodology for this thesis. I decided on what outcome measures to use and together with the rest of the PLAY Study team, came up with the intervention plan. I then created my own health literacy content to be used as part of the intervention. Questionnaires were administered by Research Assistants, however I trained each Research Assistant to administer each questionnaire. I attended all Focus Group Discussions, taking notes and giving guidance, as required. Lastly, I conducted the data analysis, data management, quality control and analysis of all data that was relevant to my study.

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NOMENCLATURE

AHEMDS-IS - Affordances in the Home Environment for Motor Development – Infant Scale

BMI - Body Mass Index

CAG - Community Advisory Group

CHBAH – Chris Hani Baragwanath Academic Hospital

CHW - Community Health Worker

Data QC – Data Quality Control

DPHRU - Developmental Pathways for Health Research Unit

DOH - Department of Health

ECD - Early Childhood Development

ECDI - Early Childhood Development Index

eHealth – Electronic Health

FGD - Focus Group Discussions

HCW – Health Care Workers

HLQ - Health Literacy Questionnaire

HIC – High-Income Country

ICF – Informed Consent Form

LMIC – Low- and middle-income country

MAMA - Mobile Alliance for Maternal Action

MHL – Maternal Health Literacy

MRC – Medical Research Council

mHealth – Mobile Health

MOU - Midwife Obstetrics Unit

NCD - Non-Communicable Disease

PA – Physical Activity

PCA - Principal Component Analysis

PLAY - Play Love and You

RTHB – Road to Health Booklet

RCT - Randomised Controlled Trial

RA - Research Assistant

RedCap - Research Electronic Data Capture

SMS - Short Message Service

UK – United Kingdom

US – United States

Wits - University of Witwatersrand

WHO - World Health Organisation

ABSTRACT

Background: Infants require their caregivers to provide opportunities to engage in playful activities that promote early development and encourage further positive health outcomes later in life. Mothers require a certain level of health literacy to access, appraise and understand information to have the capability to make decisions that encourage optimal health for their child. However, some mothers living in low-income settings do not have access to information or adequate support for encouraging play and development. Mobile Health applications have the potential to provide cost effective, scalable interventions and improve health outcomes in low-resources settings, such as South Africa, when effectively implemented. The aim of this thesis was to develop and implement an intervention aimed at improving maternal health literacy around infant play and development and to determine whether this intervention was acceptable, feasible, and effective.

Methods: A Community Advisory Group co-created and tested an intervention prototype aimed at increasing maternal health literacy around play and development, through focus group discussions and testing the activities at home. The intervention was then implemented as part of the PLAY study, a Randomised Controlled Trial, conducted from September 2022 to June 2024 (N=133). From 6-12 months postpartum, intervention group participants (n=68) received interactive App-based content promoting health literacy and encouraging infant active play and development. The control group (n=65) received the normal standard of care. The primary outcome was the Health Literacy Questionnaire scores, while secondary outcomes included maternal beliefs about infant physical activity, home affordances for motor development, and infant physical/sedentary behaviors. A combined “opportunities for active play” score was derived from the secondary measures. Data were analysed in STATA, using an intention to treat approach. Descriptive data were reported using N (%) for categorical data and means (Standard Deviation) for continuous data. Wilcoxon rank tests determined the effect of the treatment. Feasibility and acceptability of the intervention were measured and explored at the end of the study (12 months) through participant Focus Group Discussions and semi-structured questionnaire.

Results: Community Advisory Group participants suggested that the intervention content be delivered every 1-2 weeks, through a data-free app. Overall, the prototype activities tested at home were deemed

acceptable. At intervention baseline, the 67 intervention and 65 control participants averaged 29 years old; most were single (64%) and had completed secondary education (64%). No significant differences were observed at 12 months between groups in maternal Health Literacy Questionnaire ($t=-1.05$ $p=0.3$), maternal beliefs ($t=0.71$; $p=0.48$), infant physical activity ($t=0.15$; $p=0.88$) or sedentary time ($t=-0.89$; $p=0.38$), and opportunities for play ($p=0.36$). However, the change in Maternal Beliefs score from 6 to 12 months was significant ($p=0.00$), with the intervention group's scores increasing on average, 35.44 points compared to an average of 25.7 points in the control group. Participants in the intervention group showed a significant decrease of 1.53 units in the AHEMDS score, compared to the control group, at 12 months. When looking at the change in opportunities for play from 6 to 12 months, there was a significant ($p=0.001$) difference between the intervention and control group, with 27 participants (40%) in the intervention group increasing between 1 and 3 points (compared to 8% in the control group) and 43 participants (42%) of the control group decreasing between 1 and 4 score units (compared to 31% in the intervention group).

The health literacy intervention content was found to be highly acceptable based on the questionnaire and Focus Group Discussions. Over 80% of participants attended the 12 month exit appointment. Most of the participants (70%) could access the intervention content over the 12 months of the PLAY Study and of those, 59% looked at content more than once a week and 10% every day. Less than a quarter only looked at the content sporadically. Access was impacted by technical difficulties attributed to using inconsistent external service providers. Other factors which negatively impacted implementation included low intervention dosage, questionnaire burden and resource constraints.

Conclusion: While the intervention was found to be highly acceptable to participants, it did not have a significant effect on Health Literacy Questionnaire scores. While adherence numbers were positive, there were numerous implementation challenges which researchers need to consider carefully when planning a complex intervention in a similar low resource context.

PREFACE

My journey to starting this PhD started with my work as a Paediatric Occupational Therapist in both South Africa and the UK, where I saw firsthand the implications of poor maternal health literacy and its impact on child development. This was particularly significant in areas where children weren't safe to play outside or preferred to watch TV due to inclement weather, and this led me to start considering interventions that one could implement inside with minimal resources, to encourage more play. In 2019 I moved from the UK to Cape Town (my hometown) and ended up at the Division of Environmental Health working as a project manager, where my interest in the impact of the environment on children's health grew even more. When I saw the advert for this PhD position, I was immediately interested and was so happy to join with other students who shared similar values and goals. As I started in early 2022, this was still in the COVID 19 lockdown where remote working seemed to be the new normal. I was dedicated to completing this PhD remotely, which did end up happening but at a significant financial and methodological cost.

While I attempted to follow the PhD by publication structure (Introduction, Methods, Empirical Results Chapters (all in article format) and discussion and conclusion, I found that my primary outcome did not have any effect and therefore I dedicated chapter 5 to exploring potential reasons for this, as well as my learnings from it. As I had more interesting findings from my secondary outcomes, I decided to add chapter 6, which explained the findings and their implications in more detail. Therefore, chapter 5 and chapter 6 are extended and do not stick to the normal style used when publishing articles. However, they will be adapted for publication following completion of this PhD.

The outline of the thesis is as follows:

Part 1 & Part 2: Introduction & Methodology

- Parts 1 and 2 describe the introduction to the topic, the problem, conceptual frameworks, literature review and methods used in the thesis.

Part 3: Empirical Chapters

- Chapter 3: Determining the perceived acceptability of an intervention designed to improve health literacy around developmentally appropriate play during infancy, with a community advisory group of mothers in Soweto, South Africa (PLOS Global Health, 2024)
- Chapter 4: “The app was not just helping me, but all of us at home”: Exploring the feasibility and acceptability of an intervention aimed at improving maternal health literacy around play and development in Soweto, South Africa (submitted to Pilot and Feasibility Studies, in review)
- Chapter 5: Primary outcome methods and results (not submitted for publishing yet)
- Chapter 6: Secondary outcome methods and results (not submitted for publishing yet)

Part 4: Integrated Discussion and Conclusion

- Chapter 7 discusses the main findings, frameworks, themes and implications of the research and well as main learnings and conclusions.

PART 1: INTRODUCTION

1. Chapter 1: Background and literature Review

1.1. Health Literacy

Health literacy, the literacy and numeracy skills required for individuals to access, understand, appraise and use information to make decisions about their health, is imperative for taking actions that will impact an individual's health and wellbeing (1,2). Health literacy skills are required in a number of different contexts, including communication between health provider and patient, interpreting messages sent in media or when reading manufacturer instructions about medication (3). Certain factors such as lower educational attainment, older age and communicating in a non-native language can result in lower levels of health literacy in individuals (3). However, in recent years, practitioners and policy makers have become more aware of the importance of an individual's context, where even the most health literate person can be overwhelmed and unable to apply these skills when in a new environment such as a clinical setting or when caring for a new baby (1). The World Health Organisation (WHO) further expands on this concept to highlight the importance of the responsiveness of services (availability and accessibility) in partnering with individuals in decision making for health (Figure 1).

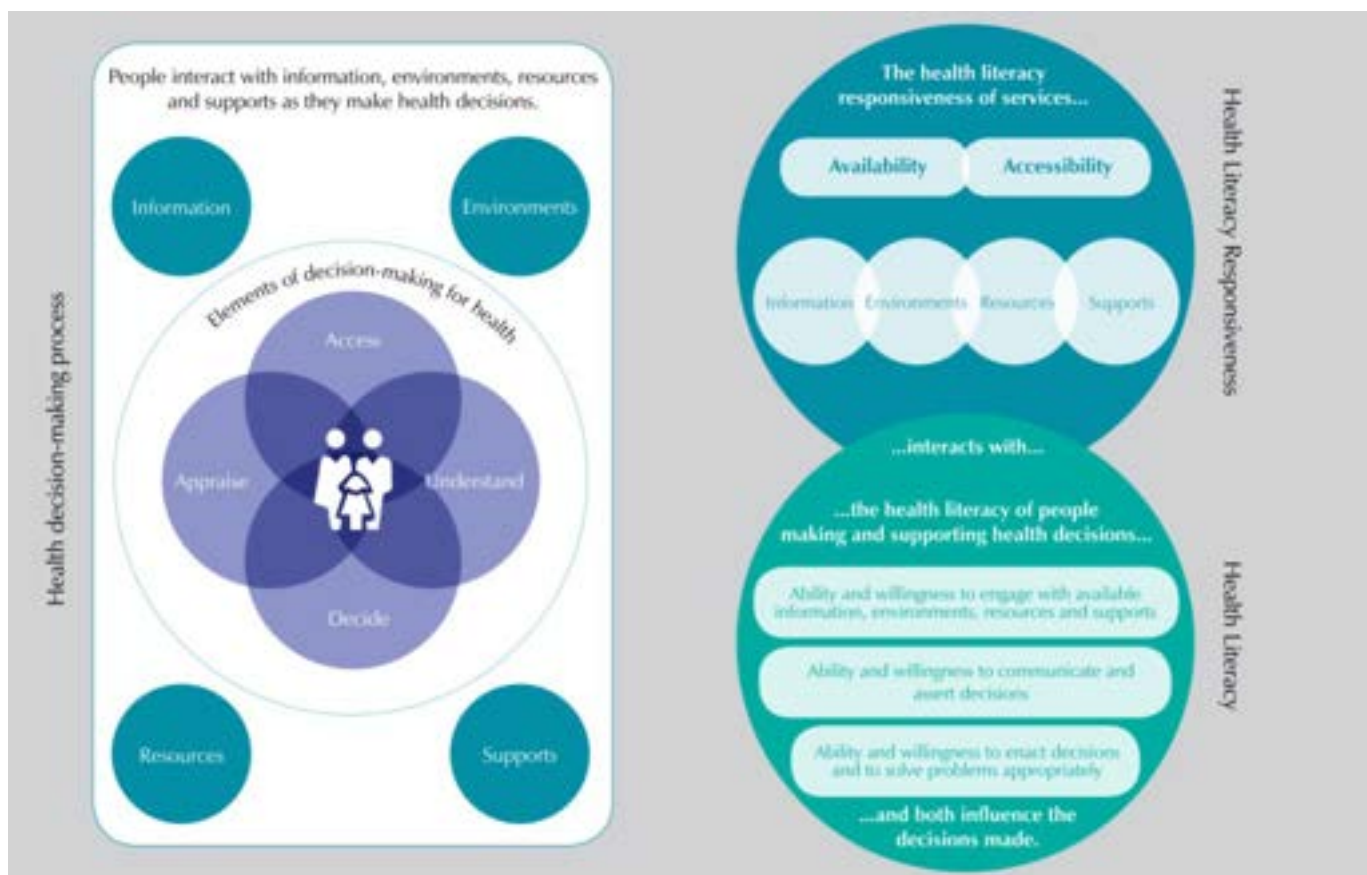


Figure 1: The WHO depiction of the interaction between health literacy and the health literacy responsiveness of services (2)

Globally, health literacy levels are difficult to measure, due to variations in health literacy measurement tools. In the United Kingdom (UK), 4 in 10 adults struggle to understand health content written for the public, and 7.1 million adults reading at or below the level of a 9 year old (4). Similarly, in the United States (US), around half of the population have adequate levels of health literacy (5). Studies conducted in African countries have found that between 35 to 85% of health users accessing health information do not have adequate levels of health literacy needed to make informed decisions about their health (6). In South Africa RA, studies have had differing findings with some reporting as little as only 18% of participants having adequate levels of health literacy (6). South Africa has 12 official languages (including sign language); however, English is often used as the primary language for health education, either orally or in written format such as posters, pamphlets,

etc. (7). A recent study investigating actual levels of comprehension in South African Primary Health Care facility patients, found that while most participants reported completing grade 11–12 schooling, only 42% of the respondents scored at this level. Many scored up to 3 grades lower than reported, with approximately 25% scoring below the 8th grade level required to understand basic health information (7). As the majority (53%) of adults (aged 25-64 years) in South Africa have not completed secondary school, it is likely that a large majority of the population do not have adequate levels of health literacy to manage their own health or their children's health (8).

1.2. Maternal health literacy and the impact on play and development

Maternal health literacy (MHL) can be defined as the ability of mothers to obtain, interpret, appraise, and apply information to maintain and promote the health of their children (9). As caregivers are responsible for their children's health and development, they need to be able to understand and access quality information to encourage informed decision making. There are several studies (with young children older than 12 months) showing the positive relationship between maternal health literacy and early childhood development (ECD), both in High-Income Countries (HICs) and Low- and Middle-Income Countries (LMICs)(10–12). According to the Early Childhood Development Index (ECDI), children with mothers who have sufficient health literacy are more likely to be developmentally on track than those who have low health literacy (10). Children whose parents have low health literacy levels are often at risk of poorer health outcomes, compared to those with adequate health literacy levels (11). Examples of adverse health outcomes include non-adherence to medications, increased mortality and morbidity rates, increase in length of hospital stays as well as difficulty in preventing and managing non-communicable diseases (7). Non-English-speaking women in the US with low health literacy have been found to be at high risk of having a child with developmental delay (12). Children of mothers with sufficient electronic health literacy levels (eHealth literacy) are more likely to be on track for meeting development milestones and have adequate support in their learning (13). Mothers with higher health literacy are also more likely to provide more affordances in the home such as activities and resources (including toys) that offer greater variation in overall stimulation in the child's environment (14). Maternal health literacy is

often correlated with higher levels of income, social support, education and parenting self-efficacy (15). Lastly, women who have higher levels of health literacy are more likely to access health facilities during pregnancy and postpartum for routine check-ups and visits (16). Self-efficacy, the belief in one's capabilities to produce a desired result because of one's actions, is an important factor in promoting nurturing and interactive care between mother and infant (17). A study conducted in the US with low literate mothers, found that parenting self-efficacy had a mediating effect on maternal mental health and early parenting practices with their infants (15).

1.3. The importance of equipping mothers to encourage infant play and development in the home

While the importance of active, unstructured play in promoting development is well documented (18)(19,20), previous studies conducted in Soweto, South Africa, found that although mothers understood the need for play in promoting development, they often lacked the incentive and motivation, as well as the knowledge of how to promote development (21). There was often a misconception that expensive toys were needed to encourage play and development (21). These behaviours and misconceptions contribute to a reduced opportunity for active, exploratory play, in the South African child population as a whole (22). Furthermore, there are certain social and environmental factors which can limit participation in play, particularly in low resource settings such as South Africa. Examples of environmental factors in outdoor areas which are not seen as safe for play, include heavy traffic, unsanitary conditions, exposure to violence, pollution, etc., as well as small and overcrowded indoor areas (21). Social conditions that impact play include, low maternal health literacy, lack of resources for toys or books, maternal beliefs around play and poor maternal mental health (21,23). In South Africa, the value of play is not generally understood amongst caregivers (22). While many parents acknowledge that play is important for bonding, learning through play is usually understood to be more for socialization, with the belief that most learning occurs at ECD groups, or through technology (i.e. playing on phones or watching television) (22). Some caregivers believe that children below the age of two are too young for books and play, with 43% of households not owning any children's books (22).

In the early years, children spend most of their time in the home environment and community where they interact with family members and other community members (18), which is particularly relevant for South African communities where in 2022, 80% of 0-2 year olds received care at home without attending any ECD programmes/ facilities (24). The South African Child Gauge suggests that support and services should be provided according to each stage of a child's development. Specifically for early learning, the report suggests that there needs to be play and learning opportunities from birth, caregivers should talk to and play with their children and play materials and books should be available in the home (24). Parents also need to be provided with the correct tools and support to promote responsive caregiving, child directed learning and positive parenting (24). However, with this in mind, in 2022 only 43% of 4-5 year olds enrolled in early learning programmes were on track for early learning and growth in South Africa (25).

For those children spending most of their time at home, their primary caregivers are their first educators and therefore have an important role in providing opportunities for play and learning (18). It is therefore essential to empower and provide support to caregivers, to promote playful learning in day-to-day activities in the home environment and broader community (18). In 2023, in the Gauteng Province, 37.1% of children lived with only their mothers, 47% with both their parents and 11.4% lived with neither parent (24). These statistics highlight the importance of improving maternal health literacy so that mothers can be better equipped to promote positive behaviours at home.

Unstructured outdoor play is particularly important for children's development as it provides opportunities for the development of gross motor skills (e.g. jumping, climbing and kicking and throwing balls, etc.) and higher intensity physical activity (PA) required to meet daily movement guidelines. (26,27). It is important to note that caregivers need to provide access and opportunities to engage in unstructured play for their children, which highlights the importance of caregiver education and modelling when attempting to encourage more unstructured play with children.

1.4. Literature review

1.4.1. Maternal Health Literacy interventions

Health literacy is a well-researched concept, however interventions to improve health literacy are predominantly focused on HIC populations and managing chronic illnesses in adults (28–30). Interventions that focus on using interactive communication methods to develop health literacy skills have been found to be effective, however many health literacy interventions are limited to clinical environments, with only a few implemented in community settings (28). For the limited number of health literacy interventions for pregnant women, only a few reported studies are from LMICs (31,32). A study in China, which aimed to improve maternal and child medical outcomes by implementing a “teach back” method in mothers with low health literacy, showed positive results in improving post-partum health behaviours following implementation of the programme (33). A scoping review reporting the global health literacy interventions for pregnant women and mothers with young children, found 2 out of twenty-five articles from LMICs (Kenya and South Africa) (34). The study from South Africa focused on health promotion in pregnant women by sending weekly Short Message Services (SMSes) (35).

1.4.2. Mhealth in maternal and child health

With the increase in access to mobile phones in LMICs, the potential to encourage positive healthy behaviour change and outcomes at a community level, through use of digital interventions, has increased over recent years (36). Mobile health (Mhealth) interventions have the potential to improve communication with providers, reduce travel time, increase uptake of services, enable sharing of expert advice and provision of cost-effective education, as well as improve treatment adherence and health outcomes (37,38). However, many Mhealth interventions are piloted but few are implemented, either due to the low efficacy of the intervention or failure in implementation (37).

There have been a variety of Mhealth interventions aimed at promoting maternal and child health in LMICs and specifically in Africa. Some of those that involved Community Health Workers (CHWs) in delivering the intervention required extra support in helping the CHWs understand how to use the app and troubleshoot any technical glitches, which often reduced the CHWs' acceptability of the interventions due to their busy schedules. However, once trained the CHWs did report greater confidence in their decision-making and knowledge, as well as improved communication with their clients (39,40). Other findings related to Mhealth interventions focusing on maternal and child health have suggested that using SMS messaging can be too simple with insufficient information, and that one of the main benefits of using a mobile app is the potential to address a range of health issues or topics within one area of health, increasing user engagement and levels of acceptability (41).

When considering maternal and child Mhealth technologies, Momconnect, implemented by the Department of Health (DoH) is well known and easy to access in South Africa. Momconnect aims to educate pregnant women and mothers and link them to health services (42). Momconnect sends regular messages via SMS at each stage of pregnancy or postnatal care. Text messages include reminders for clinic visits, as well as information about medicines, tests and where to access certain services such as immunisations, etc. (42). However, reports have shown that while it is helpful, some find the Momconnect messaging inconsistent and still prefer face-to-face services as written information can be hard to understand (43). Following on from Momconnect, a pilot study called Childconnect, provided new mothers with ECD content by providing weekly text messages (44). Childconnect showed small but promising increases in caregivers' learning gains for those who received the intervention. However, one of the main challenges of the text-based system was that if recipients changed/ lost phones or numbers, they struggled to connect to the service again and refer to messages or information already received (44). After implementing a similar text-based messaging service in South Africa, the Mobile Alliance for Maternal Action (MAMA), found that those who did receive the texts had higher numbers of antenatal and postnatal attendance as well as an increased likelihood of having a vaginal birth (45).

When considering maternal and child Mhealth interventions in South Africa, of the 26 articles included in a systematic review which reported on Mhealth interventions for improving maternal and child health outcomes in South Africa, MomConnect was the most researched (46.15%), followed by MAMA (11.53%) (46). When discussing gaps in literature, this same review discussed the lack of community stakeholder engagement in the majority of the studies, and the importance thereof. Secondly, the review noted that most of the interventions were SMS based and there is a need for use of emerging technologies in the provision of care in maternal and child health services (46).

1.5. Developing and evaluating interventions – two sides of the coin

From the review of the literature, there is a clear need for context and culturally appropriate interventions which improve health literacy around play and development in postpartum mothers. When developing and implementing an intervention which aims to change behaviour, it is important to determine whether the intervention has resulted in the desired behaviour change, and if not, why not. However, the use of behaviour change theories (BCTs) in digital interventions are often not reported, incorrectly operationalized, or incorrectly reported, making the effect incorrect or unknown (47)

This introduces the concept of having two sides of the coin, where in this study, one side focuses on developing an intervention to improve maternal health literacy around play and development and the other side of the coin focuses on evaluating said intervention. The “two sides of the coin” analogy can be further expanded upon when using the UK Medical Research Council’s (MRC) updated Framework for developing and evaluating complex interventions. This framework describes four phases of complex intervention research, namely, 1) development or identification of the intervention, 2) feasibility (and acceptability), 3) evaluation, and implementation (figure 2) (48). Each phase can be repeated, and the process can begin at any phase, however each phase has a common set of core elements which should be revisited throughout the process. They are: 1) considering

context, 2) developing and refining programme theory, 3) engaging stakeholders, 4) identifying key uncertainties, 5) refining the intervention, and 6) economic considerations (48).

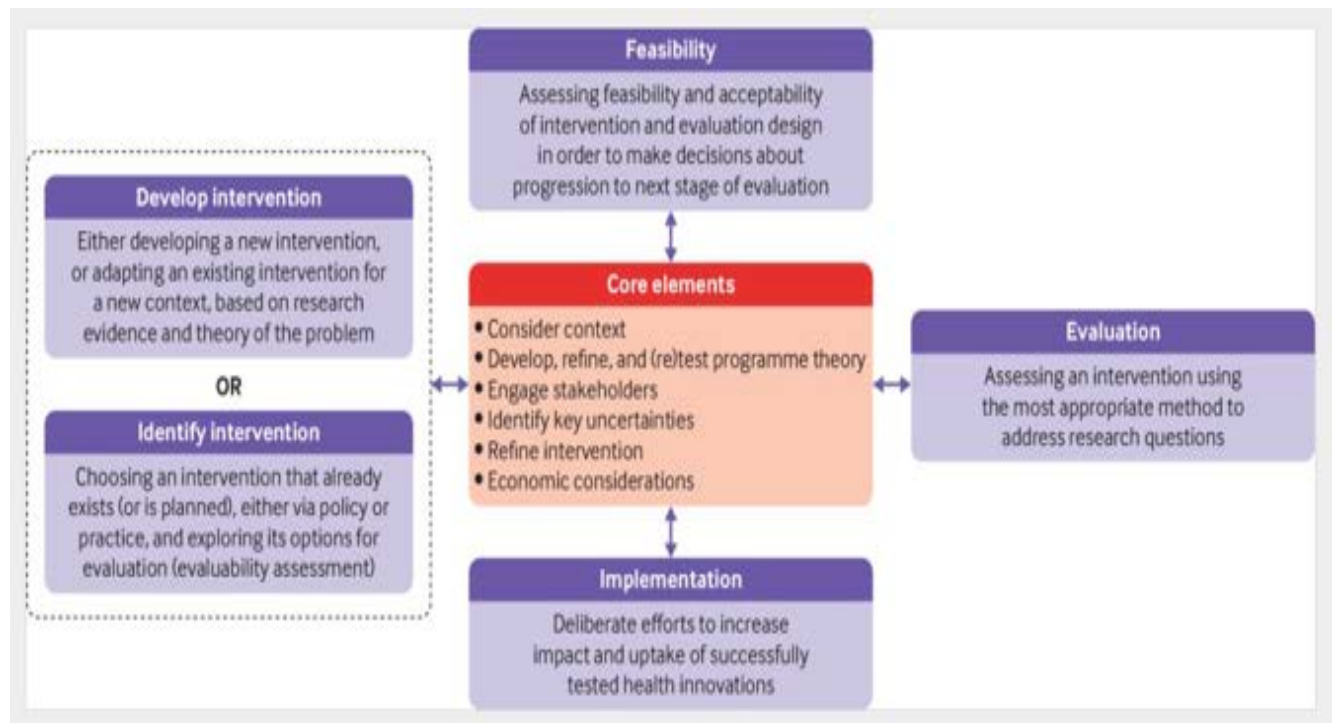


Figure 2: UK MRC Framework for developing and evaluating complex interventions (48)

Another important factor to consider when developing and evaluating complex interventions is co-creation. Co-creation is a collaborative method used to design, implement and evaluate services and interventions by including all stakeholders involved (49). Using co-creation to develop healthcare interventions in LMICs has been found to be impactful in removing researcher/participant hierarchies, understanding communities' most pressing issues, and providing further insight into the systemic issues only experienced by respective communities (49,50). While using co-creation has challenges, such as managing a good fit between researcher and end user priorities, time and financial burdens, as well as complex decision making, for the most part the outcomes are positive (50). Co-creation allows for increased ownership from the end user's side, encouraging greater adherence to, and acceptability of an intervention (50).

1.5.1. Developing the intervention - The Behaviour Change Wheel as a conceptual framework (51)

For any intervention to be effective, it is important to understand human behaviour and what drives behaviour change (52). Behaviour change interventions are often focused on capabilities and motivation in isolation, without considering the broader social and environmental contexts (52). This broader context is particularly important as effective interventions intervene simultaneously and continuously at multiple layers (53). Important questions to ask when developing an intervention include, what behaviours do we target? Why are these behaviours occurring? What needs to change to see new behaviours occur (53) The Behaviour Change Wheel (figure 3), represents a system where the behaviours interact with the environmental and policy layers (51). Behaviours occur through the interaction of three necessary conditions, 1) Capability, the psychological or physical ability to enact the behaviour, 2) Motivation, the internal mechanisms that activate or inhibit behaviours, and 3) Opportunity, the social and physical environment that enable the behaviour (51).

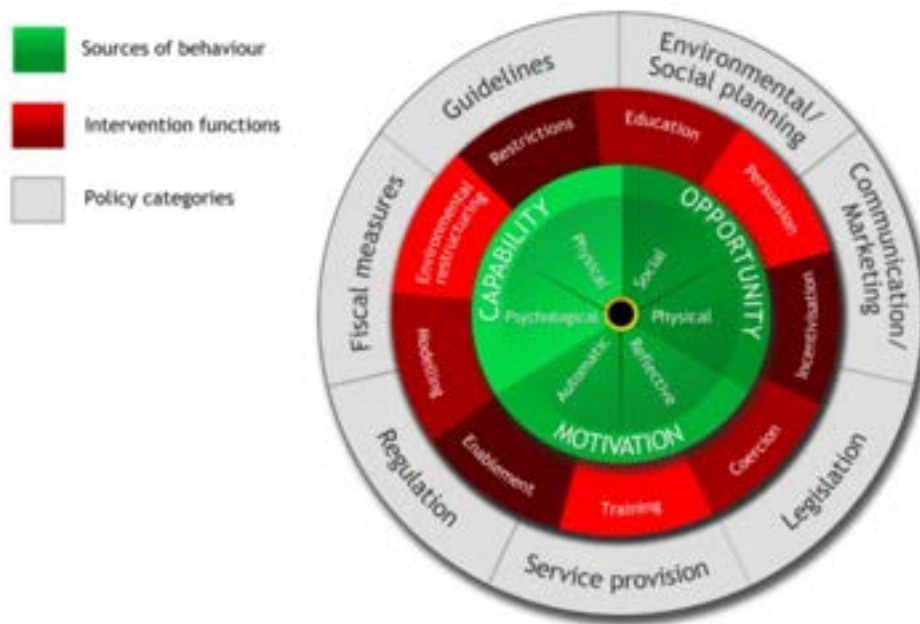


Figure 3: The Behaviour change wheel by Michie et al. (51)

The behaviour change wheel was chosen for this study (SmartPlay – described below), as it can be used as a helpful framework for developing an intervention to see changes in maternal health literacy, which ultimately results in greater opportunities for infant play and development. To achieve the desired behaviour change, the intervention focuses on targeting three sources of maternal behaviour for promoting play and development (capability, motivation and opportunity) through Modelling, Education and Environmental Restructuring (Figure 4). Specifically, the main behaviour change techniques used will be provision of information, social support and reinforcement. In the Soweto population, it is hypothesized that each mother's capability is influenced by physical and socio-emotional attributes e.g. age and mental health, and their motivation being impacted by the individual's level of self-efficacy (51). Lastly, the opportunity for encouraging play and development is largely influenced by the resources and physical environment available to each mother at home and in the community (51). The one factor that is hypothesized to influence all three sources of behaviour is health literacy, which is why this has been chosen as the focus for the intervention. By focusing on the mothers' health literacy, the hope is that this will equip the mothers to understand, process and retain information, to know how to provide low-cost resources (including toys) for their children, to adapt their environment for safe activities, and to improve their self-efficacy, thereby encouraging optimal infant development through play.

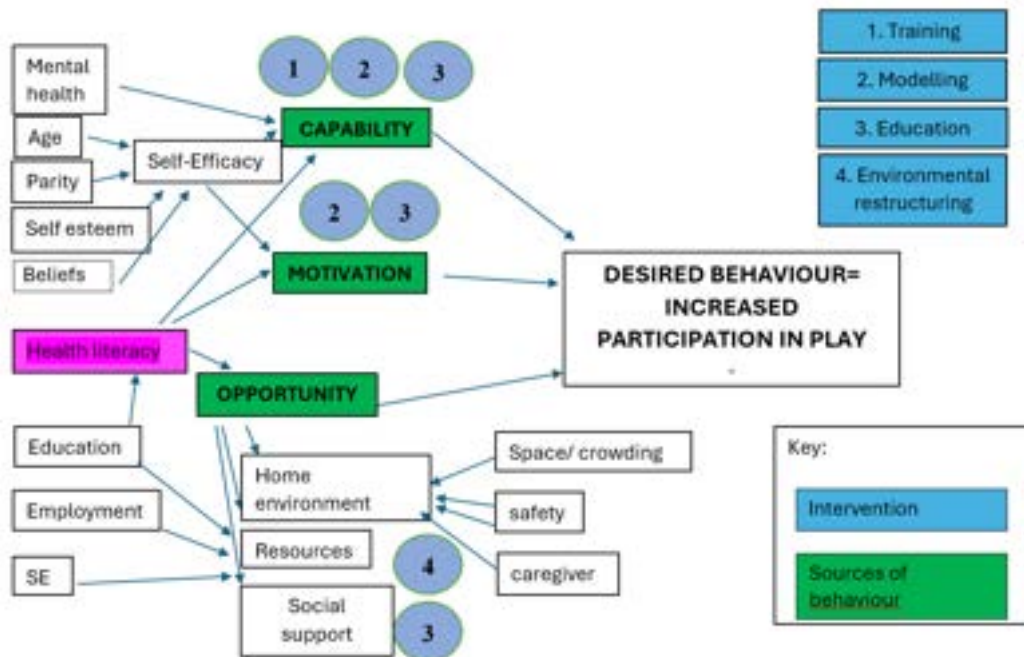


Figure 4: Conceptual framework based on the Behaviour Change Wheel (51)

However, when considering this framework and the UK MRC framework described in Figure 2 (48), it is imperative to be aware that aspects of the intervention (shown in blue) do not exist in isolation and continuous efforts need to occur throughout the planning and implementation phase to make sure that interventions are feasible and being implemented as planned, which will result in refining and adapting the intervention as required.

1.6.1. Evaluation methodologies for health interventions

Moving to the other “side of the coin”, after developing the intervention, the intervention needs to be evaluated. There are several ways in which this can be done, however, complex interventions should ideally be piloted to determine the acceptability and feasibility of the intervention, and to complete a process evaluation, which can then be used to adapt the intervention to ensure effectiveness in the final implementation phase (48).

1.5.1.1. Importance of testing acceptability and feasibility in interventions

Determining acceptability and feasibility of an intervention is imperative to understanding the suitability and practicality of an intervention for scale up and implementation in specific contexts (54). Feasibility can be measured retrospectively to determine which aspects of the study are facilitators or barriers to delivering the intervention before implementation. For a study to be feasible it needs to be appropriate and acceptable to end users for the context in which it is implemented (54). As discussed previously, there has been an increase in the use of mHealth digital interventions in low resource settings. However, where some mHealth interventions work well in higher income settings, these same interventions are not feasible in low resource settings due to significant barriers in resource availability and difficulties with implementation. Barriers include a lack of electricity to charge devices (due to power outages), limitations in hardware and software requirements and limited access to affordable data or WiFi (37,39,55). Furthermore, as previously discussed, limitations in health literacy or language restrictions can limit end-users from accessing digital information (56)(57). There are, however, certain facilitators that aid in intervention feasibility. To overcome challenges with understanding health information, studies completed in similar settings suggest using simple, lay language together with images, illustrations and interactive content, and including verbal explanations for those who cannot read (56)(58). Health content creators should also use local languages to convey health information and have a good understanding of the local context (56). Other authors have suggested that Mhealth projects that are designed for specific contexts, with wording and content of messaging being targeted to specific recipients, are most likely to be feasible (59). Furthermore, Mhealth projects that initially test feasibility as part of a smaller pilot study and use those learnings to guide follow up projects or full interventions, show high levels of feasibility in practice (59).

For a study to be feasible, it also needs to be acceptable to both health care providers and health care recipients (patients or clients). If an intervention is acceptable to the recipients, this often results in greater adherence to treatment and better overall health outcomes (40,60). The quality of care, content and context are all factors that have an impact on recipients' acceptability of an

intervention. Similarly, if the delivery of, or reason for the choice of intervention is not acceptable to health providers, the intervention may not be delivered as intended, potentially impacting patient health outcomes (60).

According to Sekhon et al., the acceptability of an intervention reflects “the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate”, based on a “cognitive and emotional response to the intervention” (60). There are seven constructs which determine whether an intervention can be determined to be acceptable. Individuals need to like the content (affective attitude), it should fit with their value system (ethicality) and not take up too much time (burden) or take the place of other important daily activities (opportunity cost) (60). The intervention should also be coherent (intervention coherence) and perceived to be effective (perceived effectiveness) while improving self-efficacy (self-efficacy). Figure 5 provides further detail regarding each construct (60). All constructs are required when evaluating acceptability using this framework.

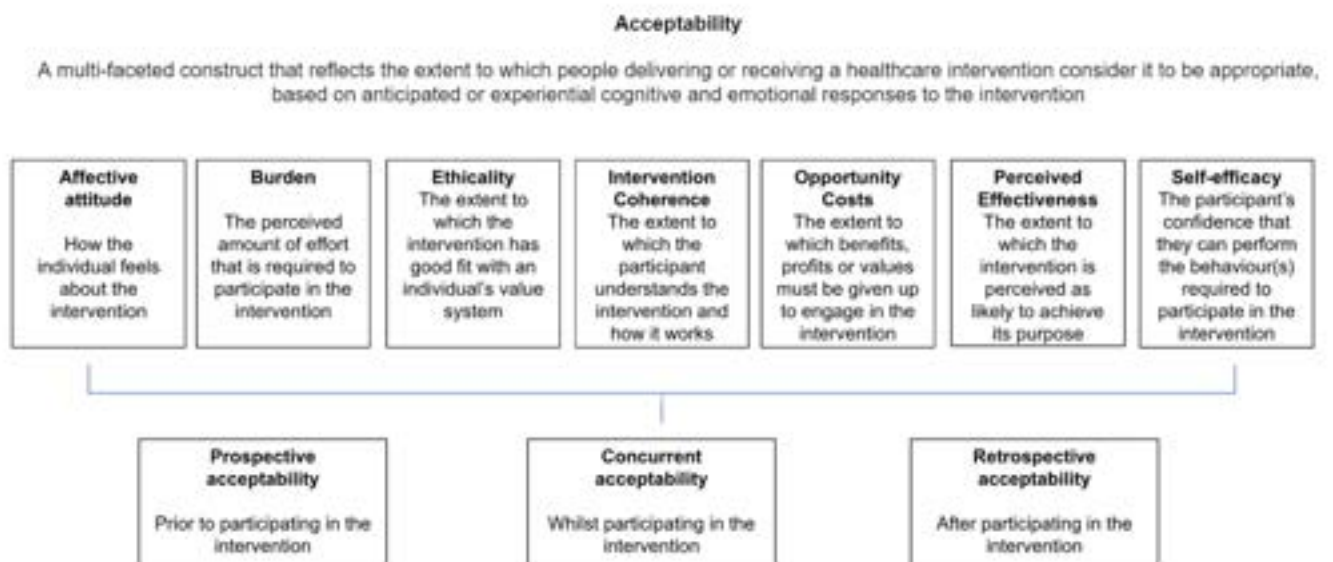


Figure 5: Definition of acceptability and the seven constructs of acceptability (60)

1.5.1.2. Process evaluation

Process evaluations assist in determining whether an intervention has been delivered and implemented as intended. These evaluations often focus on intervention fidelity, which evaluates adherence (the content, coverage, frequency, duration of intervention) as well as potential moderators which may have impacted adherence, such as quality of delivery, context and participant responsiveness(61). It is particularly important to understand whether the fidelity of an intervention has had an impact on the outcome or effect of the intervention, to determine whether any lack of effect is due to poor implementation or inadequacies in the intervention itself (61). Carroll et al. have developed an implementation fidelity framework, which clarifies these components and how they impact each other (Figure 6) (61).

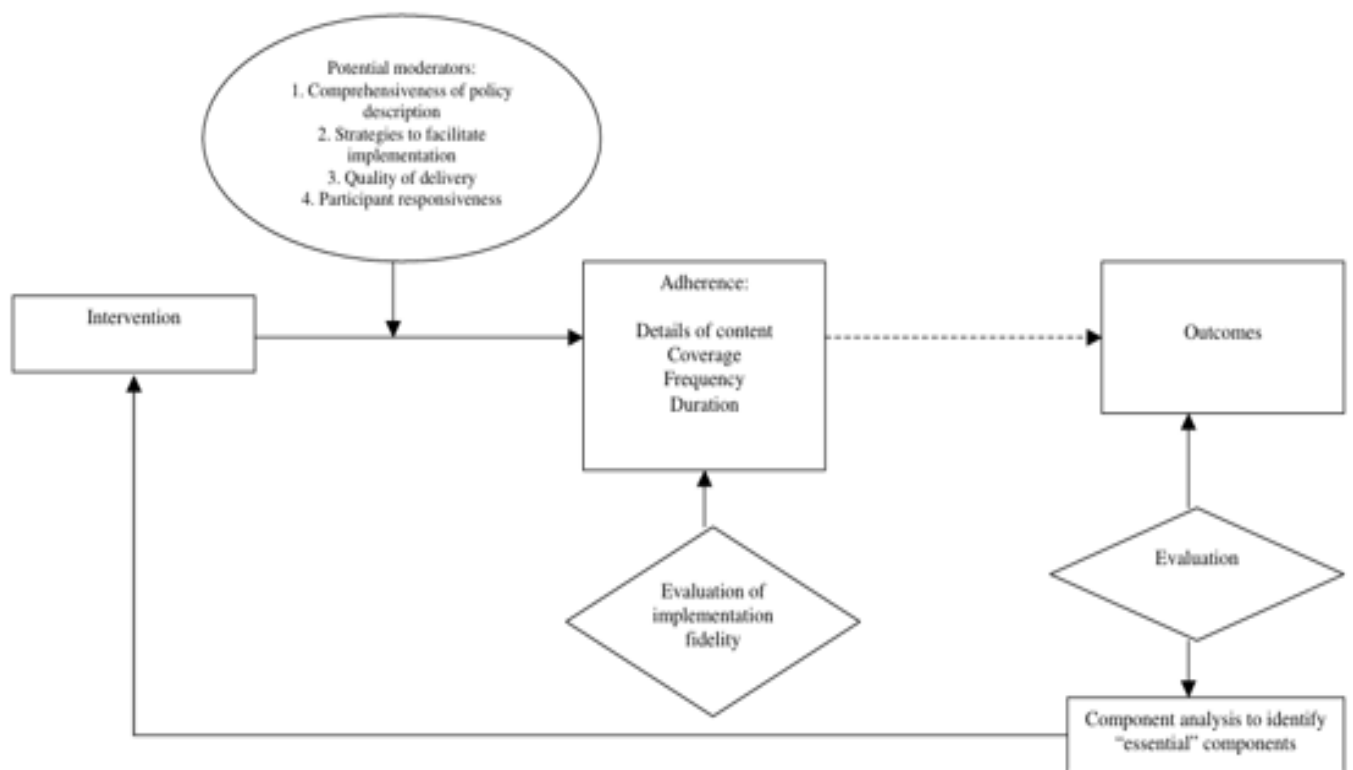


Figure 6: Conceptual framework for implementation fidelity (61)

1.6. The PLAY Study

This study is embedded in a larger Randomised Controlled Trial (RCT) called the Play Love and You (PLAY) study. To differentiate between the two studies, I named my study, “SmartPlay: Maternal Literacy for Child Development”. The PLAY study had three aims. My PhD, which forms the basis of this thesis was part of the third aim, namely “To test the efficacy, feasibility and acceptability of providing content, and increasing opportunities for early learning through play through the promotion of health literacy” (62).

1.7. Aims & Objectives

The hypothesis for the SmartPlay Study is that increased health literacy in mothers will improve their capability and motivation, and opportunity, thereby resulting in greater participation in infant play. However, it is also important to determine whether the intervention is acceptable to participants and feasible in this setting.

Therefore, the *primary objectives* for this PhD are:

1. To co-create and determine the acceptability of an intervention prototype aimed at improving maternal health literacy around play and development with a Community Advisory Group (CAG) comprised of mothers in Soweto (chapter 3).
2. To test the feasibility and acceptability of an intervention aimed at improving maternal health literacy around play and development (chapter 4).
3. To determine whether there is a difference in maternal health literacy scores at 12 months between the intervention and control groups (chapter 5).

The *secondary objectives* for this PhD were:

1. To determine the change in health literacy scores from 6 to 12 months in both groups (chapter 5).
2. To determine whether there was a difference in affordances in the home to promote motor development, maternal beliefs around play and development and time spent being physically active and/or sedentary/restrained at 12 months between the intervention and control groups (chapter 6).
3. To determine the change in affordances in the home to promote motor development, maternal beliefs around play and development and time spent being physically active and/or sedentary/restrained from 6 to 12 months in both groups (chapter 6).
4. To create a new measure determining the potential opportunities in the home environment for infant active play, by combining the maternal beliefs around play and development, time spent active and/or sedentary/ restrained, and physical space available in the infants' home for play (chapter 6).

PART 2: METHODOLOGY

2. Chapter 2: Methodology

This chapter describes the study setting, design, collection and analysis methods used for each objective. This thesis comprises three different objectives, two of which make use of mixed methods and the third, which uses quantitative methods. Convergent mixed methods (a mixture of qualitative and quantitative methods) has been chosen to measure and further explain the acceptability of the proposed content to be included in the intervention (objective 1) as well as the feasibility and acceptability of intervention content, following study completion (objective 2) (63). Quantitative methods have been chosen to determine whether the intervention had an effect on the desired study outcomes (objective 3). A concurrent triangulation approach will be used, where it is hoped that the use of both quantitative and qualitative methods will offset the weaknesses inherent within one method, with the strengths of the other (63). Furthermore, it was anticipated that the qualitative data would provide a deeper understanding and explanation of phenomena which could not be captured quantitatively, and could expand upon reasons as to why certain trends were found in the quantitative results. A detailed description of each objective's methodology can be found in chapters 3, 4, 5 and 6.

2.1. Study Setting

As a large component of the SmartPlay study focuses on factors impacting acceptability and feasibility of an intervention in a low-income community, it is important to understand the context in which the participants live and access health care. Gauteng (Figure 7) is the smallest province (geographically) in South Africa, with 16 million residents (25% of total population), making it the most populous and urban dense province in South Africa (64). In 2024, 34% of the Gauteng population was unemployed (65). Almost a quarter (23%) of Gauteng province residents are under the age of 15 (64). Although Gauteng has some of the lowest poverty rates in South Africa, 59% of children in Gauteng are living below the upper-bound poverty line (2022 value = R1417 per person per month) (66). Johannesburg is the largest city in South Africa and is found in the middle of

Gauteng. Founded in 1886 after the discovery of gold, it is South Africa's main financial and industrial metropolis (67).



Figure 7: Map of Gauteng Province (68)

The SmartPlay Study was conducted within the SAMRC/Wits Developmental Pathways for Health Research Unit (DPHRU). The main research priorities of the DPHRU aim to address the South African national priorities, including strengthening health service effectiveness, increasing life expectancy, and decreasing maternal and child mortality (69). The DPHRU forms part of the Paediatrics department at the University of Witwatersrand (Wits University) and is based at the Chris Hani Baragwanath Academic Hospital (CHBAH) in Soweto, Johannesburg (69).

Soweto is an urban “township” located in the Southwest of Johannesburg, with a population of approximately 1.9 million people (Figure 8) (70)..

Originally developed under apartheid policies to segregate Black South Africans, Soweto continues to reflect deep structural inequalities that persist in post-apartheid urban South Africa. Today,

Soweto is a vibrant and diverse urban landscape marked by contrasts - formal housing alongside informal settlements, and high levels of community solidarity in the face of persistent socioeconomic challenges. As of 2023, approximately 9.9% of the Soweto population comprised of children under 6 years old (70). The population is predominantly younger and experiences a dual burden of disease: enduring infectious diseases such as HIV and tuberculosis, and a rising tide of non-communicable conditions including obesity, hypertension, and diabetes, especially among women of reproductive age.

Soweto is a particularly important site for research on maternal and child health. Women in the area face elevated risks for adverse pregnancy outcomes, driven by intersecting factors such as obesity, food insecurity, psychosocial stress, and limited access to high-quality, person-centred antenatal and postpartum care. Women in Soweto are socially vulnerable, and even more so if they have children according to a large study of women aged 18-26. Most are single, without access to medical insurance. Furthermore, young women in Soweto have a high prevalence of depression, anxiety, and exposure to intimate partner violence with a history of adverse childhood experiences. At the same time, Soweto has a long tradition of community-based health research, including landmark longitudinal cohort studies and health system innovation. CHBAH, one of the largest hospitals in the Southern Hemisphere, and third largest in the world (72), serves as a referral centre for maternity and paediatric services and offers a critical platform for clinical and implementation research. Studies conducted in Soweto benefit from well-established community engagement structures and are uniquely positioned to generate locally relevant, policy-informing evidence with global significance. The setting allows researchers to examine the life course determinants of health in contexts of inequality and resilience, and to co-develop interventions that are responsive to the lived experiences of women, children, and families navigating complex health and social systems.

The SmartPlay study recruited from two community clinics, Lilian Ngoyi and Chiawelo community clinics. Both clinics are primary clinics linked to CHBAH. They both have Midwife Obstetrics Units (MOUs) as well as postnatal clinics which provide antenatal and postnatal care.



Figure 8: Map of Soweto with CHBAH positioned near the east border (73)

2.2. The PLAY study

The SmartPlay study was one of three sub studies embedded within a larger RCT, the PLAY study, and therefore has the same inclusion criteria, sample size ($n=210$, $n=75$ in each group) and recruitment processes as the PLAY study. Mothers were eligible for recruitment if i) they were 18 years of age or older with an infant aged 0-3 months ii) of whom they were the primary caregiver, and iii) were living in Soweto for the duration of the study. Mothers with both primigravida or multigravida birth experiences were included in the study. Participants were required to speak any of the local languages. Mothers were ineligible if infants were born preterm or if the infant had any disabilities, impairments or disease that would limit movement or impair normal development

(74).The PLAY study aimed to promote infant development through encouraging maternal self-efficacy using behavioural feedback and supportive interventions (62). The PLAY study was based on the premise that the first two years of a child's life are important for optimising growth and development, and aligned with the WHO's recommendation for improving ECD, namely, 1) exclusive breastfeeding for first 6 months 2) play and promotion of early learning, 3) responsive caregiving and 4) maternal mental health. The PLAY study defined play "as intrinsically motivated activities done for recreational purposes and enjoyment" (62). Part of the PLAY study included the provision of tools to encourage self-efficacy in mothers by encouraging their belief in their own ability to care and provide for their children. Some of these tools and strategies included social support, mental health promotion, prompting mothers to be aware of their own ability to care for their children and improving health literacy (62).

Mother–infant pairs were recruited to the PLAY study within a month following delivery from community clinics in Soweto. Each pair was individually randomised into either a control or intervention group. Assessments were made at enrolment and when the infants were 2, 4, 6, 8, 10 and 12 months of age, with the end point being an exit assessment at 12 months. Figure 9 details the assessments completed at each respective time point in the PLAY study. The trial consisted of a standard of care package (control group), and an intervention package – including standard of care as well as the intervention content (intervention group). Mothers assigned to the control group received the standard Road to Health booklet (RTHB) as well as the Side-by-Side services provided as routine postpartum care. They were also contacted every 2 months to check in, and to provide referrals to health care facilities if necessary. The intervention group received the standard of care package (provided to the control group), as well as the intervention content comprising of several micro-interventions which supported maternal mental health and encouraged mothers to exclusively breastfeed for 6 months, enabled play and development through increased health literacy and provided nurturing care (good health, adequate nutrition, safety and security, responsive caregiving and opportunities for learning as defined by WHO) (75) to their infants. Each intervention component is detailed in Figure 9.

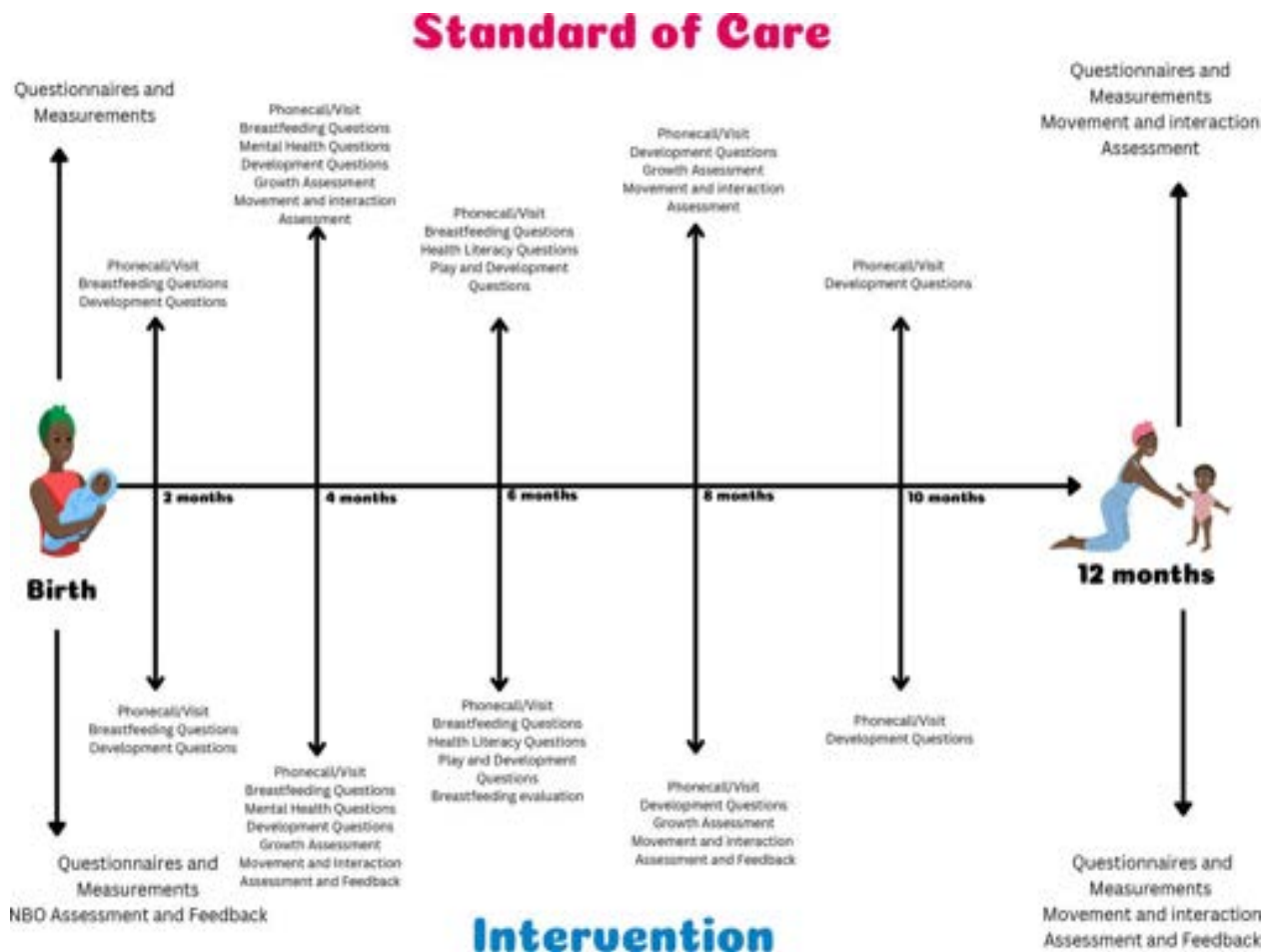


Figure 9: Play Study participant flow chart (62)

The third hypothesis of the PLAY study was, “Providing mothers with access to resources, content and activities to support their infant’s play and development will increase their health literacy and thus encourage play and promote development.” The SmartPlay Study aimed to test this hypothesis and therefore formed part of the Play and Development intervention focus of the Play Study, pictured in Figure 10. The SmartPlay Study, together with the Breastfeeding Focus and complementary interventions, combined to form the full intervention for the PLAY study, which was then evaluated at 12 months.

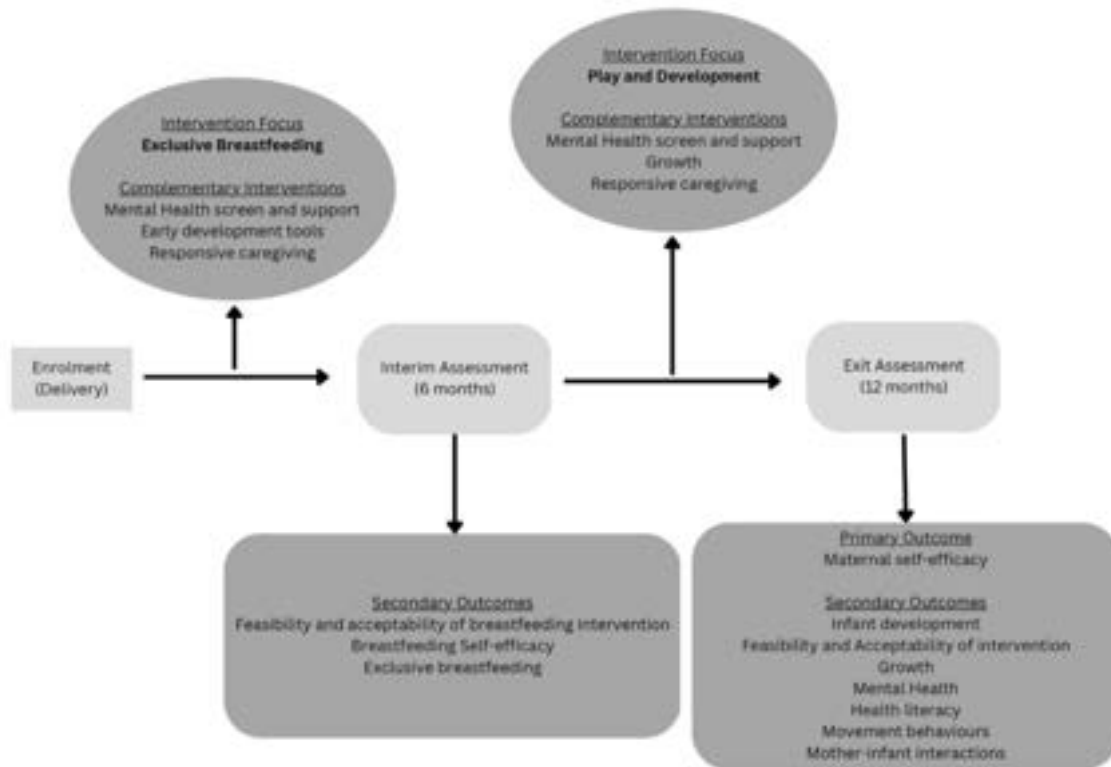


Figure 10: Play Study Intervention Themes and Assessments (62)

2.3. The SmartPlay Study

The SmartPlay Study is comprised of three components (or phases), 1) development of the intervention, 2) implementation of the intervention and 3) evaluation of the intervention. The three phases are presented in Figure 11.

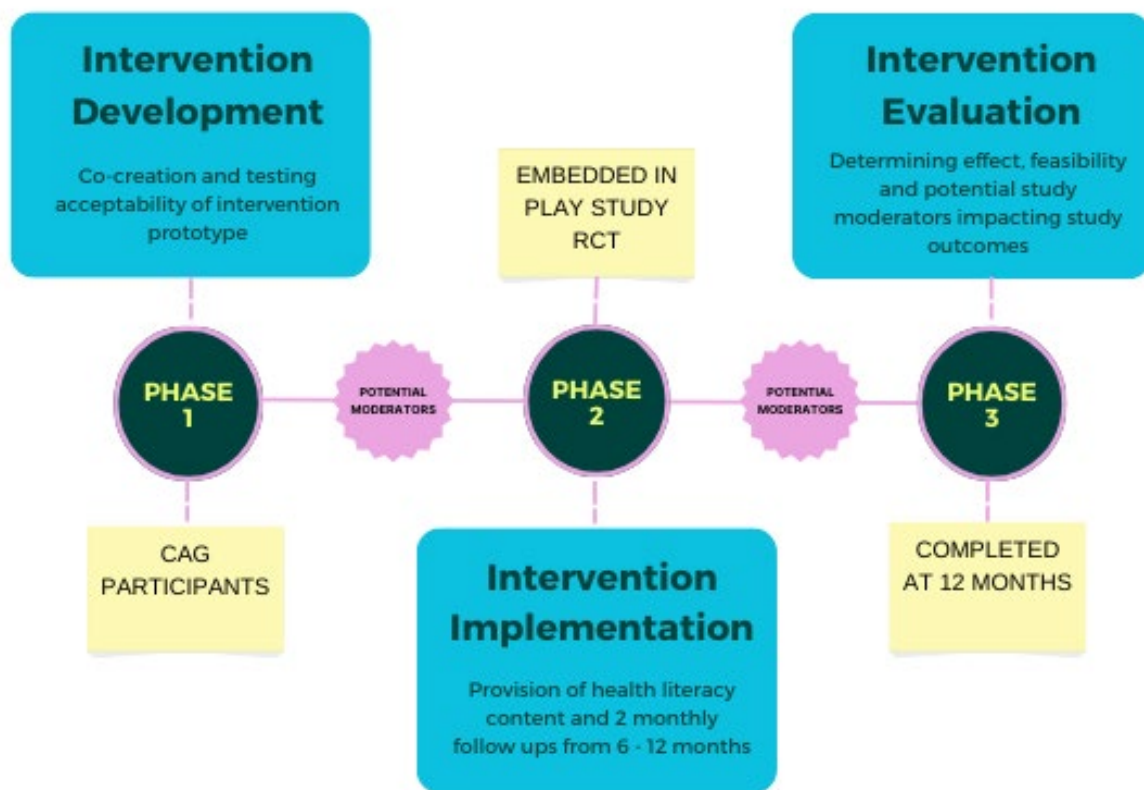


Figure 11: The 3 phases/ components of the SmartPlay Study

2.3.1. Phase 1: Intervention development

The intervention for the SmartPlay study was co-created and tested for acceptability with a CAG, using the Acceptability Framework. The details of these methods are further explained in Chapter 3. CAG participants attended FGDs where the beliefs, barriers and opportunities around play and development were explored, and participants provided feedback on a prototype for content that was included in a mobile app as part of the SmartPlay intervention. Participants tested the prototype activities at home and acceptability was measured using the seven acceptability constructs by Sekhon et al., a framework for determining whether the prototype is acceptable and appropriate to be used in the SmartPlay study intervention (60). This framework was chosen as it broke down acceptability into seven measurable constructs, providing a practical measure of acceptability that could be used throughout phase 1, phase 2 and phase 3 of the study.

2.3.2. Phase 2: Intervention implementation

Following further development of the prototype content (based on the feedback from the CAG participants), the SmartPlay intervention was implemented over 6 months, as part of the larger PLAY study through a web-based mobile application and telephone check-in at 10 months. Further details regarding this methodology are provided in Chapter 4 and Chapter 5. The content of the study was based on evidence-based practice for encouraging play and development and was aligned with the WHO and the United Nation's Children's Fund's (UNICEF) guidelines for ECD (23). When applying the behaviour change wheel to this intervention, the aim was to provide content that improved maternal health literacy, thereby increasing their capability, motivation and knowledge of how to provide opportunities for play and development with the resources and space specific to their environment.

2.3.3. Phase 3: Intervention evaluation

Once implementation was achieved, the primary outcome of the study (increase in Health Literacy Questionnaire (HLQ) scores) was measured using the HLQ questionnaire. This questionnaire was chosen as it is recommended by WHO for measuring health literacy in LMICs (2). The feasibility and acceptability of the intervention was measured at 12 months using the seven acceptability constructs (60), and a list of feasibility measures, including follow-up adherence and access to study content (dosage). The details of these methods are further explained in Chapter 4. Lastly, if we found no effect of the intervention on health literacy scores, in addition to feasibility, I planned to consider potential moderators which could have had an impact on implementation fidelity (using the conceptual framework for implementation fidelity), including quality of delivery, participant responsiveness, and any other environmental factors beyond our control (61).

2.4. Justification

I chose to embed my study within the PLAY Study, as it allowed me to use a Randomised Controlled Trial (RCT) design, one of the most robust quantitative research designs for measuring the effect of the intervention. As I had limited funds as a PhD student, this was of benefit as RCT's can be expensive and require well established data management tools and data collection personnel. I chose to measure the acceptability, feasibility and effect of the intervention to allow for important implementation learnings and suggestions for replicating this study (or a variety thereof) in a similar context.

2.5. Data Management

Details of each specific data collection and analysis approaches for the respective objectives are included in Chapters 3-6. All participants were given informed consent forms (ICF), which were read through with a study Research Assistant (RA) present, who could provide clarification as required. All participants were required to provide written informed consent to enroll in the PLAY study. Once enrolled, participants were given a unique Trial identification number. Participants were then randomised to either the intervention or control group using the Research Electronic Data Capture (REDCap) database and provided with another identification number specific to their allocated intervention or control group. Participant identifier information was kept in a separate REDCap project database to the database in which their unique identification numbers were kept, to maintain anonymity.

All quantitative data were captured by RAs straight onto the REDCap data management platform, using a University of Witwatersrand (Wits) University owned tablet. All data were stored securely at the DPHRU on secure servers. All data requests were sent to the DPHRU data manager, according to the unit's processes and procedures, who then uploaded the respective dataset onto the student's university Microsoft OneDrive storage folder. All FGD transcripts and observer notes were stored on a secure and encrypted laptop and then uploaded to REDCap. All data related to my outcomes were

extracted, cleaned and merged using participant trial identification numbers, with all identifiable information removed.

2.6. Ethical Approvals

Ethical approval was obtained from the University of the Witwatersrand Human Research Ethics Committee (Sub-study (SmartPlay) M220886 under main study (PLAY) M210846 and M220217). Written informed consent was obtained from all participants for participation in the FGDs and questionnaires, and for each FGD to be recorded. All participants were reimbursed for travel costs (R200) and provided with refreshments at FGDs and hospital-based follow-ups. All participants were given a Trial ID number which was used throughout the study to allow anonymity. All participants included in the FGDs were de-identified during the transcribing process and given a number instead e.g. Participant 1, 2, etc.

PART 3: EMPIRICAL CHAPTERS

3. Chapter 3: Paper I

Please note that this chapter has been modified post publication based on examiner feedback

Title: Determining the perceived acceptability of an intervention designed to improve health literacy around developmentally appropriate play during infancy, with a community advisory group of mothers, in Soweto, South Africa

3.1. Abstract

Introduction: Children require opportunities to participate in unstructured, unrestricted active play as infants, to encourage positive health, socioemotional and developmental outcomes in life. Certain social and environmental factors in the home setting can limit participation in play, particularly in low resource settings. As caregivers are their infants' first teachers, they have the important role of providing opportunities and space for children to learn through play. This mixed methods, cross-sectional study aimed to test the acceptability of an intervention developed to improve health literacy around play and development with mothers from Soweto, South Africa. Methods: Fifteen mothers with infants aged 0-3 months were included to form a Community Advisory Group. Two rounds of focus group discussions were conducted to explore the understanding of, and barriers to play and development, and to determine the acceptability of an intervention prototype. The prototype included developmentally appropriate activities presented in video format, demonstrations of how to make toys, infographics and other educational material which would be delivered to participants as part of the intervention. A further questionnaire was administered to participants one week after the Focus Group Discussion to determine the acceptability of intervention activities which the participants completed at home, with their infants. Results: Participants reported several barriers to play, including limited options for safe outdoor play, overcrowding, insufficient time, limited resources, and conflicting information. Participants suggested that the intervention content be delivered every 1-2 weeks, through a data-free app. Overall, the prototype activities tested at home were deemed acceptable. Discussion: The reported

barriers, together with reduced motivation and self-efficacy observed in the participants, guided the researchers to develop intervention content focused on improving health literacy in play and development, delivered in the form of an interactive mobile app. Future research will develop and test the efficacy of this intervention in a low resource setting in South Africa.

3.2. Introduction

Early childhood is one of the most important timeframes in life, due to the rapid growth and development of the brain and body during this time (76). Children are particularly receptive to their environment in the first 1000 days of life, making it an important time for developing healthy behaviours, which encourage positive outcomes later in life (76). In South Africa, obesity is a major public health concern, with 13% of South African children under 5 years being overweight in 2020 (77), making it important to start encouraging PA as soon as infants are born (78). It is imperative for early movement behaviours (for example, ‘tummy time’) to be encouraged within the first days after birth, as these activities have been consistently shown to be associated with advanced gross motor and personal-social development over time (79).

In the early months of life, infants require access to unstructured, unrestrictive play at home to encourage development and increased PA (20). This is evident in the poor developmental outcomes seen in children who spend too much time in a supine position as infants, constrained in infant seats, walkers, or in small playpens (20). Unstructured outdoor play is particularly important as it allows space and opportunities for playful activities, which encourage development of gross motor skills (e.g. kicking and throwing balls, climbing on play equipment, etc.) and higher intensity PA required to meet daily movement guidelines (27). Children need to be provided access to, and opportunities to engage in unstructured play by their caregivers, which highlights the importance of caregiver education and modelling when encouraging more unstructured play with children. By focusing on increasing participation in play from birth, infants and toddlers will naturally be more physically

active, helping to reduce the risk of developing obesity and other non-communicable diseases later in life (26).

There are a number of social and environmental factors in the home setting that can limit participation in play, particularly in low-middle income settings such as South Africa. Examples of environmental factors include outside areas which are not considered safe to play (e.g., exposure to violence, heavy traffic, pollution, unsanitary conditions, etc.) as well as inside areas which may be very small or overcrowded with no limitations on screen time and other similar sedentary behaviours (21). Social conditions that impact play include lack of resources available for toys or books, low maternal health literacy, and poor maternal mental health (21)(23).

As caregivers are their infants' first teachers, they have the important role of providing opportunities and space for children to learn through play (18). Empowerment and provision of support for caregivers is therefore essential, to allow facilitation of playful learning in day-to-day activities in the home environment and community (18). This is particularly important in a setting such as South Africa, where caregivers have expressed a lack of motivation and knowledge in how to promote development, particularly through play (21). Therefore, increasing caregiver health literacy is key to developing a greater understanding of the importance of play and development in the early months.

In light of the above, this study aimed to test the acceptability of an intervention developed to improve health literacy around play and development with mothers from the Soweto community in South Africa. The researchers hypothesized that increased health literacy in mothers would improve capability, motivation and opportunity, thereby ultimately resulting in greater participation in infant play. The specific objectives in this paper were:

1. To understand the challenges and barriers that a group of Soweto mothers experience when facilitating play with their young infants.

2. To present a prototype of intervention activities and content, discuss perceptions as to how the activities and content may improve health literacy (thereby encouraging participation in play), and how best to present the intervention.
3. To determine the acceptability of the intervention prototype after being tested by the mothers in Soweto.

3.3. Methods

3.3.1. Study setting and participants

This study (SmartPlay) was nested in the larger Play Love and You (PLAY) study, which was developed with the overriding theme that all that infants need is Play (opportunities for movement and development), Love (responsive and interactive caregiving) and You (the mother herself) (62). The PLAY study had three aims. The current study was part of the third aim, namely, “To test the efficacy, feasibility and acceptability of providing content, and increasing opportunities for early learning through play to promote literacy”(74) .

In order to develop the intervention, a Community Advisory Group (CAG) was established with the intention of testing the acceptability of the intervention before implementing it in the PLAY Study [12]. Twenty mothers from Soweto with infants aged 0-3 months were recruited in April 2022 to form the CAG. Participants were recruited by approaching women at the taxi rank outside Chris Hani Baragwanath Academic Hospital (CHBAH) to ask whether they would be interested in participating. Mothers were eligible for recruitment if i) they were 18 years of age or older with an infant aged 0-3 months ii) of whom they were the primary caregiver, and iii) were living in Soweto for the duration of the study. Mothers with both primigravida or multigravida birth experiences were included in the study. Participants were required to speak any of the local languages. Mothers were ineligible if infants were born preterm or if the infant had any disabilities, impairments or disease that would limit movement or impair normal development. 0-3 month old infants were included as this was the

age group that would be included in the PLAY study, and as a result of the evidence showing that an increase in movement and play in very young infants is associated with advanced gross motor and personal-social development later in childhood and beyond (79).

Ethics Statement

Ethical approval was obtained from the University of the Witwatersrand Human Research Ethics Committee (Sub-study M220886 under main study M210846). Written, formal informed consent was obtained from all participants, for participation in the focus group discussions (FGDs) and questionnaires, and for each FGD to be recorded. All participants were reimbursed for travel costs and provided with refreshments.

3.4. Data collection

Two rounds of FDGs (named “Round 1” and “Round 2”, respectively) were conducted for each participant, approximately two weeks apart in April 2022. All FGDs were conducted at CHBAH in Soweto, Johannesburg by staff (RAs) trained in qualitative research data collection, who were proficient in speaking English and Zulu and understood the other languages local to the area (e.g. Venda, Sotho, etc). Although questions were asked in English, participants could speak in their home language and conversations progressed in the vernacular. This was later translated into English if the response was in a different language, and transcribed for analysis. Lastly, Round 3 of data collection, a telephonic questionnaire, was conducted approximately one week after the completion of the FGDs with the same group of participants. All FGDs and telephone calls were audio recorded with the participants’ consent and transcribed into English verbatim.

Round 1:

Round 1 comprised of three FGDs, conducted over 3 days with 8 participants in the first FGD, 6 participants in the second FGD and 6 participants in the third FGD (total N=20). All participants

started the session by providing socio-demographic information in a questionnaire. The aim of the Round 1 FGDs was to understand the challenges and barriers that the CAG members experienced when facilitating play with their infants. Participants were given a detailed explanation of what the PLAY study was, including the study's aims and objectives, themes, contact points between the different arms of the trial, as well as examples of the types of assessments and interventions that would be included in the study [12]. The theme in the PLAY study that participants were asked to focus on, was around interactive play and promotion of early learning, using a semi-structured discussion guide. As a result, discussions were largely around the participants' understanding of play and development, as well as the effect of their home environment on participating in play with their infants. As part of this discussion, participants were shown a number of photos/ pictures depicting different home environments, which invoked a discussion around which environments enabled or discouraged active play. The stock photos were chosen to show a variety of home environments that would be similar to those found in Soweto, including single roomed homes, shacks and hostels, as well as different settings where children may play e.g. on the side of the road, in a yard, etc. Participants also had a general discussion around the delivery of the intervention, e.g. the preferred means of contact and how often participants should be contacted.

Round 2:

All participants from Round 1 FGDs were invited back for Round 2, approximately two weeks later, however, five of the twenty participants did not attend. Round 2 comprised of two FGDs conducted on the same day, with seven and eight participants in each respective FGD (fifteen in total, n=15). Round 2 was primarily focused on a semi-structured discussion around the acceptability of the play and development aspect of the content to be included in the study intervention (Appendix C). Drawing from the themes which emerged in Round 1 as well as previous research conducted in this same population group, we created a 'prototype' or an example of intervention content appropriate for infants aged 0-3 months, which was introduced to the groups in Round 2. This content was in the form of developmentally appropriate activities, which would be delivered to participants as part of the intervention. The content included videos (for example, singing games, clapping hands, rolling

games etc), demonstrations of how to make toys from recycling materials, as well as infographics and other educational material (such as monthly developmental milestones). Participants were asked to give feedback based on their perceptions as to how the activities and content may improve health literacy, as well as how best to present the intervention. Participants were then asked to engage in and complete three specific activities at home. The first activity was based on videos consisting of games to play with baby and trying different tummy time positions. The second activity was for the participants to make a sensory toy, which was demonstrated in person. The last activity was to determine the potential acceptability of the content in the home setting from the perspective of the caregiver. They were encouraged to pick a few that they liked and try those, instead of attempting to complete all of them. The videos were sent to the participants via Whatsapp.

Round 3:

The participants from Round 2 (n=15) were then individually contacted a week later by the study team to complete a structured acceptability questionnaire (Appendix D), comprising of 24 questions over the phone (see appendix 3). The first question determined which prototype activities (sensory square, shaker and five games) were completed at home. The rest of the questions focused on determining whether the participants found the prototype activities “acceptable” after testing them at home (60). The acceptability of the activities was determined by asking questions specifically based on the seven component constructs of acceptability by Sekhon et al. (60), which were used to measure acceptability in this study. Examples of questions included, “Were the instructions clear?” (measuring intervention coherence), “Do you think the games are beneficial for you and the baby?” (measuring perceived effectiveness), etc. Each component construct (namely, affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness, and self-efficacy) is described further in Figure 5 (Chapter 1). Figure 12 shows a summary of all three data collection points.

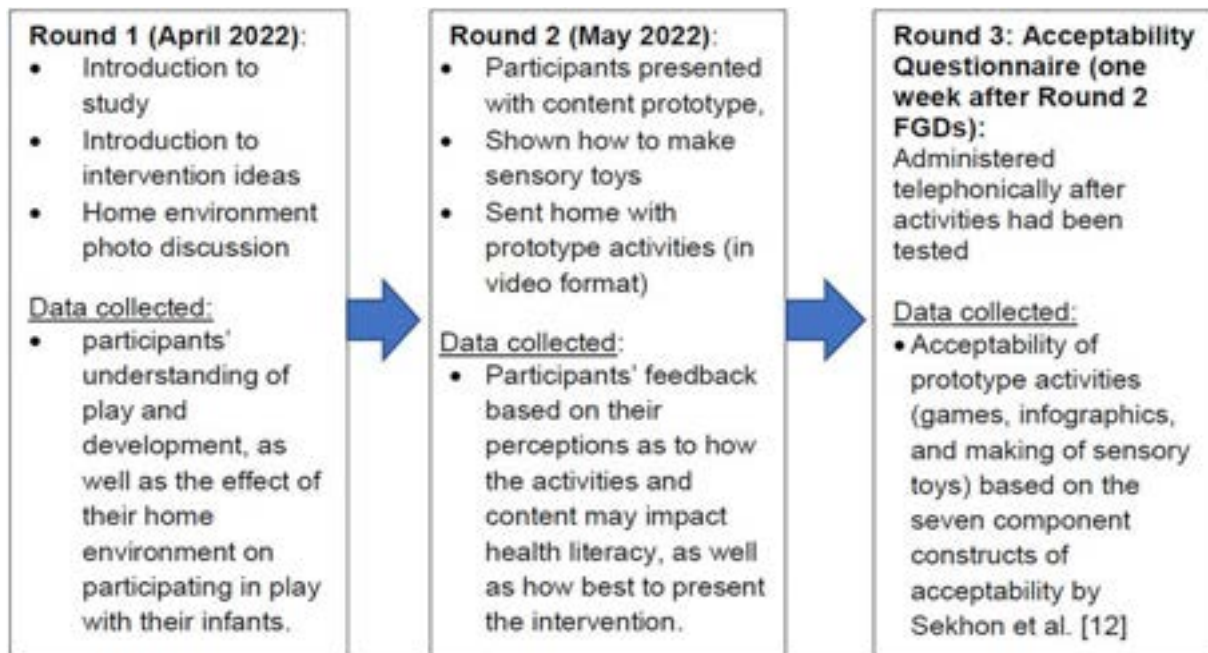


Figure 12: Summary of CAG data collection

3.5. Data analysis

All participants' identities were protected by assigning a unique identifier to each participant, making all qualitative data non-identifiable during the analysis. The quantitative data were de-identified at the point of data entry, using the study ID number, so that the researchers could not link the participants to their data. The data used in analysis only had a study ID number, without names or any other identifying information available. The qualitative data were analysed using thematic networks analysis (80). Meaningful statements and ideas were coded and then grouped into themes. Similar themes were then grouped and placed in thematic networks, which were subsequently summarised and discussed in relation to the original research question. The three transcripts from Round 1, and two transcripts from Round 2 were divided among three researchers who assigned codes to each statement and grouped the codes into themes. The researchers then swapped transcripts to cross-check all the identified themes and codes, which were further checked by a fourth researcher. Thereafter, all researchers met as a group to discuss and refine the themes until

no new themes emerged. Means, medians and ranges were calculated on Microsoft Excel and used to describe the demographics of the participants and the quantitative data from the acceptability questionnaire.

This study incorporated reflexivity and positionality throughout the research process to enhance trustworthiness. As researchers embedded in the health sector, the authros remained aware of how our perspectives might influence the research and made conscious efforts to critically reflect on our role. Trustworthiness was supported through triangulation, member checking, and transparent documentation of the analytic process."

3.6. Results

The average (mean) age of the twenty participants was 24 years old and the median was 23.5, ranging from 18 to 43 years old. 16 (80%) of the participants described themselves as single, while the other 4 (20%) reported themselves to be married, engaged or in a relationship. 14 (70%) were unemployed while 6 (30%) had some form of employment. The majority (65%) (n=15) of the mothers had completed their Matric (final year of secondary school), while 5 (35%) had not completed secondary school. Only one participant had a tertiary degree. Six of the participants were first time mothers. There was a fairly equal distribution of male and female infants, with half being female (n=10), 9 (45%) male), and one infant whose mother preferred not to say. The youngest baby was new-born, and the oldest baby was 5 months old, with the average infant age being 2 months and the median age being 3 months old. The time between enrolling participants and the first FGD was just over a month, which explains why some infants were older than the 3 months inclusion criteria.

Round 1 & 2:

The following eight themes emerged from Round 1 FGDs: 1) Being a mother, 2) Environment, 3) Play and Development, 4) Intervention, 5) Physical Wellbeing, 6) Health Literacy, 7) Breastfeeding, and 8) Mental Health. "Being a mother" included discussions around the challenges and joys that

motherhood brings, while the “Environment” theme gave insight into factors in the participants’ home and residential areas which impacted their activities, support (or lack thereof), safety and movements. The participants discussed their knowledge and perceptions of the importance of “play and development” in their infants, while the “Intervention” theme largely focused on preferences around the delivery of the intervention. The “Physical Wellbeing” theme explored how the participants manage their infants’ and own physical health, and the “health literacy” discussion focused on access to information and ability to understand information provided. The ‘Breastfeeding’ theme was a prominent discussion exploring reasons for breastfeeding (or not), factors impacting continuation of breastfeeding, support available, etc. Lastly, “Mental Health” explored all factors impacting the participants’ mental health as mothers. The Health Literacy, Environment, and Play and Development themes were relevant to this study, while the rest are discussed in papers currently in review.

During the second round of FGDs, the three themes which emerged from Round 1 (Health Literacy, Environment and Play and Development) that were pertinent to this study, were discussed again and expanded upon further. Furthermore, one new theme emerged, namely Acceptability of the intervention prototype content, which was the primary focus of the discussion. The themes were further divided into subthemes and are discussed below.

Health Literacy

Clinics/ Healthcare workers

The participants relayed a sense of distrust in the health workers at the clinics. Many reported that they are provided with minimal information around the importance of play or how to encourage normal development, and health workers can be rude or make new mothers feel ashamed for asking certain questions.

“No you know at the clinic they don’t explain anything, they just give you Road to Health [booklet]¹ (81) after giving birth to the baby. You will figure out when you get home when to take the baby in for the three day check-up, and when you have to take them in for six weeks. They don’t explain anything. You just have to give yourself time and read the Road to Health book because at the back they have symptoms that explain the things to watch out for in a child. They don’t explain. You have to sit and read that book.” (Round 1, grp 2).

Family/ peers/ other sources

A few of the participants expressed an interest in receiving additional information on how and when to play with their infants as they did not have access to family and/ friends who could provide them with advice when it came to their infants’ development. Participants expressed that even when they did have family members involved, they often did not know who to trust and would prefer objective information from a trusted source. However, they did not tend to trust and/ or understand the objective information given to them (such as the Road to Health Booklet), or did not see its relevance, but did not discuss what/ who they would trust.

“My mother is there to help me about the baby but I take care of most of the things because my mother loves going out. So most of the time I have to look after the baby so I have to know a lot of things. To clean the belly button and things like that.” (Round 1, grp 2).

“I would be happy [to receive this intervention], because when you go to the Road to Health [booklet], there are some things which are different, if you go to some pages, they talk about SASSA²) and I don’t understand what SASSA has to do with Road to Health. (Round 1, grp 2)

¹ (a booklet given to parents by clinic staff when children are born which keeps record of the child’s growth and other key developmental milestones, as well as providing the parent with information on nutrition, loving & bonding, protection of the child including immunisation schedule, basic health care e.g. treating common illnesses and “extra care” for those living with HIV, disabilities, etc)

² An agency that aims to provide comprehensive social security services against vulnerability and poverty

Environment

The discussion around the photos of children playing in different settings evoked various thoughts around safety, space and the effect on the child.

Physical safety

The participants were quick to point out that they felt there was a risk of children being kidnapped or subjected to abuse when an area was not enclosed or when there were many men around. There was also mention of children needing to be kept inside or in an enclosed yard to avoid them being involved in motor vehicle accidents.

“The house is not in a busy part of the township, but you need to keep the gate closed as there is a small child. A car can come and drive over the baby if the baby gets out of the yard” (Round 1, Grp 3)

“You know, to be honest, these days, you saw how the first picture was [picture of children playing on the street] ... I won’t feel free if my child lives in a place like that. A girl especially, not only a girl, because sometimes boys do get raped as well, you understand, I won’t feel happy”. (Round 1, grp 2)

Effect on Development

Many felt that it was important for children to be around other family members such as grandmothers. This was so that they could also look after the child when the mothers were not able to, without the child experiencing separation anxiety. The participants were also aware of the importance of playing with other children and being around other people for their children’s social

development. However, there was minimal mention of how the lack of space and outdoor play areas would impact their children's gross or fine motor play and development.

"For me, I think it is something good [for a child to play freely], ... I did not want him to play outside with other kids... so when you close a child up, he can't communicate with other people. I saw right now at school, to get [him] to understand a lot of things, it is hard for him, so I think [you need] to give a child the freedom to play. Yeah, it is a good thing. (Round 1, grp 2)

In the house: Occupants and space

The participants were of differing opinions when it came to the condition of a home and how this may impact the child. Many identified that some of the photos showed unsafe conditions for children, such as exposed wires, potential for injury from kettles/ stoves, lack of running water, etc. Others felt that while certain conditions in their own home were unsanitary or unsafe, they were used to living that way (and taking appropriate precautions) as they had always lived in these conditions. It was suggested that any accident that may occur as a result of the home environment was due to the parent/s' negligence.

"As she says that there is no ideal place where a child can be raised. I feel that the mother can be careless and put water in a dish and not be mindful of the child. If the child falls in the dish and drowns, I feel it would be the mother's negligence, not that the place is not safe for the child". (Round 1, Grp 3).

Some participants reported that they live in one-room houses where the bedroom and kitchen would be combined and felt that the space constraints did have an effect on what activities they were able to do with their children. However, those with bigger houses also expressed difficulties with space due to overcrowding.

“So did you see the games that you showed us, did you see them, they need open space. I said last time, we live in a four room [house], there are a lot of us. There is no time to do these sorts of things. When you are sitting like this, you are sitting like this, and that is the end of it. When you move, you don’t have space anymore. When you go to the bedroom, they follow you. So the time that you get is when you go outside and sit under a tree and sit on the grass, and play. When it is raining, we are not playing we will just be sitting in the house only”. (Round 2, grp 2)

Factors hindering play

The main reasons for respondents not engaging in play with their children included lack of time due to having to go to work, doing chores, and spending time on social media. Some felt that there were no hinderances as they liked to play with their infants, especially as they did not need toys in the first few months.

“Maybe [you don’t play] when you are on the phone and on WhatsApp. Sometimes I am on the phone and when the baby is crying I am like wait a bit you, it is WhatsApp. It is when I am looking at statuses”. (Round 1, grp 2)

“The chores is what I can say when I think about something that is stopping me, because most of the chores are looking at me at home.” (Round 1, grp 2)

Play and Development

Activities with infants

As all the participants had infants below six months of age, they tended to engage in activities which were appropriate for this age range, such as singing and dancing. Some participants also liked to talk to their infants, massage their feet and laugh with them. After seeing a video about ways to engage

in “tummy time” with their infants, some participants mentioned that they were not aware that they could put their infant on their tummies in so many different positions.

“For me, I play with him by singing, and he laughs and enjoys it.” (Round 1, grp 2)

“... I play with my child by talking to him. I will talk to him and then sometimes the child shows reactions. He laughs a bit, and then sometimes when I am playing with him, he will look at me but when my other [child] is playing with him, he will laugh.” (Round 1, grp 2)

Maternal Beliefs

Many of the participants were aware of what the term “development” meant, and some were aware that “milestones” were indicators of how their infant was developing. Some felt that play was good for monitoring how their infant was growing and some had insight into the effect of play on motor development.

“She develops muscles if she plays and you also see the change in her body”. (Round 1, Grp 1)

One of the main beliefs discussed in Round 2 was around tummy time and sleep. Most participants believed that infants slept better when they slept on their stomachs and were not aware of the dangers associated with this.

“When a baby is sleeping on their tummy, they become better than when they are in other positions and when they’re sleeping on their tummy they sleep”. (Round 2, grp 1).

Acceptability

The main purpose of Round 2 FGDs was to determine the acceptability of the prototype and therefore, this theme was only introduced in Round 2.

The acceptability concept was introduced with a general discussion around the intervention activities, specifically how often the content should be delivered and whether it should be delivered through an app or WhatsApp. Access to mobile data (or lack thereof) for delivery purposes was also explored. All of the participants requested a data free option, and some preferred WhatsApp, while others preferred the idea of using an app. The frequency of the content delivery varied, ranging from daily to weekly and bi-weekly (app content).

Regarding the app content, participants did not mind if the videos were in English, as long as there were subtitles accompanying the audio, moving slowly across the screen. As many of the videos available on the internet are usually North American/ Eurocentric, many of the participants suggested using local videos or having actors who were more representative of the Sowetan Community when it came to their race and culture.

“It should be maybe it could be a black person. You see?”

Sometimes we as people, we say these things are done by white people.” (Round 2, Grp 1)

After being presented with the prototype activities, the participants further discussed their thoughts and perceptions of each activity. Subthemes were then created to align with the seven acceptability component constructs as described in Sekhon et al. (60) and the discussion points were placed into each subtheme, accordingly. Table 1 expands on subthemes and their supporting quotes.

Table 1: Subthemes and supporting quotes from Round 2 FGDs

Component constructs	Supporting Quotes
Affective attitude (How the individual feels about an intervention)	
Overall, the participants liked the content that was shown to them. They liked that it showed them something they did not know, that it included fathers, that it would help their children grow.	<i>"What do you think about this paper in front of you, this one of milestones?" "I feel like it's right, it helps". (Round 2, grp 1)</i>
	<i>"And I also like that they included the father, father figure on the video...To show that parenting is not only for the mother, it is for fathers." (Round 2, grp 2)</i>
Burden (The perceived amount of effort that is required to participate in the intervention)	
The participants felt that the activities (games and crafts) would not take up too much of their time and that they would find time in the day to do the activities with their infants.	<i>"It won't waste our time. For me it won't waste my time because I also like to teach my baby how we are supposed to play, it won't waste my time." (Round 2, grp 1)</i>
	<i>"Me too I don't see it as something difficult because sometimes you find that you finished cleaning at about eleven, you have nothing to do, I can do it." (Round 2, grp 1)</i>
Ethicality (the extent to which the intervention has good fit with an individual's value system)	
This subtheme was not explored as much as the other subthemes, but participants did not show any reason for the content not fitting in with their individual value system.	<i>"Okay I see that it's right because it's the way we live, the way at home, at the location we live like that, I mean in one room. (Round 2, grp 1)</i>
	<i>"It is relatable." (Round 2, grp 2)</i>
Intervention Coherence (The extent to which the participant understands the intervention and how it works)	
The participants understood the prototype activities shown and understood why they were important.	<i>"It is important to have knowledge about your baby that when they are one month what does your baby</i>

	<i>do, two months what does your baby do. (Round 2, grp 1)</i>
	<i>"I am going to do it more often because I only did that tummy time, it was very informative." (Round 2, grp 2)</i>
Opportunity Costs (The extent to which profits, benefits or values must be given up to engage in the intervention)	
The participants did not seem to mind that there may be opportunity costs as they tended to see the benefit outweighing the "cost".	<i>"There's nothing that takes time, it's your baby who is important at that time, when they're still young you need to play with them you need to do that, you must. (Round 2, grp 1)</i>
Perceived effectiveness (The extent to which the intervention is perceived to achieve its purpose)	
As this discussion took place before engaging in the activities it was difficult to determine how effective the participants perceived the prototype to be in the FGDs, but some did acknowledge that the content had been effective in teaching them how to play more with their infants.	<i>"It helps us, it teaches us new things that we can do with our babies, we did have others, but they also add [to this]." (Round 2, grp 1)</i>
Self-efficacy (The participant's confidence that they can perform the behaviour(s) required to participate in the intervention)	
Similarly with self-efficacy, it was difficult for the participants to judge their level of self-efficacy in completing the activities in the FGDs, but most seemed confident that they would be able to complete them independently at home.	<i>"But do you think that that is something that you could make?" "Yes, it sounds easy." (Round 2, grp 2)</i>

Round 3

Acceptability questionnaire

The percentage of participants participating in each respective activity is shown in Figure 13. The results of the acceptability questionnaire and participant's free responses, (separated into each component structure) are reported below.

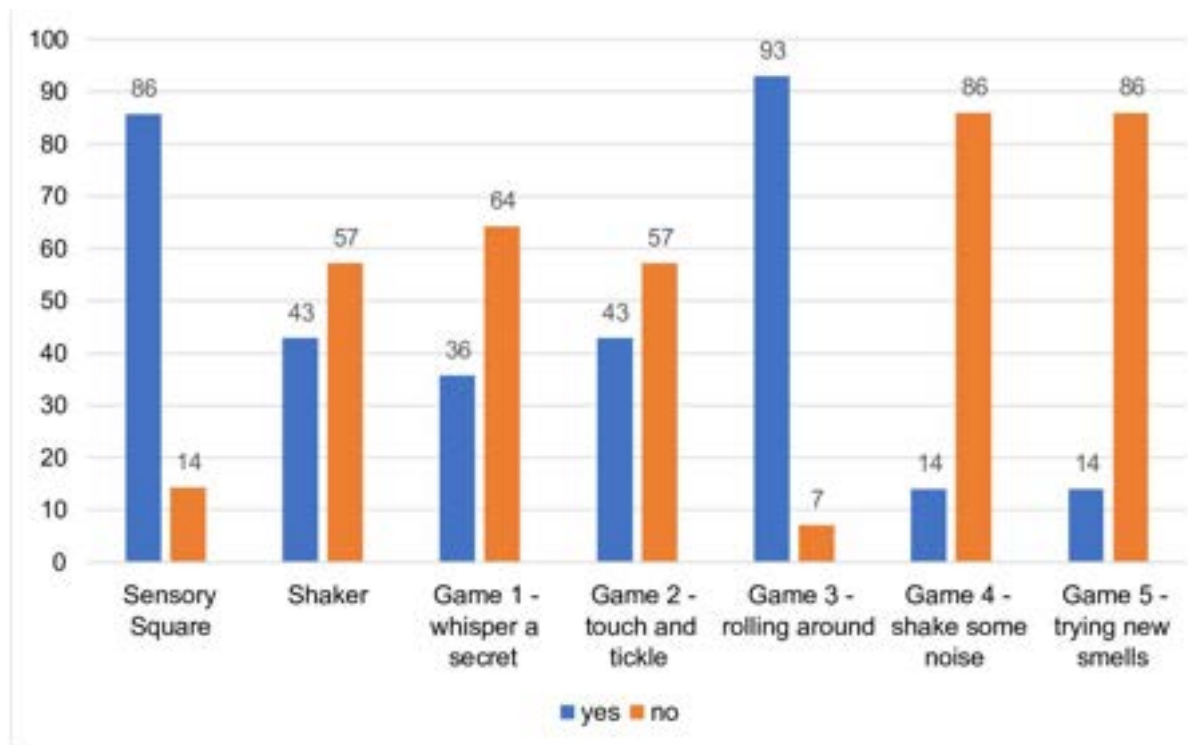


Figure 13: Percentage (%) of participants completing the sensory toys and video activities at home

One participant was not contactable and therefore only fourteen participants completed the telephonic questionnaire. This participant's data were excluded from the final quantitative analysis. The number of participants completing each respective activity is represented in Figure 13. The discrepancy in the number of mothers completing the activities is due to the mothers only being

instructed to pick a few activities to complete at home (i.e. they were not required to complete all of them in the week).

Every participant reported that they liked playing the games with their infants, largely due to both the baby and participant's enjoyment, seeing their baby's development and because it encouraged bonding with their infants.

"Well I like them a lot because I could see that the baby was developing and I was able to see what he likes and what he thought he did not like and he was smiling and showing me that he was enjoying it. That's why I was able to see that he was enjoying the rolling because for me it seemed like the most uncomfortable one but he was enjoying it. And my son is very picky so I was surprised when he enjoyed rolling. The thing about the games basically you are interacting with your baby and bonding in the time we do these games so I don't think there is anything that I did not like about the games." – participant with baby aged 5 months.

"They make her strong, I can see that she is getting used to them. I am also teaching her the tummy to tummy and I have started doing it a lot. She also likes the games but I can also see that some are helping her with development. She can see and follow sounds, that shows me that there is something that she likes and enjoys. There's a lot that I enjoyed about the games". – participant with baby aged 2 months.

Only one participant mentioned that they did not like the sensory square because it was too loud for them even though the baby enjoyed it. Otherwise, the rest of the participants stated that they liked the sensory toys because the infants liked the noise, the colours, and holding the square. Other reasons for liking the toys included: using the toys to calm the infant down when they cried, making the infant happy, and encouraging further learning.

"They make the baby to be more playful when they touch their toys especially the one with the plastic inside [sensory square] it makes the baby so happy" – participant with baby aged 4 months.

"I loved everything about it, my baby loves it, I can also see that she can hear it and she wants to hold it" - participant with baby aged 4 months.

"I loved the sound that it make because now that she is used to it when she cries it calms her down". - participant with baby aged 1 month.

Every participant felt that the activities were beneficial. Reasons for finding them beneficial included: enjoying the bonding time, both mom and infant (and family) being happy when engaging in the activities, learning and development for both mom and infant, and safety.

"[It is beneficial] because they help me to understand my baby and they help her to develop and to learn many things." - participant with baby aged 2 months.

"[It is beneficial] because when I saw the baby smiling and laughing I was also happy so I am happy that they don't only benefit the baby but myself as well" - participant with baby aged 1 month.

"[It is beneficial] because the games are safe" - participant with baby aged 2 months.

Every participant found the activities easy to do. The participants had varying reasons for finding them easy. These included the fact that they were easy to understand, that they were bonding with their infants and the infant was enjoying it. The participants agreed that they had the resources needed for making the sensory square or rice shaker. A couple of participants reported that it was easy because they did not need to buy any toys, which is not something they knew beforehand.

"I found them easy, they were not as hard as I thought they would be because we only think that playing with the baby requires toys." – participant with baby aged 1 month.

“I can sew, so when I was making the toys I was also enjoying it. She enjoyed all of those and they were easy to do because most of the time these are the games that we play with the baby, it’s just that we did not know that this is what we must do with our children.” - participant with baby aged 1 month.

“They were easy because it was just playing with the baby.” - participant with baby aged 2 months.

Every participant reported that they understood how to play the games with their infants, however one participant reported that the instructions were not clear. When asked what could be done to make the instructions clearer, the participant responded,

“Yeah actually I think there should be a person with training to [show us how to] play the games sometimes because we forget. So it's easy if we do a practical because other people are slow so it's easy to do a practical for everyone to remember.” – participant with baby aged 5 months

The majority of the participants (over eighty percent stated that they had time to complete the activities. The remaining two participants were not able to complete the activities due to illness and not knowing that they were required to complete the activities again, respectively. When asked what would help them to make time in future, these two participants stated that they would like to be sent the videos again and reminders through SMS.

All of the participants felt confident that they knew how to do the activities and were doing them correctly. When asked if there was anything that would make them feel even more confident, most of the respondents suggested sending more activities to do, along with instructions on how to do the new activities. Only one participant did not find the toys easy to make.

Of the fourteen participants, just over half (eight) of the participants found it very easy to find the resources to make the toys at home, five participants found it easy to find the resources and one participant found it difficult. While most of the participants had the resources at home, one

participant needed to buy a packet of chips to add the packet to the sensory square, and another participant needed to buy a needle, which they could both afford.

When it came to how and when the activities were presented, most (ninety seven percent) of the participants preferred being shown a video instead of it being presented in person, so that they could watch in their own time, slow down and pause the video, and could refer back to it as needed. When asked about how often the participants would like to receive more activities, there were varying responses. Five of the participants wanted to receive content once a week, while three participants wanted to receive the content monthly, every two weeks and every day, respectively.

3.7. Discussion

This study aimed to determine the acceptability of a set of activities which would be included in a study intervention for mothers in Soweto. The findings suggest that while many of the participants did enjoy playing with their infants and seeing the impact of play on their child's development, the mothers were also dealing with a range of complex factors, all at the same time, which hindered their participation in play. Some of these factors discussed included lack of time or motivation, environmental constraints as well as limited availability of information from health workers and/ or limited use of the information available, for example, in the Road to Health booklet.

Understanding the complexity of the mothers' lived experience

When it came to the mothers' understanding of play and development, many of the mothers were only aware of the gross motor developmental milestones and perceived their infant reaching these milestones to be a good sign of growth. Another study with a similar population group in Soweto, similarly found that mothers were aware of the different developmental milestones and would use them as a tool for tracking development and progress (21). While the participants understood the value of play in the younger months, it seemed that the participants were not aware of the importance of play in every aspect of development (e.g. not just physical/ motor development), or of the importance of their own role in promoting play with their infants in the early months. Likewise,

a Bangladeshi study found that rural mothers had basic knowledge about the benefits of play but lacked insight into the importance of it in every aspect of development, particularly the positive impact on cognitive development (82).

Round 1's discussions highlighted a significant lack of self-efficacy in the mothers, because of their difficult and complex lived experiences. Some of this was due to lack of knowledge and experience but some was linked to difficult circumstances and the environment around them, such as lack of resources and space. This was largely noticeable when many participants showed a sense of excitement and pride in knowing that they could use toys that they had made themselves for their infant's enjoyment and development, despite their financial constraints. Supporting mothers with education and increased sense of capability, has been shown to have a positive impact on children's development, seen in a study conducted in India, which found that maternal education and mental health were one of the primary indicators for a positive home environment at 6 and 24 months of age (83).

The participants expressed a strong distrust of the health workers at the clinic (who, in South Africa, are predominantly nurse-led). This distrust is largely as a result of the lack of confidentiality and mistreatment by certain health workers, resulting in a distrust in the information provided to mothers in the clinics. Unfortunately, this is something that is widely reported throughout Southern Africa. (84–87). Studies conducted in similar settings have reported women feeling insulted by healthcare workers during birth and ante/postnatal care, with health workers being apathetic to their pain or current needs. This resulted in women feeling disempowered to ask for information or not receiving information when asked. (88)(89). As some participants expressed a distrust in information provided by health workers, and others did not trust information given by family or friends, it's clear that there needs to be alternative sources of accurate information that can be relied on. Furthermore, better health literacy in the communities would allow mothers to know where to seek factual, evidence-based information, to know which sources of information to trust, and to know how to apply the information to their own context. To better equip the mothers to know how to access reliable and trustworthy health information, these findings guided the researchers to

provide intervention content on reliable online play and development resources, as well as how to prepare for clinic visits and meetings with Health Care Professionals.

One of the dominant themes that was repeatedly mentioned, was the impact of the home environment (both inside and outside) on the participants' movement behaviours and activities for both them and their children. Regarding the outside environment, the main concern around physical safety for the child is valid given the surroundings in which the participants live. Soweto is an informal settlement or "township" situated on the southwest of Johannesburg, where the number of child kidnappings, and pedestrian road traffic injuries are high. (90)(91). Similar concerns have been voiced by other mothers in the same Sowetan community. Pioreschi et al. (21) found that mothers expressed concerns around their children being hit by cars, being abducted, kidnapped or raped, as well as other concerns which weren't mentioned in this study but would also be applicable, such as the child hurting themselves or falling into communal toilets. The literature is clear in showing the impact of limited opportunities for movement in home environments (either due to lack of space, overcrowding, etc.) on active play and therefore, motor and cognitive development in infants (92)(19)(93). Most of the participants reported having limited space indoors and their environment outside being unsafe. This had major implications in the mother's ability to encourage active play, both inside and outside. In view of these circumstances, it was imperative that for any intervention involving active play to be feasible in this community, limited indoor and outdoor space needed to be considered. This resulted in the researchers focusing on increasing health literacy around the value and benefits of play, and specifically how to adapt the home environment, to encourage safe and active infant play.

Prototype development and engagement

The development and testing of the prototype provided some important insight into how the participants wanted content to be presented. Overall, the participants were happy to try out the activities at home. However, when presenting the activities as part of the prototype, many of the videos or activities did not have a diverse range of ethnicities or socioeconomic groups represented,

which the participants indicated would not be their preference. This led to the intervention only including people, environments and resources that were representative of the Soweto community.

With regards to “tummy time” and sleep related content, many of the participants felt that babies slept better in prone position and were not aware of the associated dangers compared to supine sleeping. This finding is similar to a South African study which found that only 3% of 6-week old babies were sleeping exclusively in a supine position (94) further highlighting the need for greater levels of health literacy within the community, and encouraging the researchers to include tummy time information and associated safety precautions in the intervention activities (94).

Acceptability of the intervention

Despite the small sample size, the results of the study provided important guidance when creating an acceptable intervention. Firstly, the intervention needed to include simple activities that encouraged age-appropriate play, using very limited resources which were available in the home. Secondly, the activities needed to be culturally appropriate for this specific group, and thirdly, due to crowded living spaces and limited outside play areas, the activities needed to encourage active play within the constraints of small spaces. Lastly, due to the lack of reliable information (and support) available to the mothers, the intervention needed to work alongside the current health system, by providing additional information on play and development that corresponded with information provided by the health care providers. For the activities to be feasible in a real-world setting, activities needed to be simple and achievable, to develop a sense of self-efficacy in the mothers. Content also needed to be accessible given that access to WiFi and data are significant barriers for mothers in accessing information digitally (26).

This study has certain limitations, which the researchers tried to mitigate wherever possible. We did not collect data on how actively mothers truly engaged with the intervention material, and only assessed their perception of a small sample of content. As this study had a small sample size, the findings may not be generalisable and cannot be extrapolated to higher income settings. However,

some of the findings may still be considered transferrable to other women in Soweto as certain demographic data, such as parity, education and marital status were similar to demographic data found in other studies completed in the same age group in this area (95,96). A common risk when using FGDs is the discussion being led based on the researchers' agenda, or the agenda of specific participants in the group. This risk was minimised by having a trained facilitator who was external to the project and an expert in dealing with group dynamics to allow for equal contribution from each participant. As the author is an outsider to the study population community, with their own ideas and presuppositions, as well as this study being completed as part of a doctoral degree, it is expected that some interpreter bias was present. However, where possible, interpreter bias was minimised by having three researchers code and re-code the data as described in the methods section. Despite these limitations, this study has a number of strengths. Including the participants (end users) from the point of intervention development allowed them to shape and create health interventions that were appropriate, acceptable and feasible in their own context. This is essential for seeing real success in changing health behaviours in real world settings (97). Implementing this intervention has the potential to increase mothers' self-efficacy and health literacy around their and the environment's role in their child's play and development. With the right information and tools, each participant has the potential to positively impact their child's development, which if expanded to the larger community, could see large scale positive growth and developmental outcomes throughout the life course. Given the lack of trust in the healthcare system, policy makers should focus on providing evidence-based knowledge to new mothers through other means such as data free digital products. A focus on providing safe, security patrolled open spaces and playgrounds needs to be prioritized to encourage access to active play for children and adults.

3.8. Conclusion

In conclusion, this study has provided insight into the acceptability of an intervention designed to improve health literacy around developmentally appropriate play during infancy, with a CAG of mothers in the Soweto community. The findings presented in this study will guide the development of an intervention in the form of an interactive mobile app and provide further insight and guidance

for developing future interventions in low-income settings. Future health and social policies need to account for the complexity of factors and experiences which impact mothers' decisions related to their children's play and development. Further research should focus on the impact and feasibility of using digital technologies to create behaviour change in low-income settings.

4. Chapter 4: Paper II

Please note that this chapter has been modified post publication based on examiner feedback

Title: The feasibility and acceptability of an app-based intervention aimed at improving maternal health literacy around infant play and development: A mixed methods study.

4.1. Abstract

Background: In the early months of life, allowing infants access to unstructured, unrestricted play in their home environment is imperative for development and increased PA. It is therefore important to focus interventions on these formative months, encouraging healthy movement behaviours as early as possible. In real world settings, determining feasibility and acceptability of an intervention is important to understand the practicality and suitability of an intervention for scale up and implementation in specific contexts. This study aimed to 1) Test the feasibility and acceptability of an intervention aimed at improving maternal health literacy around infant play and development, and 2) determine participants' understanding and perceived relevance of the study outcome questionnaires.

Methods: Mothers assigned to the PLAY Study intervention group at 6 months postpartum (n=68) received telephonic or in-person check-in and assessments every 2 months, and health literacy intervention content and resources delivered via a mobile app, every week. Feasibility was measured by calculating participant contact (adherence) and frequency of access to the content via the app. An acceptability questionnaire and two participant Focus Group Discussions captured and explored the acceptability of the intervention at the end of the study (12 months).

Results: 17 participants attended FGD1 (n=8) and FGD2 (n=9). 49 participants completed the acceptability questionnaire. The health literacy content was found to be highly acceptable in the questionnaire and FGDs. Over 80% of participants attended the 12 month exit appointment. Most of the participants (70%) could access the intervention content over the 12 months of the PLAY Study and of those 59% looked at content more than once a week and 10% every day. Less than a quarter only looked

at the content sporadically. Access was impacted by technical difficulties attributed to using inconsistent external service providers.

Conclusion: The study was found to be acceptable to participants and feasible in this setting, highlighting the importance of developing the intervention content with the guidance of community members. The high acceptability of the intervention content and belief that other mothers would benefit from it, provides great potential for seeing effectiveness in similar communities.

4.2. Introduction

Due to the importance and plasticity of the first 1000 days of an infant's life, it is necessary to start developing a range of healthy behaviours from birth (76). The many negative side effects of an inactive, sedentary lifestyle can take years to present; however, there is evidence for an association between increased PA in infants (1-12 months) and improved motor and cognitive development, as well as adiposity in infancy and later life (98). In the early months of life, allowing infants access to unstructured, unrestricted play in their home environment is imperative for development and for encouraging increased PA (20). It is therefore vital to focus interventions on these formative months, to encourage healthy movement behaviours as early as possible.

Previous research suggests that improving an individual's health literacy, has potential to positively impact their self-efficacy, resulting in a positive effect on their health outcomes (99). Similarly, when mothers are provided with the skills required to understand and implement parenting-related information, this can increase their motivation levels and ability to cope with their infant's demands, resulting in favourable infant health outcomes (100). It has therefore been hypothesised that increasing caregiver health literacy is key to caregivers developing a deeper understanding of the importance of play and development, and increased self-efficacy and motivation, resulting in greater participation in play in the early months and years to follow.

In real world settings, determining acceptability and feasibility of an intervention is important to understand the practicality and suitability of an intervention for scale up and implementation in specific

contexts (54). Feasibility is usually measured retrospectively to provide an explanation as to why certain aspects of the study were a failure or a success; however, for a study to be feasible it also needs to be acceptable and appropriate for the context in which it is implemented (54). With the increase in access to mobile phones in Lower- and Middle-Income Countries (LMICs), there has been an increased potential to encourage positive healthy behaviour change and outcomes, at a community level, by making use of digital interventions (36). Conversely, there are significant resource barriers to implementing mobile health (mHealth) interventions in low-resource settings, which impact the feasibility of these interventions. Barriers include a lack of electricity to charge devices (due to power outages at health facilities), limitations in hardware and software requirements, and limited access to affordable data or WiFi (37,39,55). Furthermore, when end-users can access digital information, some individuals do not have the health literacy or language skills needed to understand and use health information appropriately (43,56).

There are, however, certain facilitators that aid in intervention feasibility. To overcome challenges in understanding health information, studies completed in similar settings suggest using simple, lay language together with images, illustrations and interactive content, and including verbal explanations for those who cannot read (56,58). Health content creators should also use local languages to convey health information and possess a good understanding of the local context (56). According to Sekhon et al., for an intervention to be acceptable, individuals need to like the content, it should fit with their value system and not take up too much time or take the place of other important daily activities (60). The intervention should also be coherent, perceived to be effective while improving self-efficacy (60).

The PLAY (Play Love And You) Study is a Randomised Controlled Study with an intervention designed to promote infant development through encouraging maternal self-efficacy using behavioural feedback and supportive interventions (62). This study was nested within the PLAY Study, and fell under one of the study's secondary objectives, which aimed to test the efficacy, feasibility and acceptability of providing intervention content, and increasing opportunities for early learning through play to promote health literacy in mothers (in a low-resource setting) (62). Findings from this study were to be used to guide development of a high-fidelity intervention, implemented at scale.

The specific objectives of this study were:

- 1) To test the feasibility and acceptability of an intervention aimed at improving maternal health literacy around infant play and development.
- 2) To determine participants' understanding and perceived relevance of the study outcome questionnaires, considering the context in which they live.

2.1 Study setting and participants

As per the PLAY study protocol, 207 mother–infant pairs were recruited to the study, within a month following delivery, from community clinics in Soweto (62). Mothers were eligible for recruitment if i) they were 18 years of age or older with an infant <1 month ii) of whom they were the primary caregiver, and iii) were living in Soweto for the duration of the study. Each pair was individually randomised into either a control or intervention group. The intervention lasted for 12 months, and assessments were made at enrolment and when the infants were 2, 4, 6, 8, 10 and 12 months of age. Recruitment ran from August 2022 to June 2024. The full details of the PLAY Study are described in the published PLAY protocol elsewhere (62). Regarding this sub study, health literacy intervention content and delivery methods were initially developed and piloted with a CAG, and examples of the developed content were found to be acceptable (101). The health literacy intervention was implemented with the PLAY study intervention group from when the infants were 6 months old, which constituted enrolment for this sub-study. Exit assessments were done at 12 months. Follow up happened at 8 and 10 months.

Ethical approval was obtained from the University of the Witwatersrand Human Research Ethics Committee (Sub-study M220886 under main study M210846 and M220217). Written informed consent was obtained from all participants for participation in the FGDs and questionnaires, and for each FGD to be recorded. All participants were reimbursed for travel costs and provided with refreshments at FGDs and hospital-based follow-ups.

2.2. Study design

This sub-study used convergent mixed methods to describe and explore the acceptability and feasibility of the health literacy intervention amongst the PLAY Study intervention group between 6-12 months. A concurrent triangulation approach was used, use of both quantitative and qualitative methods will offset the weaknesses inherent within one method, with the strengths of the other (63). Mothers assigned to the intervention group (n=68) received telephonic or in-person check-in and assessments conducted at 6, 8 and 10 months and referrals to healthcare facilities and community services (such as mental health provision), if necessary (standard of care), as per the PLAY protocol (62), as well as the intervention content and resources delivered weekly via a mobile app. The app was downloaded and set up on the participants' smartphones at enrolment and content was updated weekly. The health literacy content included infographics and videos showing examples of toys that could be made from recycling at home, as well as age-appropriate activities and games for infants to encourage active play and development. Informative content such as monthly developmental milestones and information, and suggestions around safe active play in the home were also included. This content was co-developed with a CAG and designed to be specifically contextually relevant for this community (16). The initial in-person appointment and enrolment provided a general check-in with the participants to discuss the content and to assist with any technical difficulties they may have had when accessing the content through the app. At the 8- and 10 month appointments, specific questions were asked about the infant's play and development, and the content was discussed again.

2.3. Data collection

Quantitative data

All quantitative data were collected by the PLAY Study team's RA using REDCap software. Data were collected either in person or telephonically, depending on the availability and preferences of the participants. The participants' age, education and income status were collected via a questionnaire at the initial PLAY Study enrolment (within 1 month of delivery). The acceptability questionnaire was

administered to all intervention group participants as part of the 12 month exit assessment from October 2023 – June 2024.

Feasibility

Participant contact (adherence) data were extracted from Redcap to determine the number of participants who attended the 6-, 8-, 10- and 12 month appointments, respectively. As an attrition of over 20% has the potential to introduce significant bias to the study findings, the intervention was considered feasible if 80% of those participants enrolled in the sub-study at 6 months attended the 12 month exit appointment (102). Lastly, questionnaire data on compliance was used to determine how many participants could access content via the app, and how frequently they accessed content over the full 12 months of the PLAY study. As this could not be disaggregated to include access to content only from 6-12 months, feasibility of this sub-study alone could not be accurately measured using these data, which were included for interest and discussion.

Acceptability

The acceptability questionnaire, consisting of 22 questions, was compiled by the study team and included questions that captured the acceptability of the health literacy intervention, using an ordinal scale. This questionnaire focused specifically on health literacy acceptability to discern from the overall acceptability of the larger study. The acceptability questions were based on the constructs developed by Sekhon et al., namely, affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness, and self-efficacy (60). These constructs were also used to inform the development of the intervention content and therefore allowed for continuity of measuring acceptability before and after the study (60,101). See Figure 5 (Chapter 1) for a further description of each construct.

Qualitative data

Two qualitative FGDs were conducted by experienced RAs in December 2023 (FGD 1) (n=8) and February 2024 (FGD2) (n=9) with intervention group participants who had completed the intervention (N=17). Participants who had completed the acceptability questionnaire by December 2023 were invited to attend FGD 1. This was repeated again for FGD 2; however, those attending the second FGD were required to have also attended the 10 month visit by February 2024 to ensure we could assess the acceptability of that visit properly.

The FGD guide expanded on the questions asked in the quantitative questionnaire, to allow for a better understanding around acceptability of the intervention content. The FGD also included questions exploring the participants' understanding of the 4 four study outcome measure questionnaires collected at both 6- and 12 months, namely the HLQ (103). Affordances in the Home Environment for Motor Development – Infant Scale (AHEMDS-IS) (104), Assessing Children's Sedentary and Active Pursuits Questionnaire and Maternal Beliefs Questionnaire (105,106). The HLQ is a standardized questionnaire measuring health literacy according to the following categories: 1) Feeling understood and supported by healthcare providers, 2) Having sufficient information to manage their child's health, 3) Actively managing their child's health, 4) Social support for health, 5) Appraisal of health information, 6) Ability to actively engage with healthcare providers, 7) Navigating the healthcare system, 8) Ability to find good health information and 9) Understand health information well enough to know what to do (103). The AHEMDS-IS is an instrument measuring the affordances available for motor development in the child's environment, asking questions around availability of physical space, variety of stimulation and play materials in the home (104). The Maternal Beliefs Questionnaire explores the mother's belief, attitudes and intentions around their infant's PA specifically around PA knowledge, views on children's PA, PA optimism, self-efficacy for promoting PA, future expectations around infant's PA and TV viewing, and floor play concerns (105,106). The Accessing Children's Active and Sedentary Pursuits questionnaire has two parts: 1) Mothers are asked to report the amount of time (minutes) their infant spent in various activities on an average day and, 2) asked to report whether their child had access to, or is likely to have access to, age-specific toys and equipment (such as balls, push toys, bicycles, etc.) within the next year

(105,106). As most of the participants were not first-language English speakers and the questions were primarily asked in English (and translated for further clarity if needed), they were asked to discuss any barriers in understanding the questions in each questionnaire, respectively. Furthermore, participants were asked to discuss the relevance of each questionnaire in relation to their context.

All FGDs were conducted at Chris Hani Baragwanath Academic Hospital (CHBAH) in Soweto, Johannesburg by staff trained in qualitative research data collection. Although questions were asked in English, participants could respond in their home language and conversations progressed in the vernacular. This was later translated into English (if the response was in a different language) and transcribed for analysis.

3. Statistical analysis

Descriptive statistics (frequencies and percentages for categorical data, medians and standard deviations for continuous data) were used to describe socio-demographic data of the participants, as well as the quantitative acceptability and feasibility data. Similarly, descriptive statistics summarised how many participants attended each appointment and how many participants could access the app. The number of participants who attended the 6-, 8-, 10- and 12 month follow-up visits, were calculated (Figure 2). For each acceptability question, the two lowest (1 & 2) and two highest (4 & 5) Likert scores were combined respectively, resulting in a “low”, “neutral” and “high” result.

The qualitative data were analysed by two researchers (FB and AP), using thematic network analysis (80). Meaningful statements and ideas were coded and then grouped into themes, which were summarised and discussed in relation to the original research question. FGD 1 data were coded and placed into loose themes linked to the acceptability constructs. These findings led to the development of the focus group guide for FGD 2, focusing mostly on providing further insight into the themes already established, as well as exploring other themes that were not discussed in depth in FGD1, such as validity of the outcome measure questionnaires. The data from FGD 2 was then analysed using the themes from FGD1, allowing for new themes to emerge. The two FGD themes codes were then combined or adjusted

accordingly to create new themes and subthemes. At each stage, the analysis was iterative, with researchers double coding the data, as well as cross coding the analyses. When disparities existed, discussions were held, and themes collapsed/adjusted until agreement was reached.

4.3. Results

Feasibility

Of the 171 participants randomised into the PLAY study, 87 and 84 participants were randomised into the intervention group and control group respectively after completing the PLAY study enrolment assessment. Of the 87 participants in the PLAY study intervention group, 68 participants attended the 6 month assessment, which was the enrolment visit for this sub-study. The number of participants who attended the 6-, 8-, 10- and 12 month follow-up visits for this sub-study are summarised in Figure 14.

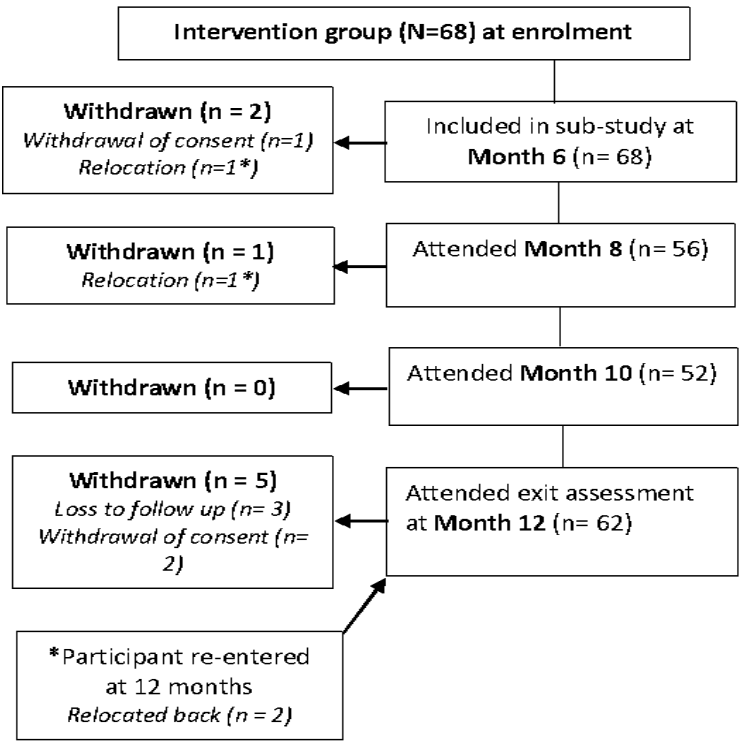


Figure 14: Intervention group attendance at 6-, 8-, 10- and 12 month follow-up appointments

Participants' access to the intervention content is shown in Figure 15. Most of the participants (70%) could access the intervention content over the entire 12 months of the PLAY Study. Of these 59% looked at content more than once a week and 10% looked at it every day, yet just under a quarter only looked at the content a few times.

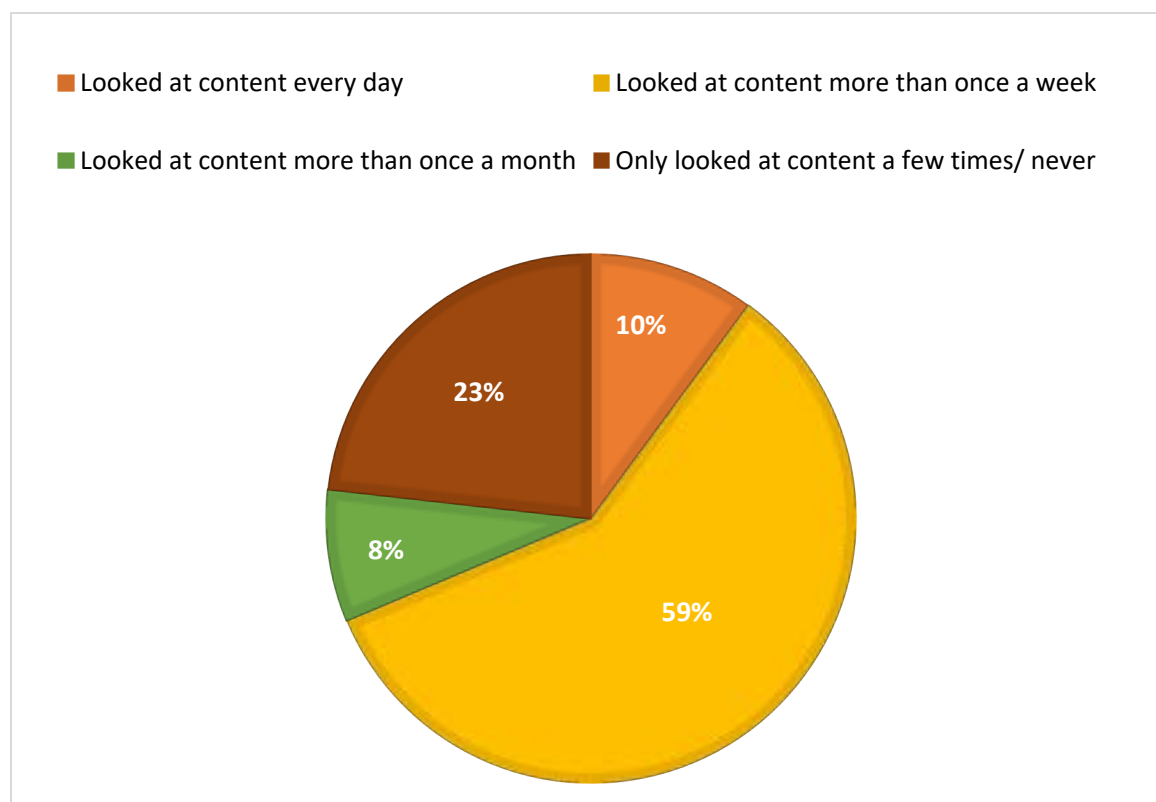


Figure 15: Access to intervention content over 12 months

Acceptability

Of the 62 participants who attended the 12 month exit assessment, 49 (79%) completed an acceptability questionnaire. The average age of those who completed the acceptability questionnaire was 29 years. Table 2 shows the results of the acceptability questionnaire. Overall, most of the questions received very positive responses, with the majority of questions having a 98% positive result. However, the effort it took to engage with the play and development information on the app (75.5%) was not as positive

(see Figure 16). Furthermore, only 51% of the participants always used the information presented to them when deciding which activities to do with their infants (see Figure 17). Reasons for not having enough time to engage with the play and development intervention (opportunity cost) was due to a participant not having enough time (n=1) and another participant losing their phone (n=1).

Table 2: 12 Month Acceptability Questionnaire (Intervention Group) detailing Affective Attitude, Intervention, Ethicality, Perceived Effectiveness and Opportunity Cost findings (N=49)

Acceptability component constructs	Value		
Total number of completed questionnaires (N), percentage (%)	49 (100)		
Affective Attitude			
Generally, did you like looking at and reading the play and development related information that was shared with you on the app?	like/strongly like	neutral	dislike/strongly dislike
	41 (83.7)	8 (16.3)	0 (0)
Did you like having discussions with the study team (phone calls/visits) about the play & development related information?	like/ strongly like	neutral	dislike/strongly dislike
	48 (98)	1 (2)	0(0)
Did you want to use the play and development information that was presented to you?	agree/ strongly agree	neutral	disagree/strongly disagree
	48 (98)	1 (2)	0(0)
Do you think other mothers in Soweto would like to have access to this play and development information?	agree/ strongly agree	neutral	disagree/strongly disagree
	48 (98)	1 (2)	0(0)
Do you think other mothers in Soweto would benefit from having access to this play and development information?	agree/ strongly agree	neutral	disagree/strongly disagree
	48 (98)	1 (2)	0(0)

Do you think that this play and development information is relevant to mothers in Soweto?	agree/ strongly agree	neutral	disagree/ strongly disagree
	49 (98)	1 (2)	0(0)
Do you think that this play and development information covers all the necessary information on play and development that mothers in Soweto require?	agree/ strongly agree	neutral	disagree/ strongly disagree
	48 (98)	1 (2)	0(0)
What aspect of the play and development intervention did you like most (select one)?	Videos	Pictures with information (infographics)	Discussions with the study team (visits/ phone calls)
	19 (38.8)	0 (0)	30 (61.2)
Intervention Coherence			
Generally, did you find that the play and development information presented in the app was easy or difficult to understand?	Easy/very easy	neutral	difficult/ very difficult
	41 (83.7)	8 (16.3)	0(0)
Did you find that the play and development information discussed with you during phone calls / visits was easy or difficult to understand?	Easy/ very easy	neutral	difficult/ very difficult
	48 (98)	1 (2)	0(0)
Was it clear to you how the play and development intervention would help you to be more informed about how to play with your baby and improve their development?	agree/ strongly agree	neutral	disagree/ strongly disagree
	48 (98)	1 (2)	0(0)
Ethicality			
Did you agree with most of the play and development information provided to you	agree/ strongly agree	neutral	disagree/ strongly disagree
	48 (98)	1 (2)	0(0)

Perceived effectiveness			
Was the play and development information that was presented to you useful/beneficial to you?	agree/ strongly agree	neutral	disagree/ strongly disagree
	48 (98)	1 (2)	0(0)
Did you learn something new from the play and development information that was presented to you?	agree/ strongly agree	neutral	disagree/ strongly disagree
	47 (96)	1 (2)	1 (2)
Did the information make you feel more confident in your ability to play with your baby?	confident/ very confident	neutral	unconfident/ very unconfident
	47 (96)	2 (4)	0(0)
Did the information change the way you played with your baby	agree/ strongly agree	neutral	disagree/ strongly disagree
	45 (91.9)	1 (2)	3 (6.1)
Opportunity cost			
Did receiving the play and development intervention interfere with your daily priorities?	agree/ strongly agree	neutral	disagree/ strongly disagree
	4 (8.2)	2 (4.1)	43 (87.8)
Did you have enough time to engage with play and development intervention that was presented to you?	agree/ strongly agree	neutral	disagree/ strongly disagree
	46 (93.9)	1 (2)	2 (4.1)
Why didn't you have enough time?	the information was too long (N=2)	lost phone (N=2)	
	1 (50)	1 (50)	

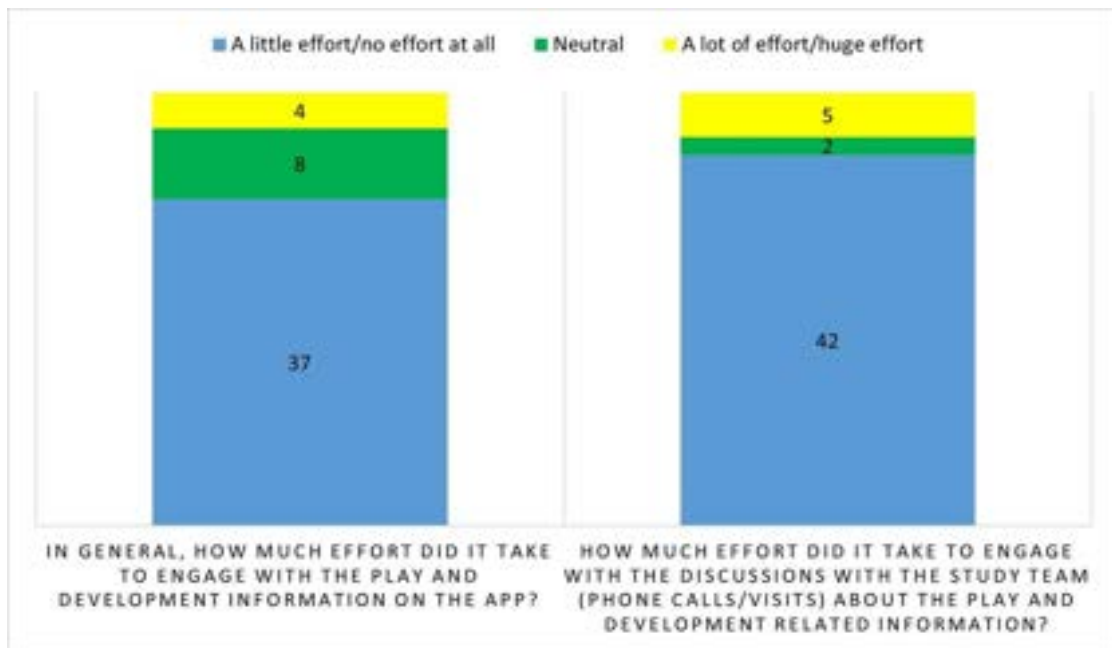


Figure 16: Acceptability questionnaire findings for Burden category (N=49)

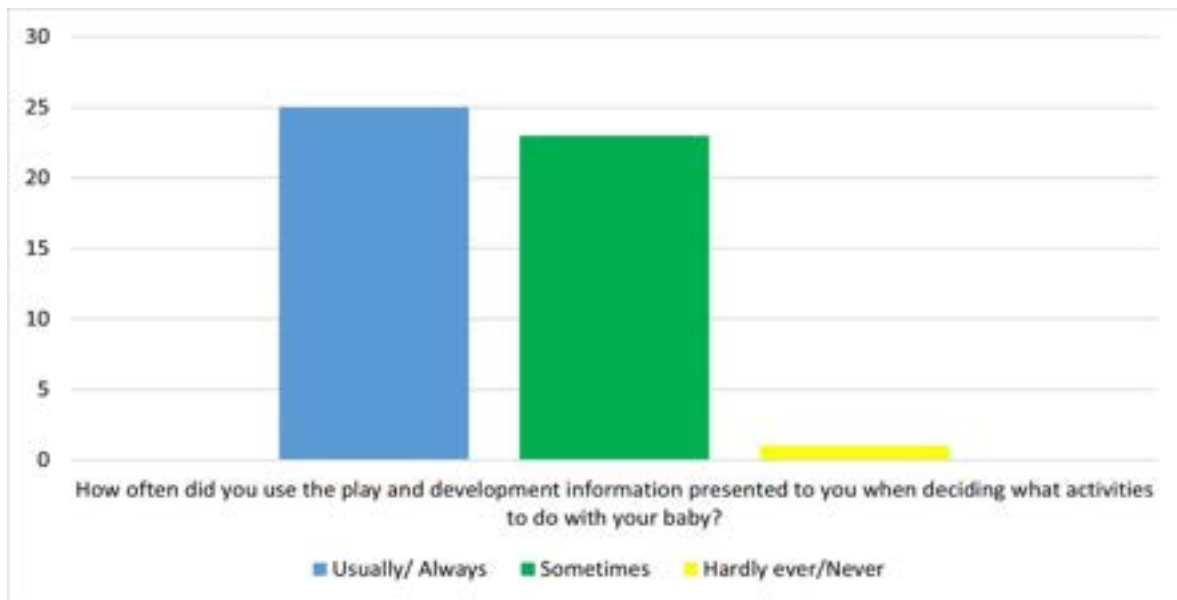


Figure 17: Acceptability questionnaire findings for self-efficacy category (N=49)

Focus Group Discussions

The combined average age of the participants who attended the Focus Groups was 30 years. 8 participants attended FGD1, and 9 participants attended FGD2. The themes and subthemes which emerged from the FGDs are discussed below.

Affective Attitude

Participants spoke about what they liked or did not like regarding the intervention content, as well as which aspects they enjoyed the most. Overall, the participants particularly liked the content around making toys and promoting play and development, presented in both video and infographic format.

Making Toys

The participants enjoyed how the content gave them possibilities of having toys for their infants, even when they could not afford to buy them. As the content showed the participants how to make toys out of recycling material (e.g. a shaker out of a toilet-roll holder and rice), they appreciated that the toys were low cost and easy to make.

“It was exciting because we got to learn how to create toys out of nothing. I learned how to make a shaker for a child using a bottle with beads or sand or maybe using eggshells. That turned out to be something that the child can use to shake. We got to know that if we are not able to afford buying toys, we can make them ourselves.” (FGD 2)

“It could be a box and maybe coke plastic bottle [sic] and then they would help demonstrate how to create your own toy instead of going to buy one. They were [sic] accommodating those who do not have money so that they can also be able to make the choice themselves.” (FGD 1)

“We are all going to say the same things. What I like the most about the app is about making the toys.” (FGD 2)

Participants expressed enjoying the video content which showed them step-by-step instructions for making certain toys:

“I liked the videos because they would teach us on how to make a toy. They would show you what you needed to make that particular toy.” (FGD 1)

The participants demonstrated a sense of pride in knowing that they received information and ideas from the study, despite one participant talking about being ridiculed by others for using recycled material to make the toys.

“...There is another child where I am staying [who] likes buying juices packaged in a cell phone-like bottle and then when they are done drinking, they would give me those bottles so I put beads inside and then I burned the opening to close it up and then when the child shakes it, it would make sounds. The child enjoyed it a lot and people would laugh at me and then I would tell them not to laugh at me because they had no idea where I got the information about making this toy.” (FGD1)

Promoting play and development

Participants enjoyed the content which encouraged them to play with their children and engage in activities that promoted development. The content spanned across different areas of development, from cognitive (basic concepts) to gross motor development.

“I made different colourful shapes and put them for them [the infant] to choose. Whichever shape they would pick I will tell them if maybe it is a circle. I would encourage them to pick whichever shape I would tell them to. (FGD 2)

“I liked the information especially about how to encourage the child to sit or crawl.” (FGD1)

Some participants reported that the content helped them to learn about the importance of play, not just as a means to an end, but an end itself, and how to spend time actively playing with their child. The mothers enjoyed seeing their children enjoying themselves during the activities. Singing and dancing activities were particularly popular.

“This Play Study has helped me to know that I should have time for my child and play with him. Not just playing to pass time but I can spend maybe one hour and it must be a routine that we do that every day.” (FGD 1)

“I also liked songs such as ‘head, shoulders, knees and toes.’ We would sing while showing them by pointing their hands, shoulder, knees and toes. I would also sing the song in IsiZulu. We usually sing in front of a mirror and it would excite my child even though they were not understanding what it means [sic]. Sometimes I would also point at other body parts while telling them what they are.”

“What I liked the most was when I got to sing for my child and I could see that they would start dancing because they were enjoying it.”

Burden, coherence and opportunity cost

For those participants who could access the intervention content, all of them found it easy to access and use, with no one reporting any problems with access and useability.

“I think it was user friendly and simple to understand, depending on the information that I was looking for and I was able to access the information. Sometimes I would refer on the [sic] YouTube links for the videos.” (FGD 1)

When discussing how often the participants engaged with the intervention content, many participants reported that there were other competing priorities, such as work and attending to older children, that would limit their time on the app. This resulted in most participants engaging with the content ad hoc, when they had time.

“For me it was finding time to go through the app because I go to work and when I get back, I still need to spend time with the children. On weekends I would be busy with house chores. I hardly had time to go into the app and that was my challenge.” (FGD 2)

“It will be sometimes (going through the app) when I am just sitting alone, I would say let me take the phone and go through the app and read the contents.” (FGD 2)

Furthermore, most participants found the content easy to understand, however those who struggled were those who had other tasks or children vying for their attention, therefore limiting their ability to concentrate and comprehend the content information. One participant reported that providing graphics or videos to accompany the written information helped with understanding the content.

“I do not think there is anything I came across that was difficult. Every information that was there was simple for me to understand. If there was information that I did not understand at the end there will [sic] be a video or some pictures which would help me to understand better what they were talking about. For each and every information you would read about there would be a picture attached to it explaining to you that this is what we are talking about.” (FGD 2)

“...Most of the time I am left alone at home because children go to school. I would be on the app but my mind would be wandering somewhere. I could be reading and understanding but my mind would not be in the same space...I know that there is a child in the house and have to keep an eye on them but because there are a lot of things going on and there is no one to talk to. I would tell myself that I need to be focused on the child but my mind would not be there.” (FGD 2)

Perceived effectiveness

Overall, the participants wanted the content to be accessible to all mothers in their community, and were positive about the effectiveness of the content, particularly with regards to its impact on their health literacy and their infant's development.

Infant development

While many of the participants were aware of the major developmental milestones that children should be reaching at certain ages, they found that the intervention content provided examples of activities to assist their infants in reaching these milestones. The intervention content also assisted in knowing what was considered “normal” with regards to their infant's development. Furthermore, the participants gained understanding in the importance of play for promoting development.

“We knew that we can hold your child [sic] to help them to learn to stand or walk on their own for a little while but with the app, you become aware of the milestones and how to assist your child reach them.” (FGD 1)

“I think playing with your child helps with their brain development and stimulating [sic] them. At first, I would just think that Thabiso is just playing and I did not know that while he is playing, development process [sic] is also taking place.” (FGD 1)

Health literacy

Many of the participants reported an increase in their own knowledge around play and development, and that their immediate and extended families gained more knowledge as a result of engaging with and sharing the intervention content. The participants felt that the alignment with the information provided by the clinics gave validity to the intervention content and made it seem trustworthy.

“Another thing that I have found very important is the fact that I can always reference between the study and the road to health card, that I know what I am doing is right, it is not something that was created from nowhere. So, the fact that there is a backup of the information that I have received.” (FGD 2)

“My eldest daughter is 21 years old and she is the one who made those toys because she would also read through the app. She is studying towards teaching qualification, so this was helpful for her as well. She would play most of the games with the child and with the other sibling. The app was not just helping me but all of us at home.” (FGD 1)

Some of the participants discussed how the intervention content helped to develop their self-efficacy and gave them a sense of independence, which was particularly important for those who did not have support from partners or immediate family.

“Another thing that I have just picked up from our sister who was speaking now, when you are a first-time mom and you do not have a mother, there are fathers who are hands on and are able to offer you support. But if you do not have that support structure and you know nothing and you have to teach yourself everything, even with me they just showed me once and then I was able to do everything for myself afterwards” (FGD 1)

The participants reported that the intervention content was particularly helpful for those who could not read, in teaching them activities to encourage their infants to reach their developmental milestones, and the average timelines for each milestone.

“I would like to add on that part of people who cannot read... If I am a new mother and do not know anything about the baby, the app shows me step by step. They mentioned the developments expected from the child month to month and if they are not doing what they were supposed to be doing they will tell you to do this and this to encourage the baby. It also shows that your baby will do this and that and this is how you should respond as the mother, you do not have to go to the clinic every time.” (FGD 2)

Effect of assessments on health literacy

While the FGD's sought to determine whether the participants understood the questions asked during the study assessments, it was found that just being asked questions about play and development as part of the assessment questionnaires, had an impact on the participants' behaviour, and thoughts and decision-making around play environments and resources/ toys. These are explored further in the subthemes below.

Change in health literacy and behaviour following questionnaires about play

The participants found the assessments relatable and often wanted to find out more about the assessment topic after the session was completed. Many learned more about the stages of development and what behaviour was appropriate at the different stages from questionnaires about milestone attainment.

"I would say the importance of the milestones. That is the one thing that I can take away for 10 months because immediately after you guys called you asking about if the child can see small objects, can you tell to see [sic] a pin and so forth. Some of the questions were eye opening because I never used to take notice of that but after the phone call, I realised that there are few milestones that I have not looked into but now the phone call came, and I wanted to see if my child could do those things you were asking us about." (FGD2)

Play environments

Many of the participants reported that the questions encouraged them to reflect on their home and outdoor environments, particularly related to where their infant could play safely. The participants started to think about how their children could move around actively, while being supervised and safe, depending on their own home circumstances.

“You remember those questions where they asked that, when the child is playing outside, is there anything that they can hold onto for support. I did not realise that when the child is playing outside, I need to guard them. They also asked if there are steps [sic] and how big they were. Those questions were very eye opening. I was now able to know what things to look out for when the child is playing to know whether they are in a friendly or danger zone.” (FGD 2)

“For me those questions made me feel somehow because she would be asking if I prefer my child playing or carrying them on my back. At that time, I would then think to myself that if I carry my child on my back, he will not be free to play, but if I put him on the floor, he will be free to play whatever he wants to. For me those questions were relevant because I got to understand that I do not need to confine my child in a small space because of being scared that they were get hurt while playing. Eventually the child will grow and go outside to play.” (FGD 2)

Resources/ toys

Many of the participants discussed how the questions encouraged them to think about what type of toys their infants were playing with, and when they should play with different types of toys, according to their stage of development. Some did not know that they could introduce toys at an early age, while others learned more about the quality of toys and how they can impact their infant’s development in different ways.

“For me I can say I was not aware at that time because when the questions were asked, I thought my child was still very young to know about toys. I had not even bought him one toy because I thought he was still young; he cannot play with toys but only with us.” (FGD 2)

“It was eye opening in a sense that toys are not the same and they do not offer the same qualities in terms of the child's development. Like when you are asked about the book, whether the child has a book. My child has a book, and it is called a Peekaboo Book. The book itself asks about animals, who is hiding behind? It flips open, peekaboo and then it will show you that animal. That was eye opening

because firstly the child gets to hear the sounds of the peekaboo that you are saying, and the child can see the colours and animals. For me those kinds of toys felt like they were more educational. As much as they were playful, they were more educational. It was better than having a toy that does not do anything, and it is dark, you do not know. Maybe if it was brighter the child would want it...” (FGD 2)

4.4. Discussion

This study aimed to determine the feasibility and acceptability of an intervention aimed at improving maternal health literacy around play and development and to determine the participants’ understanding and perceived relevance of the study outcome questionnaires. Recent studies have found the provision of content through mobile application to be successful in supporting and improving maternal health during the peri- and postnatal period (107–109). However, there is an increasing awareness that for mobile health interventions to improve maternal and child health, they need to be accessible, culturally appropriate and relevant to the social and physical setting (107,110).. While the intervention was found to be acceptable and feasible, some factors, such as access to information on the mobile app were less so, due to software specific issues and preference for information in video format.

Feasibility

As more than 80% of participants attended the 12 month exit assessment, according to our definition, the study was found to be feasible. When exploring the feasibility of the intervention content and delivery, there were several factors which impacted the participants’ ability to access the play and development content on the app. These were largely linked to issues beyond the researchers’ control such as relying on external stakeholders to upload content and update participant profiles in a timely manner as well as issues with the software, which prevented certain videos being downloaded, despite the content being data-free. The study intervention RAs tried to overcome content access challenges by a) attempting to troubleshoot any software issues when physically with the participant at follow-

ups, and if not successful, b) going through any missed content with the participant at follow-up visits. These barriers are not limited to this study, and similar problems have been reported in existing maternal/ child mHealth technologies (using text/SMS) available in South Africa, such as MomConnect (111), which have been reported as being helpful but inconsistent in delivery (43). Other external factors such as phone sharing, losing phones or having phones stolen, and changing of phone numbers, etc, were apparent but expected. These are common problems impacting adherence and delivery of mHealth interventions in similar low resource settings (38,40,43). Despite these difficulties, more than half of participants were engaging with the content more than once a week. Other mHealth (SMS) studies in low-resource settings have found this frequency of content delivery to be acceptable amongst users (112). For those who engaged less frequently, other priorities, such as work and looking after other children, often took preference. This was similarly noted in the prototyping work with a CAG that informed this study (101).

Study follow-up attendance was found to be relatively high despite the decrease seen in the 8- and 10 month follow-ups, respectively. Reasons for the low attrition could have been attributed to the RAs developing an effective track and trace system, where all uncontactable participants were visited at home. From here, the RA would make contact again with the participant or be provided with the participant's location/ contact details from a family member or neighbour. The telephonic nature of the 10 month follow-up could have had an impact on adherence, due to the factors around phone usage discussed above. Lastly, as there was a focus on collecting data for the outcome analysis time points, this led to higher attendance rates at both the 6 and 12 month follow-up time points, respectively. It is also important to note that even though participants may not have attended each follow-up visit, they were still engaging in the weekly content via the app.

Acceptability

Overall, there was a high level of acceptability of the intervention amongst the participants. The least acceptable components of the intervention (that were still considered very high at 75% acceptability) were around how often the participants used the information when deciding on what activities to do

and the effort it took to engage with the information. In the questionnaire, the participants preferred meeting in person and no participants reported that they preferred engaging with the infographics. This correlates with findings from the preliminary prototyping work with the CAG, which found that 90% of the group preferred team discussions and videos compared to the infographics when asked in a questionnaire but were more favourable towards the pictures during the discussion (101). Unfortunately, due to limited resources for producing high quality videos in this pilot study, the researchers had to provide a combination of videos and infographics to ensure the validity of the information shared. Similarly, while some participants liked reading the content information, some reported that they particularly liked the videos as it gave them step by step instructions that were easy to follow. This has also been reported in other low resource settings where low (health) literacy levels can result in misinformation and limit understanding of written materials, such that verbal instructions or other traditional communication (e.g. radio, TV, etc) are deemed more acceptable and feasible (43,113). While other exploratory work in a similar setting found that women were skeptical about receiving information that would not elicit any change in behaviour due to constraints in their environment (43), participants in this study were very positive about the intervention, and the change it could achieve, particularly when used alongside the Road to Health card and information provided by health facilities. This can largely be attributed to the content being so contextually relevant, as a result of involving a small group of mothers from this setting (CAG) in testing the initial prototype, which was then used to create our final intervention content (101). Furthermore, aligning the content with the government-provided information played an important role in increasing the intervention's acceptability and the participants' ability to trust the information, and their ability to use it alongside the resources they already had. This has been seen in text-based mobile interventions in a similar context, where the provision of trusted health information resulted in positive health outcomes (45).

The participants found the questionnaires easy to understand, but this was largely impacted by having an RA who was able to translate any difficult words into the participants' home language if required. While participants found the questionnaires relatable to their context, an interesting finding was how the questionnaires did not just serve as outcome measures but acted as a means of improving knowledge around play, development and the environment. This was largely due to participants being

required to consider whether their environments were conducive for their children to play safely and discussing the importance of toy usage at different ages to encourage development. This phenomenon is an extension of the Hawthorne Effect (occurring when individuals modify their behaviour in response to being observed or knowing that they are part of an experiment), also known as measurement bias or 'measurement reactivity' (114). Measurement bias is commonly seen when repeating the same questionnaires (response shift) and when the act of completing a questionnaire results in new beliefs and behaviours about the research topic (115). However, the HE usually disappears in well-designed RCTs, as would be expected in this study (114).

Potential for Effectiveness

The high acceptability of the intervention content and belief that other mothers would benefit from it, provides great potential for seeing effectiveness in similar communities. As there was such a positive response from the participants around being able to make their own toys and learn new skills, in practice, this would allow other mothers in similar settings to have access to these resources, therefore encouraging and equipping them to foster more play, and subsequently, further development in their infants. The participants reported an increase in knowledge around infant play and development and self-efficacy, after engaging with the content, which supports other studies highlighting a positive association between health literacy and self-efficacy (30,116). As self-efficacy has been found to be a mediator between maternal health literacy and positive parenting behaviours (i.e. encouraging participation in infant play) (117), this links positively to the overall trial study objective of encouraging maternal self-efficacy using different micro interventions. Testing feasibility and acceptability is an important first step as it provides important guidelines when scaling up studies or implementing these interventions in practice.

Strengths, limitations and implications for future research and implementation

The study's main limitations were linked to the feasibility of using inconsistent external providers to deliver the content via a prototype mobile app, which resulted in technical issues (despite it being data

free). To resolve this, the researchers have created an independent app containing the resource content, which counteracts the issues encountered in this feasibility study and can be implemented at scale. With regards to measuring feasibility, the health literacy intervention was provided from the age of 6-12 months, but the larger study provided other content from 0-12 months. We therefore could not determine what content was received by each individual, and when. However, purposively recruiting FGD participants who had received the whole 6–12-month intervention, including app content and 10 month follow-up attendance, allowed us to have a better, in-depth understanding of the acceptability of the intervention specifically provided during those months. Using mixed methodology helped to improve the validity of the findings, where insight into the quantitative finding could be challenged or consolidated in the qualitative FGDs. While there were technical issues related to delivering the app in this study (which can be easily rectified), the content of the app and overall intervention was found to be highly acceptable to the participants and feasible in this setting. These findings therefore suggest that interventions which provide meaningful, clear and easily accessible information around play and development in infants, would be useful and well received by mothers and caregivers in similar settings, and show potential for effectiveness in improving health literacy around play and development. Given the digital limitations in this population, researchers and policy makers need to develop interventions that provide information through a variety of platforms, to enable equitable access for all.

4.5. Conclusion

This study provides insight into the acceptability and feasibility of an intervention aimed at improving maternal health literacy around play and development in a low-resource setting. While the intervention was considered feasible within the setting and highly acceptable to participants, barriers related to external management of the app resulted in some issues with accessibility. Importantly, developing the intervention content with the guidance of community members resulted in very high acceptability, and potential for effectiveness.

5. Chapter 5: Paper III

Title: Evaluating the impact of an app-based intervention aimed at improving maternal health literacy around infant play and development, using the Health Literacy Questionnaire (HLQ), in Soweto, South Africa.

5.1. Abstract

Background: In the early months of life, allowing infants access to unstructured, unrestrictive play in their home environment is important for development and for encouraging increased physical activity. Research suggests that improving an individual's health literacy has potential to positively impact their self-efficacy, resulting in a positive effect on their health outcomes. Similarly, when mothers are provided with the skills required to understand and implement parenting-related information, this can increase their motivation levels and ability to cope with their infant's demands, resulting in favourable infant health outcomes. The primary objective of this study was to determine whether 12 months of a co-created intervention resulted in higher health literacy scores in the group that received the intervention, compared to the group that did not.

Methods: This study was nested in a Randomised Controlled Trial, the Play Love And You (PLAY) study. Mothers assigned to the PLAY Study intervention group at 6 months postpartum (n=68) received telephonic or in-person check-in and assessments every 2 months, and Health literacy intervention content and resources delivered via a mobile app, every week. Control group participants (n=65) received the standard of care. Maternal health literacy was measured at baseline (6 months) and exit (12 months) using the parent Health Literacy Questionnaire.

Results: At baseline (6 month follow-up), there were 67 participants included in the intervention group and 65 participants included in the control group (N=132). 61 participants completed the 12 month exit assessment (intervention group) and there were 61 participants in the control group at 12 months.

There was no significant difference between the intervention and control group HLQ scores at 12 months ($p=0.45$), yet there was a significant difference between the two groups at baseline (6

months), with those in the control group having higher HLQ scores than those in the intervention group ($p=0.002$). After recoding the HLQ continuous scores according to the categorical cutoff, a linear regression found that being in the intervention group was associated with a significant 1.44 point increase in HLQ change scores (coded as (-1 to 1) from 6 to 12 months ($p=0.01$).

Discussion: While there was not enough evidence to suggest that the intervention had a significant effect on those who received it, compared to those who did not, after adjusting for the skewed 6 month data, being in the intervention group was associated with a significant increase in HLQ scores from 6 to 12 months, with fewer participants in the intervention group showing a negative change and more participants in the intervention group showing a positive change over time, compared to the control group. This change was driven by mothers' ability to actively manage their child's health, their social support for health, and their ability to identify good information and reliable sources of information. Certain limitations linked to intervention dosage, reliable data collection and the chosen outcome measure may have reduced the effect of the intervention in the intervention group.

Conclusion: This study found that the health literacy intervention did not have a significant effect on those who received the intervention, compared to those who did not, however there was a significant increase in health literacy scores in the intervention group over time. Developing and using a health literacy questionnaire that is more appropriate for postpartum mothers in low resource settings, as well as increasing the dosage of the intervention, may result in a greater effect in future studies.

5.2. Introduction

Given the critical importance and sensitivity of the first 1,000 days of an infant's life, it is essential to establish healthy behaviours from birth (118). While the harmful effects of a sedentary lifestyle may take years to become apparent, research shows that increased PA during infancy (1–12 months) is linked to better motor and cognitive development, as well as healthier adiposity levels both in infancy and later in life (119,120). (24)(121). Unstructured play (play which is led by the child without an expected or imposed outcome) is considered imperative for increasing levels of PA in children (26). In the early months of life, allowing infants access to unstructured, unrestrictive play in their home environment is

important for development and for encouraging increased PA (20). However, there are factors in the child's environment that can limit opportunities for play, particularly in low resource settings. In South Africa, the value of play is not generally understood amongst caregivers. While many parents acknowledge that play is important for bonding, learning through play is usually understood to be more for socialisation and the belief is that most learning occurs at ECD groups, or through technology (i.e. playing on phones or watching TV) (22). Some caregivers believe that children below the age of two are too young for books and play, with 43% of households not owning any children's books (22).

It is therefore imperative that parents be provided with the correct tools and support to promote responsive caregiving, child directed learning and positive parenting in the early months/ years of their children's lives (24). Empowerment and provision of support for caregivers is essential for allowing facilitation of playful learning in day-to-day activities in the home environment and community (18). Previous research suggests that improving an individual's health literacy has potential to positively impact their self-efficacy, resulting in a positive effect on their health outcomes (99). Similarly, when mothers are provided with the skills required to understand and implement parenting-related information, this can increase their motivation levels and ability to cope with their infant's demands, resulting in favourable infant health outcomes (10). It is therefore hypothesized that increasing caregiver (in this case, mothers') health literacy is key to caregivers developing a deeper understanding of the importance of play and development, and increased self-efficacy and motivation, resulting in greater levels of infant active play in the early months and years to follow. The primary objective of this study was to determine whether 12 months of a co-created intervention resulted in higher health literacy scores in the group that received the intervention, compared to the group that did not. The secondary objective was to determine whether there was a greater change in health literacy scores from 6 to 12 months in the intervention group compared to the control group.

5.3. Methods

5.3.1. Study setting and participants

This study was nested in a Randomised Controlled Trial (RCT), the Play Love And You (PLAY) study, a 12 month intervention designed to promote infant development through encouraging maternal self-efficacy using behavioural feedback and supportive interventions (74). This study (the SmartPlay Study), fell under one of the PLAY study's secondary objectives, which aimed to test the efficacy, feasibility and acceptability of providing intervention content, and increasing opportunities for early learning through play to promote health literacy in mothers (in a low-resource setting) (74). Mothers and recently delivered infants (3-10 days old) were recruited from two primary care clinic maternity wards in Soweto, (a low resource peri-urban informal settlement), Johannesburg and enrolled into the PLAY study. Further details of the enrolment procedures and inclusion criteria are described elsewhere (74).

Ethical approval was obtained from the University of the Witwatersrand Human Research Ethics Committee (Sub-study M220886 under main study M210846 and M220217). Written, formal informed consent was obtained from all participants. All participants were reimbursed for travel costs and provided with refreshments at hospital-based follow-ups.

2.2. Study Design

The PLAY study RCT consisted of a standard of care package (control group), and an intervention package – including standard of care as well as the intervention content (intervention group). Mothers assigned to the control group received the standard Road to Health booklet as well as the Side-by-Side services provided as routine postpartum standard of care. The intervention group received the standard of care package, as well as the intervention (74). The intervention for the SmartPlay study focused on improving maternal health literacy, thereby encouraging age-appropriate active play and development in infants from 6 to 12 months, using an interactive App with content and resources (weekly), as well as in-person and telephonic follow-ups (every two months). Content provided through the app which specifically

related to increasing maternal health literacy for promoting play and development included the following:

- 1) Infographics on age-appropriate games to play, monthly milestones, activities to promote sensory development, sitting, fine motor development as well as how to make a low-cost picture book
- 2) A variety of videos, including how to encourage active play inside, how to safely encourage crawling, finding reliable information online as well as how to make a variety of toys and a standing activity table from recycled goods.

The 10 month telephone call discussed the infant's developmental milestones and mother's concerns (if any). Details of how the content was developed with a CAG as well as the acceptability and feasibility of the 6–12 month intervention are described in chapter 3 and 4, respectively.

2.3. Data collection and management

Participant sociodemographic data were collected shortly after enrollment into the PLAY Study. The baseline sample for the SmartPlay study was calculated as the number of participants who attended the 6 month follow-up time point. The following baseline variables (exposures) were included in the PLAY Study baseline data collection: Maternal age (years), Socioeconomic Status Score, Home Density (average number of people in home), Number of children in home, Infant sex (male/ female), Maternal Education (Not completed high school/ completed high school/ completed postgraduate studies), Employment (never employed, currently employed, looking for employment) and Relationship Status (Single/ In a relationship). All outcome data were collected in person by one of the PLAY Study team's RA's at the 6- and 12 month's follow-up timepoints, however, all sociodemographic data were collected at enrolment into the PLAY study. Questionnaires were completed in English but more detailed explanation was provided in the participant's first language if further clarity was needed.

2.4. Outcome measure

Primary outcome measure

Health Literacy Questionnaire (HLQ)

Maternal health literacy was measured at baseline (6 months) and exit (12 months) using the parent HLQ, as it has been recommended by the World Health Organisation (WHO) for use in low- and middle-income settings (2). The HLQ contains 44 questions across 9 independent domains, with 4 or 5 questions per domain (103). The domains are as follows: 1) Feeling understood and supported by healthcare providers, 2) Having sufficient information to manage my child's health, 3) Actively managing my child's health, 4) Social support for health, 5) Appraisal of health information, 6) Ability to actively engage with healthcare providers, 7) Navigating the healthcare system, 8) Ability to find good health information and 9) Understand health information well enough to know what to do (103). Domains 1 to 5 assess the strength of participants' agreement with a statement on a 4-point ordinal scale (strongly disagree = 1 to strongly agree = 4) while domains 6 to 9 assess participants' perceived ease in task completion on a 5-point ordinal scale (cannot do or always difficult = 1 to very easy = 5). The median reliability of the HLQ domains is 0.88, with a range from 0.77 to 0.90 (103). For the 4-point scales with response options of strongly disagree to strongly agree (Scales 1 – 5), average domain scores below 2.5 indicate that respondents, on average, tend to disagree with the statements within a scale. For the 5-point scales with response options of cannot do or always difficult to always easy (Scales 6 – 9), average domain scores below 3.5 indicate that respondents, on average, find the task within a scale difficult to do (122). A higher overall score indicates higher levels of health literacy. Although each sub-scale is usually calculated as a high/low variable, we used the continuous total score in the primary analysis to maintain the power of the study.

2.5. Statistical analysis

STATA (version 18) was used to analyse all data (123).. Sociodemographic data were summarized and reported using frequency (%) for categorical data and means (SD) for continuous data. Missing outcome data were imputed using a multiple imputation method to reduce potential bias dependent on the pattern of missingness, which was assessed by comparing missing data between the two groups, and by comparing sociodemographic variables in those with missing, versus those with complete data. Imputation of missing data was chosen (as opposed to a comparison analyses between the analytical sample and those excluded from analysis), as the data were missing at random (MAR) and the proportion of missing data was deemed small enough that it was feasible to estimate the missing values without introducing substantial error. As the data were not normally distributed, Wilcoxon rank tests were carried out to determine whether there was a statistically significant difference in HLQ scores at 12 months between the control and intervention groups, to provide the average treatment effect of the intervention.

However, after completing the initial analysis, it became clear that the 6 month control group data were highly skewed, and any analysis between the two groups and over time would be skewed due to the outliers in the data. As a result, the total HLQ continuous score was recoded, where “0” equaled a total continuous score <36 and “1” equaled a total continuous score ≥ 36 . 36 was chosen as it was the median value in the control group (see results section, Figure 13). A new “change” score variable was generated for each participant to determine the change in HLQ scores between 6 and 12 months by subtracting the 6 month total HLQ score from the 12 month total HLQ score. This was completed using both the continuous HLQ scores and recoded continuous scores (which were now categorized as 0 or 1 as explained above), respectively. Chi squared tests were performed using the categorical change variable to determine where there was a significant change in HLQ scores in the intervention group compared to the control group, where 0 equalled no change in score, -1 equalled a reduction in score and +1 equalled an increase in score.

Lastly, to further determine where the exact change was taking place in each domain, a change variable was generated for each participant to determine the change in HLQ scores between 6 and 12 months by subtracting the 6 month continuous HLQ score from the 12 month continuous HLQ score for each of the respective 44 HLQ questions. T-tests (or Wilcoxon rank sum tests if data were not normally distributed) were performed to determine whether there was a statistically significant difference in each of the individual HLQ question change variable scores between the two groups. 95% confidence intervals were calculated, with a p-value <0.05 assumed for statistical significance.

5.4. Results

5.4.1. Participant characteristics:

At baseline (6 month follow-up), there were 67 participants included in the intervention group and 65 participants included in the control group (N=132). Figure 18 shows the number of participants in each group and their respective reasons for withdrawal and re-entering the study. In the intervention group, eight participants were withdrawn from the study, however two of these participants re-entered at 12 months due to relocating back to Soweto, resulting in 61 participants completing the 12 month exit assessment. Four participants withdrew from the control group and no participants re-entered the study, resulting in 61 control group participants at 12 months.

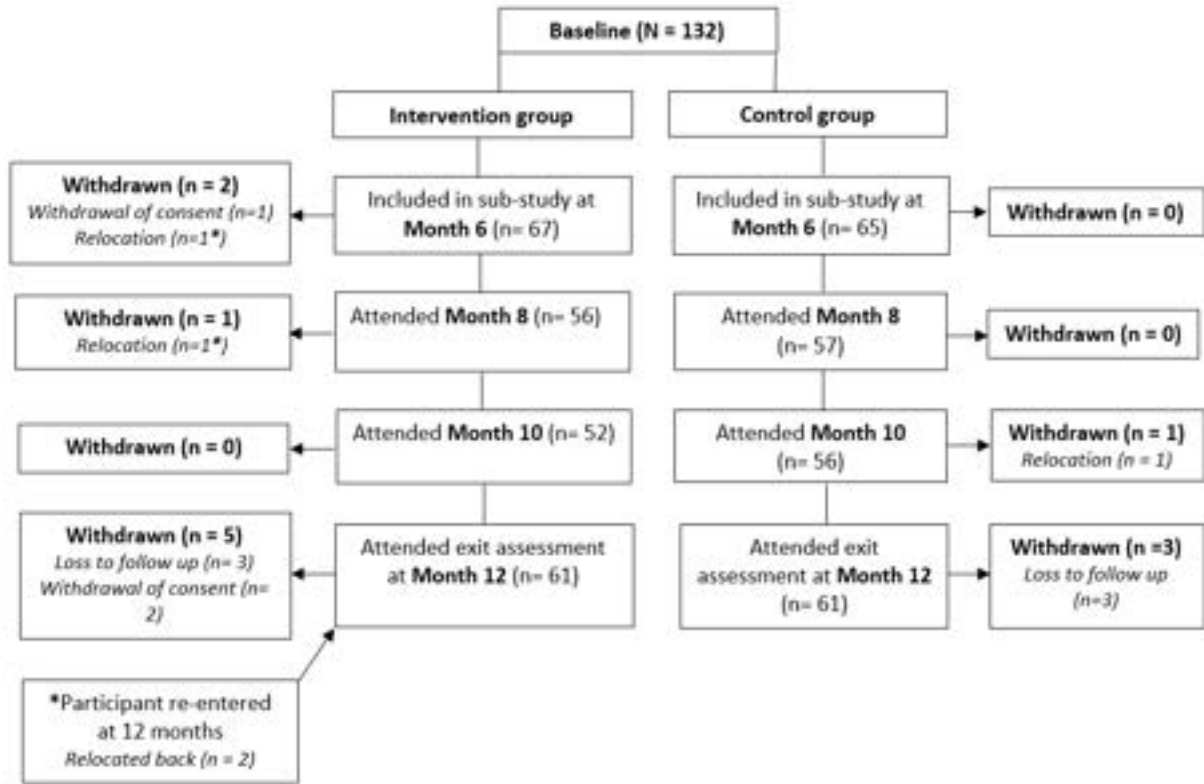


Figure 18: Number of participants enrolled at baseline (6 months), followed up, withdrawn and re-entered at each time point.

Table 3 shows the sociodemographics for each group. The average maternal age for the whole sample was 29.2 years. Both groups had a median of 2 children, and there were more males than female infants in the overall group.

Table 3: Sociodemographics of total number of participants (n=132), stratified by intervention (n=67) and control group (n=65)

	Whole sample (n=132)	Intervention group (n=67)	Control group (n=65)
Maternal age , mean (SD)	29.2 (6.0)	28.6 (5.7)	29.7 (6.2)
SES , mean (SD)	8.1 (2.1)	8.2 (2.1)	8 (2.2)
Density , median (IQR)	2.3 (0.75; 6.0)	2.3 (1.0; 6.0)	2.2 (1.0; 5.0)
No. of children in home , median (IQR)	2 (1.0; 5.0)	2 (1.0; 5.0)	2 (1.0; 5.0)
Infant sex , n (%)			
Female	52 (39.4)	25 (48.1)	27 (51.9)
Male	80 (60.6)	42 (52.5)	38 (47.5)
Education , n (%)			
Not completed High School	47 (35.6)	24 (51.1)	23 (48.9)
Completed High School	62 (47.0)	31 (50.0)	31 (50.0)
Completed Postgraduate	23 (17.4)	12 (52.2)	11 (47.8)
Employment , n (%)			
Never been employed	42 (31.8)	21 (50.0)	21 (50.0)
Currently employed	57 (43.2)	28 (49.1)	29 (50.1)
Looking for employment	33 (25.0)	18 (54.5)	15 (45.5)
Relationship status , n (%)			
Single	84 (63.6)	39 (46.4)	45 (53.6)
In a relationship	48 (36.4)	28 (58.3)	20 (41.7)

5.4.2. Health Literacy

The median, IQR and Wilcoxon sum rank test p-values for the 6 month and 12 month total HLQ continuous scores are reported in Table 4. There was no significant difference between the intervention and control group HLQ scores at 12 months, yet there was a significant difference between the two groups at baseline (6 months), with those in the control group having higher HLQ scores than those in the intervention group. The scores at baseline (maximum score is 40) were relatively high, showing a limited potential for change over time.

Table 4: Median, IQR and Wilcoxon sum rank test for 6- and 12 month total HLQ continuous scores)

HLQ	Intervention (n=67)		Control (n=65)		p-value
	Median	IQR	Median	IQR	
6 months total HLQ	35.55	(31.0; 36.0)	36	(36.0; 36.0)	0.002*
12 months total HLQ	36.34	(35.45; 39.35)	37.08	(35.5; 39.3)	0.45

Figure 19 and figure 20 show the distribution of data between the two groups at the two respective time point). The 6 month control group score shows an abnormal and skewed distribution, with 10 participants having the lowest possible scores (21) and the majority of the rest of group scoring extremely high (36) (Figure 19).

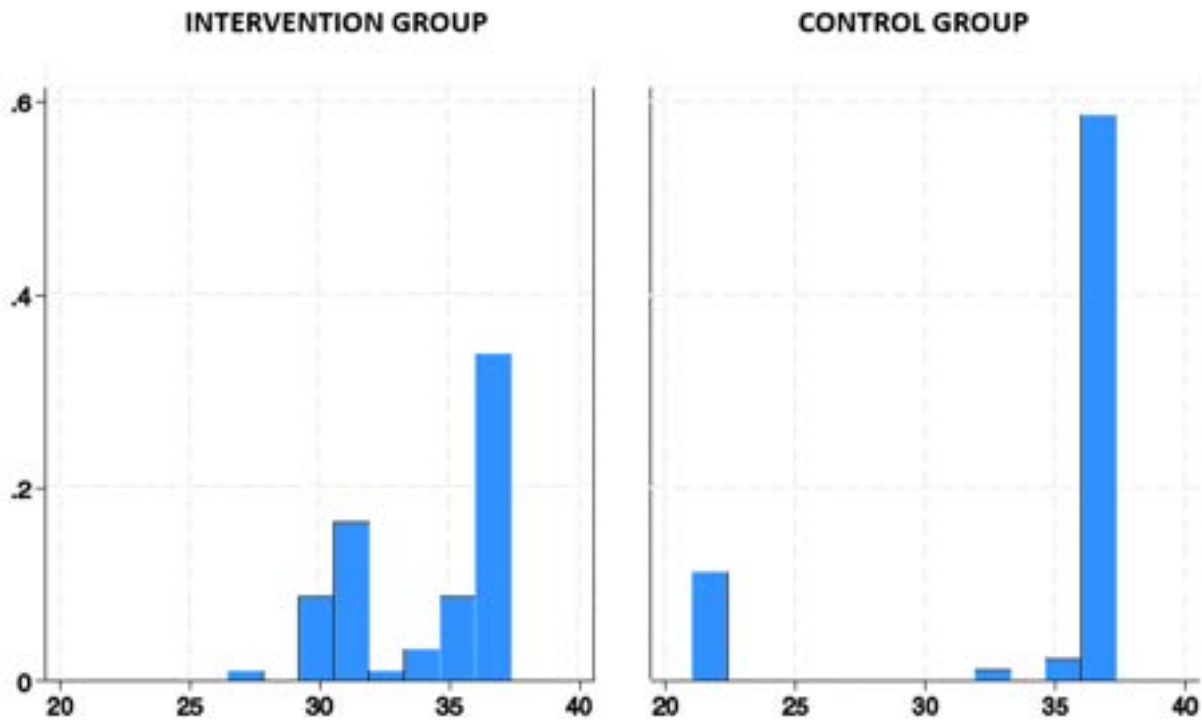


Figure 19: Histogram showing distribution of HLQ scores at 6 months (maximum score = 40; minimum score = 21)

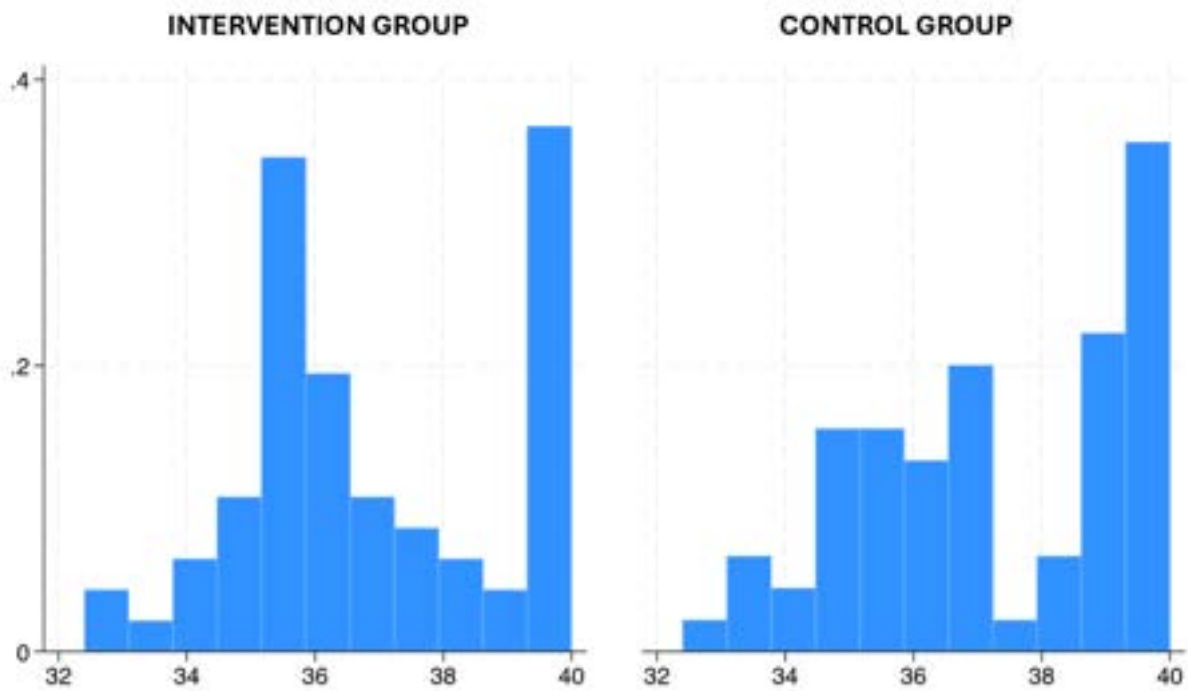


Figure 20: Histogram showing distribution of HLQ scores at 12 months (maximum score = 40; minimum score = 21)

Table 5: Linear regression for 12 month HLQ score regressed on group membership

HLQ12 months	Coefficient	Standard Error	t-value	p-value	[95%Confidence	Interval]
Intervention group	-0.38	0.36	-1.05	0.3	-1.09	0.33
Control group	0.00	(base)				
Constant	37.26	0.26	145.18	0.00	36.75	37.77
Number of observations	132					
F-test	1.11					
R-squared	0.01					
Root MSE	2.07					
Probability >F	0.29					
Adj R-squared	0.00					

Being in the control group, was associated with a higher 12 month HLQ score, compared to the intervention group, however this association was not significant ($p=0.295$) (Table 5). Figure 21 shows the change in HLQ scores from 6 to 12 months, after recoding the HLQ scores to account for the skewed 6-month HLQ score data distribution. Those participants who scored “0” ($n=42$ in intervention group; $n=45$ in control group) showed no change in HLQ scores. 14 (21.5%) control group participants and 9 (13.4%) intervention group participants showed a negative change, respectively. 16 (23.9%) intervention group participants and 6 (9.2%) control group participants showed a positive change in HLQ scores from 6 to 12 months. The chi square test shows distributions within each category of change between the two groups, and there was no significant difference in distributions between the two groups ($p=0.06$).

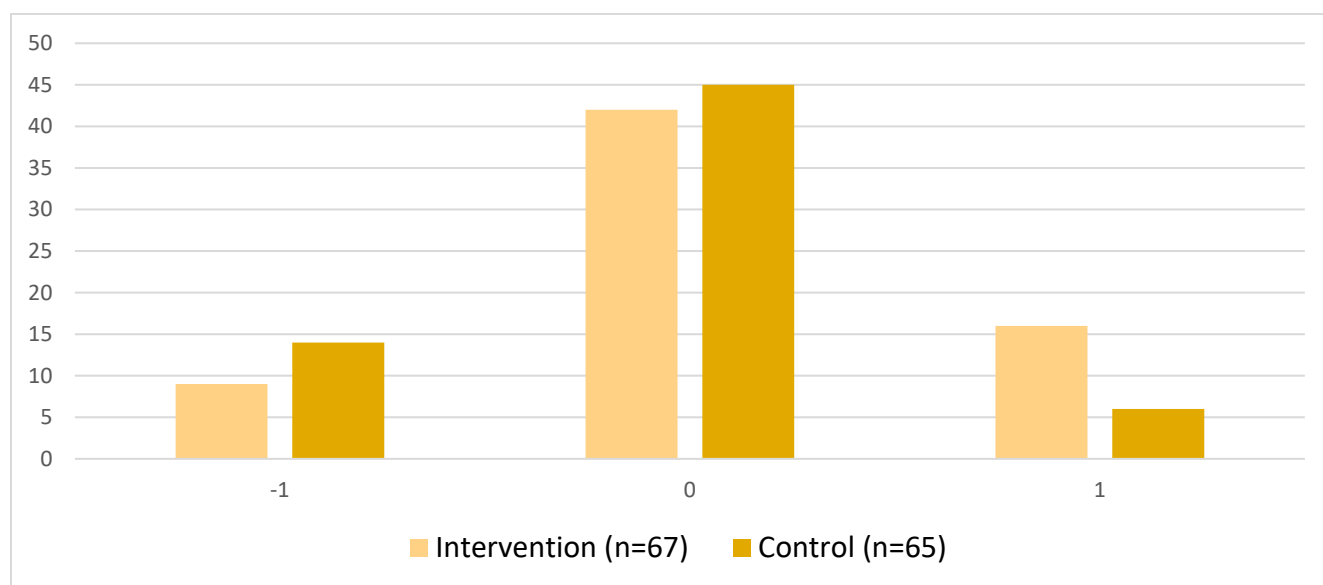


Figure 21: Change in HLQ scores from 6-12 months after categorical recoding ($p=0.06$) using chi square test

Table 6 shows the non-linear relationship between being in the intervention group and having a positive change in score. After recoding the HLQ continuous scores according to the categorical cutoff, it was found that being in the intervention group was associated with a significant 1.44 point increase in HLQ change scores (coded as (-1 to 1) from 6 to 12 months ($p=0.01$) (Table 6).

Table 6: Logistic regression showing change in HLQ from 6 to 12 months regressed on group membership

HLQ change (6-12months)	Coefficient	Standard Error	z score	p-value	[95%Confiendce	Interval]
Intervention group	1.44	0.43	3.33	0.01	0.59	2.30
Control group	0.00	(base)				
/cut1	-0.87	0.28			-1.41	-0.32
/cut2	2.83	0.42			2.01	3.65

Out of the 44 questions in the HLQ questionnaire, there were 5 question items which showed a significantly higher and positive change over time (6 to 12 months) in the intervention group compared to the control group (see Table 7). These fell into 3 categories, namely: 1) Actively managing my (child's) health, 2) Social support for health and, 3) Appraisal of health information.

Table 7: Wilcoxon sum rank test scores showing the 5 HLQ variables which had a significantly higher and positive change over time (6 to 12 months) in the intervention group compared to the control group

Scale Name	Item	p-value
Actively managing my health (AMH)	Despite other things in my life, I make time (for my child) to be healthy	0.04*
	I set my own goals about (my child's) health and fitness	0.01*
Social support for health (SS)	I can get access to several people who understand and support me	0.05*
	When (my child) feels ill, the people around me really understand what I am going through	0.01*
Appraisal of health information	I ask healthcare providers about the quality of health information I find	0.01*

5.5. Discussion

This study aimed to determine whether 12 months of a co-created intervention resulted in higher health literacy scores in the intervention group compared to the control group. Furthermore, it aimed to determine whether there was a greater change in health literacy scores from 6 to 12 months in the intervention group compared to the control group. While there was evidence of a meaningful increase in health literacy scores from 6 to 12 months in the intervention group compared to the control group, there was not enough evidence to suggest that the intervention had a significant effect on those who received it, compared to those who did not. However, after adjusting for the skewed 6 month data, being in the intervention group was associated with a significant increase in HLQ scores from 6 to 12 months, with fewer participants in the intervention group showing a negative change and more participants in the intervention group showing a positive change over time, compared to the control group. As there is a gap in literature researching maternal health literacy interventions in low-income settings, the results of this study are largely compared with studies in higher income settings or different health outcomes (124). While a systematic review of eHealth interventions to improve health literacy found positive changes in health literacy post intervention, all studies included in the review were from high-income countries using computer-based applications, with no implementation difficulties reported (29). Similarly, a scoping review looking at global health literacy interventions for pregnant and postpartum women found that most of the impactful interventions used a combination of technology and in person support (e.g. text messages combined with live health coaching), however, these were conducted in higher resource settings (124). In low-income countries, it is imperative to consider potential difficulties with implementation, which is further supported by a study which aimed to increase antenatal health knowledge by disseminating text messages to pregnant women in South Africa (125). While participants found the text messages acceptable, the study found no statistical difference in knowledge at exit, as well as substantial loss to follow-up (57%) which could have impacted the dosage of information received (125).

When exploring which questions showed the most significant change between the two groups, it was interesting to find that these questions fell under the “Actively managing my (child’s) health”, “Social

support for health”, and “Appraisal of health information”. While it is difficult to determine which part of the intervention impacted on this change, there are a few factors which could have had an influence. Regarding actively managing their child’s health, it is important to consider the qualitative findings discussed in chapter 4, around health literacy. Several participants reported that the content increased their knowledge and helped to develop self-efficacy as well as a sense of independence when they had limited support, which could have acted as an enabler in being able to manage their child’s health. While not discussed in this thesis, findings discussed elsewhere found that mothers in this sample felt socially isolated, without enough social support (126). Conversely, many of the mothers in the 12 month FGDs discussed how they had built up a support system just by being part of this study, which could account for the change in social support over time. One of the videos provided as part of the health literacy content on the app was called, “How to find reliable information online”, which focused on knowing which sources to trust and testing the validity of information found on the internet. While there were known difficulties with some participants accessing the app, the change in ability to appraise health information shows some evidence of the impact on parts of the intervention on health literacy.

Limitations

There are several limitations identified that need to be considered when discussing the results as possible reasons for no effect among the two participant groups, and to learn from when conducting similar research in the future. These can be grouped into the following themes, 1) using the HLQ as the outcome measure, 2) study methodology (design and data collection), and 3) the intervention.

The HLQ as an outcome measure

The HLQ was used in this study as it was recommended by the WHO for use in LMICs and has been found to have high reliability and validity in community settings (2,103) (127). One of the strengths of the HLQ is the breadth of questions asked that cover many of the components that make up health literacy in an individual. However, when the HLQ authors measured health literacy in individuals accessing community services in Australia, they found significantly lower health literacy scores in participants who did not

speak English at home and were born overseas (compared to English speaking Australian born individuals) (128). Other studies found similar results, but these were also from high-income countries. The HLQ scales have been found to have a minor bias in scales 7 to 9, which in practice can result in an over-estimate of health literacy in individuals with second language English speakers and those with lower levels of education (128). A scoping review of 20 articles measuring health literacy assessment tools in LMICs, found that many of the current health literacy measurement tools rely too much on measuring individuals' functional literacy levels (based on literacy) and do not measure the full extent of an individual's health literacy beyond how they understand or interpret the question being asked (129).

Practically, the HLQ is very specific in its guidelines, that the questionnaire can only be asked in English unless using one of the languages already validated (e.g. French, Spanish, etc). As the Sowetan population are predominantly second language English speakers, it was expected that administering in English would be a limitation (even when clarification was given in the participant's home language from the RAs). Our baseline health literacy scores were relatively high, and this could be linked to the over-estimate mentioned above, or our study hypothesis (based on supporting literature), that assumed that the participants had low health literacy around play and development, could have been incorrect. Furthermore, the HLQ may not have been accurately measuring true levels of health literacy due to the context - when looking at the individual questions, some answers are largely influenced by the South African context, where many individuals using the public health system do not have agency or choice when it comes to navigating the health system and engaging with healthcare providers, and there is very rarely continuity of care. The findings from chapter 3 of this thesis highlight how mothers do not trust their healthcare providers, some feeling that they are not respected by healthcare providers and often leave healthcare visits without receiving essential information (101). As a result, it seems that in this context, the HLQ does not accurately measure one's level of health literacy, but rather their experience of being a part of a larger social and health context, of which they are unlikely to be able to change.

Study methodology (study design and fidelity)

When analysing the data, one of the main discrepancies found was the skewed 6 month control group data. This was seen in the HLQ data as well as the secondary outcome data (discussed in chapter 6). As this study was part of a larger RCT, separate RAs completed the 6 month baseline questionnaires for the intervention and control groups, and two more blinded RAs completed the 12 month questionnaires for both groups. This helped to reduce the risk of interviewer and respondent bias, which could impact the reliability of the primary outcome data. Reasons for the skewed 6 month data are unknown, however, one of the main limitations was linked to having an RA administer my questionnaires on my behalf, without me being consistently present to conduct quality assurance check-ins and provide informal training as and when necessary. As I did not live in Johannesburg for the duration of the study, I was able to physically attend trainings, FGDs and other important data collection timepoints, however I could not provide continuous physical support. Due to the nature of the blinded study design, while I was able to perform random quality control checks on RedCAP, I could not test if there were significant trends or differences between the two groups. Lastly, a significant limitation could be attributed to the number of outcome measures administered as part of the larger PLAY study. As my study was part of a complex trial with multiple secondary outcomes, there were many questionnaires (some very lengthy) to complete at each assessment. This, paired with mothers being accompanied by their infants, made the sessions very long and tiring for both the RA and participant, which could have had an impact on their respective ability to administer and answer the questionnaires reliably. As part of the PLAY Study process evaluation, staff discussed that they would find ways to shorten the questionnaires to move through them as quickly as possible. Lastly, it is unknown whether a larger sample size would have had an impact on the effect size, however the number of participants at baseline was dependent on the number of participants attending the 6 month visit, and this could not be changed.

Dosage and engagement with the Smart Play health literacy intervention

The focus of the health literacy intervention in the SmartPlay Study was from 6 to 12 months. As studies measuring change in health literacy after implementing Mhealth interventions have found significant

changes in health literacy from baseline to 4 month and 6 months respectively, one can deduce that 6 months is a sufficient amount of time to see the intervention effect when measuring health literacy (130–132). Although the health literacy content was the main focus of the SmartPlay study, other content around breastfeeding, mental health, reading and nurturing care was also included sporadically throughout these months as part of the PLAY Study. This highlights one of the limitations of embedding a study in a complex intervention, as the SmartPlay health literacy intervention may have been diluted (and therefore the dosage was insufficient), given the health literacy content was not delivered on its own. Secondly, as discussed in Chapter 4, there were significant issues with accessing the app, which could have contributed to participants not engaging with the health literacy content. Unfortunately, the health literacy content included a few videos which participants were unable to download due to lack of data for accessing video content.

Learnings for future research

There are a few lessons learned that would guide my study design if I were to plan and complete this study again. Firstly, I would have tried to broaden my search to find a different questionnaire to measure health literacy in this context, specifically one which is simpler to understand and shorter to administer. For example, other health literacy questionnaires, such as the HELT-LL, which have been designed and validated in South Africa with low literature populations in mind, have been found to be helpful in determining the true levels of health literacy in adults (133). However, the HELT-LL does not have the same amount of depth as the HLQ, which provide a broader understanding of an individual's health literacy. Furthermore, it would be preferable to use a questionnaire which specifically measures maternal health literacy and the caregiver's ability to manage their child's health in the postpartum period and beyond. As this seems to be a gap in the literature, a next step could be to develop and validate a maternal health literacy questionnaire, specifically in populations with low health literacy and/or groups that do not speak English as their first language.

If budget and time resources had allowed, an important step in understanding the population better would have been to pilot the HLQ in a small sample to determine whether there was any variability in

the data and whether it was valid in this context. With regards to data collection, I would have provided more training to the RAs as needed and attempted to observe data collection at random times to ensure consistency across questionnaires and RAs. I would have also completed more quality control on Redcap to keep on top of the data as it was being entered. Regarding the intervention, it would be interesting to test the health literacy intervention in isolation, to determine whether the health literacy intervention did have an effect, when delivered as a primary intervention.

5.6. Conclusion

This study found that the health literacy intervention did not have a significant effect on those who received the intervention, compared to those who did not, however there was a significant increase in health literacy scores in the intervention group over time. This change was driven by mothers' ability to actively manage their child's health, their social support for health, and their ability to identify good information and reliable sources of information. Developing and using a health literacy questionnaire that is more appropriate for postpartum mothers in low resource settings, as well as increasing the dosage of the intervention, may result in a greater effect in future studies.

Chapter 6: Paper III

Title: Movement behaviours and affordances in the home: The effect of a 6 month app-based intervention to improve maternal health literacy in providing opportunities for active play in Johannesburg, South Africa.

6.1. Abstract

Background: In the first months of life, allowing infants access to unstructured, unrestrictive play in their home environment is imperative for development and for encouraging increased physical activity. However, many South African mothers in low resource settings have reported that there are often barriers to providing opportunities for play, resulting in reduced opportunities for active, exploratory play, in the South African child population as a whole. However, caregivers can be equipped to facilitate and encourage active play and development using low-cost activities which can be adapted to indoor environments. This study aimed to determine whether there was a difference in infant physical activity, sedentary behaviour, affordances in the home and maternal beliefs around physical activity between the intervention and control group at 12 months, after receiving a 6 month intervention.

Methods: This study was nested in a Randomised Controlled Trial, the Play Love And You (PLAY) study. Mothers assigned to the PLAY Study intervention group at 6 months postpartum (n=68) received telephonic or in-person check-in and assessments every 2 months, and Health literacy intervention content and resources delivered via a mobile app, every week. Control group participants (n=65) received the standard of care. Affordances in the home, maternal beliefs, physical activity and sedentary behaviour as well as new score, “Opportunities for active play”, were measured at 6 and 12 months in both the intervention and control group.

Results: The change in Maternal Beliefs score from 6 to 12 months was significant ($p=0.00$), with the intervention group’s scores increasing on average, 35.44 points compared to an average of 25.7 points in the control group. While the intervention group, on average, engaged in more time doing physical

activity and less time being sedentary/ restrained or watching tv (or both), than the control group, this difference was not significant. There was no significant difference between the intervention and control group, except for a higher Physical Space score ($p=0.004$) (particularly outdoor space ($p=0.03$)) and change in AHEMDS between 6 and 12 months, in the control group compared to the intervention group ($p=0.00$). When looking at the change in opportunities for play from 6 to 12 months, there was a significant ($p=0.001$) difference between the intervention and control group, with 27 participants (40%) in the intervention group increasing between 1 and 3 points (compared to 8% in the control group) and 43 participants (42%) of the control group decreasing between 1 and 4 score units (compared to 31% in the intervention group).

Discussion: At 12 months, the intervention group showed a significantly higher maternal beliefs score and time spent being physically active, compared to the control group. However, those in the control group were found to have greater affordances in the home environment for motor development over time, compared to the intervention group. Overall, there was a significant increase in the opportunities for active play score from 6 to 12 months in the intervention group. Despite there being fewer affordances in the home for motor development in the intervention group, particularly with regards to physical outdoor space, there was still an increase in opportunities for active play over time.

Conclusion: Mother and infant dyads who received the intervention were found to have higher maternal beliefs and increased time spent being physically active. Many of the activities and information included as part of the intervention content focused on providing opportunities for active play within small indoor living spaces and with limited resources. Interventions that provide activities that can be implemented in small spaces with resources available at home, can be effective in promoting active play for infants in low resources settings.

6.2. Introduction

Due to the importance and vulnerability of the first 1000 days of an infant's life, it is necessary to start developing a range of healthy behaviours from birth (118). The numerous negative side effects of an inactive, sedentary lifestyle can take years to present, however there is evidence for an association

between increased physical activity in infants (1-12 months) and improved motor and cognitive development, as well as adiposity in infancy and later life (119,120). (24)(121)(134)(27)(27)

Unstructured play (play which is led by the child without an expected or imposed outcome) is considered imperative for increasing levels of PA in children (26). In the first months of life, allowing infants access to unstructured, unrestrictive play in their home environment is imperative for development and for encouraging increased PA (20). The benefits of outdoor play are widely documented, with the majority of the evidence demonstrating that children are more active when outdoors and that they engage in less sedentary time when outdoors, compared to being indoors (135). Unstructured outdoor play is particularly important for children's development as it provides opportunities for the development of gross motor skills (e.g. jumping, climbing and kicking and throwing balls, etc.) and higher intensity PA required to meet daily movement guidelines. (26,27). However, many South African mothers in low resource settings have reported that there are often barriers to providing opportunities for play (particularly outdoors), due to a lack of financial resources and concerns around environmental factors such as lack of safety, fear of abduction and other structural barriers, which prevent them from encouraging children to play outside (21). Play inside the home can also be limited, when houses are too small and/ or overcrowded or when there is no limit to screen time and other sedentary behaviours. This has led to a reduced opportunity for active, exploratory play, in the South African child population as a whole (22). However, despite these barriers indoors and outdoors, with enough guidance and information (health literacy), caregivers can be equipped to facilitate and encourage active play and development using low-cost activities which can be adapted to indoor environments.

The SmartPlay Study intervention content was designed to increase health literacy specifically around play and development. Therefore, the intervention content included a variety of tools and resources aimed at facilitating active play and development through age and context specific activities. The overall aim for this chapter was to determine whether the intervention aimed at improving health literacy (in Chapter 5), increased infants' opportunity for active play at 12 months in the intervention group compared to the control group, and whether there was a change in opportunity for active play from 6 to 12 months.

The specific objectives were:

1. To determine whether there was a difference in maternal beliefs around PA between the intervention and control group at 12 months, and whether there was a change in beliefs from 6 to 12 months.
2. To determine whether there was a difference in time engaging in PA, time spent being sedentary/ restrained and time spent watching tv in the intervention and control group at 12 months, and whether there was a change in these activities from 6 to 12 months.
3. To determine whether there was a difference in affordances in the home environment for promoting motor development in the intervention and control group at 12 months, and whether there was a change in these affordances from 6 to 12 months.
4. To combine each participant's maternal belief score, time spent being physically active, time spent being sedentary/ restrained and amount of physical space available at home to create a new score named "Opportunities for active play".
5. To determine whether there was a difference in opportunities for active play in the intervention and control group at 12 months, and whether there was a change in these opportunities from 6 to 12 months.

6.3. Methods

6.3.1. Study setting and participants

This study (SmartPlay Study) was nested in the Play Love and You (PLAY) study, a 12 month intervention designed to promote infant development through encouraging maternal self-efficacy using behavioural feedback and supportive interventions (74). This study fell under one of the PLAY study's secondary objectives, which aimed to test the efficacy, feasibility and acceptability of providing intervention content, and increasing opportunities for early learning through play to promote health literacy in mothers (in a low-resource setting) (74). Mothers and recently delivered infants (3-10 days old) were recruited from two primary care clinic maternity wards in Soweto, (a low resource peri-urban informal

settlement), Johannesburg and enrolled into the PLAY study. Further details of the enrolment procedures and inclusion criteria are described elsewhere (74).

Ethical approval was obtained from the University of the Witwatersrand Human Research Ethics Committee (Sub-study M220886 under main study M210846 and M220217). Written, formal informed consent was obtained from all participants. All participants were reimbursed for travel costs and provided with refreshments at hospital-based follow-ups.

6.3.2. Study Design

The PLAY study RCT consisted of a standard of care package (control group), and an intervention package – including standard of care as well as the intervention content (intervention group). Mothers assigned to the control group received the standard Road to Health booklet as well as the Side-by-Side services provided as routine postpartum standard of care. The intervention group received the standard of care package, as well as the intervention (74). The intervention for this study focused on improving maternal health literacy, thereby encouraging age-appropriate active play and development in infants from 6 to 12 months, using an interactive App with content and resources (weekly), as well as in-person and telephonic follow-ups (every two months). Content included infographics and videos about age-appropriate games to play, monthly milestones, activities to promote sensory and motor development and how to make recycled low-cost toys, to encourage active play and reduce sedentary time (based on the 24 hour movement guidelines) (27). The details of the content and telephonic follow-ups have been described in Chapter 5. Details of how the content was developed with a CAG as well as the acceptability and feasibility of the 6–12 month intervention are described in chapter 3 and 4, respectively.

6.3.3. Data collection and management

Participant sociodemographic data were collected shortly after enrollment into the PLAY Study. The baseline sample for the SmartPlay study was calculated as the number of participants who attended the 6 month follow-up time point. The following baseline variables were included in the PLAY Study baseline

data collection: Maternal age (years), Socioeconomic Status Score, Home Density (average number of people in home), Number of children in home, Infant sex (male/ female), Maternal Education (Not completed high school/ completed high school/ completed postgraduate studies), Employment (never employed, currently employed, looking for employment) and Relationship Status (Single/ In a relationship). All quantitative outcome data were collected in person by one of the PLAY Study team's RAs at the 6- (baseline) and 12 month's (study exit) follow-up timepoints, in the intervention and control groups, respectively. All sociodemographic data were collected at enrolment into the PLAY study. Questionnaires were completed in English, but more detailed explanation was provided in the participant's first language if further clarity was needed.

6.3.4. Outcome measures

Four questionnaires were used to measure the outcomes:

Affordances in the Home Environment for Motor Development–Infant Scale (AHEMDS-IS)

The scale is divided into four sub-scales: 1) Physical Space, 2) Variety of Stimulation, 3) Fine-Motor Toys, 4) Gross-motor toys. Total sub-scale scores can be used as continuous scores and are classified into 4 descriptive categories: Less than adequate, moderately adequate, adequate and excellent. These are interpreted as follows:

1. LESS THAN ADEQUATE: Environment opportunities (affordances) for motor development are missing or need improvement.
2. MODERATELY ADEQUATE: Environment provides some opportunities (affordances) for motor development but could be improved.
3. ADEQUATE: Environment shows sufficient quantity and quality of opportunities (affordances).
4. EXCELLENT: Provides ample amount and variety of opportunities (affordances).

This questionnaire provides descriptive data around the participants' access to physical space, variety of stimulation and age-appropriate toys. As we were only made aware of the newly validated questionnaire

after starting data collection, we used the original questionnaire (136) but adapted the score to fit the descriptive categories listed above (104). The four sub-scale totals were added together to form a total continuous score. The scoring categories and maximum/ minimum scores are highlighted in Table 8.

Table 8: Adapted AHEMDS categories and respective 12 month score ranges

Age (mo)	Descriptive categories	Physical Space	Variety of Stimulation	Fine-Motor Toys	Gross-Motor Toys	Total Score
12	Less than adequate	0-2	0-1	0-3	0-2	0-8
	Moderately adequate	3-4	2	4-7	3-5	12-18
	Adequate	5-7	3-4	8-11	6-9	22-31
	Excellent	8-10	5	12-14	10-12	35-41

Maternal Beliefs Questionnaire

This questionnaire was adapted from the Melbourne INFANT programme (18) to be more language and context specific in Soweto, mainly by rewording sections that were not well understood in a South African context (i.e.: “...a baby that is very active” was changed to “...a baby that moves a lot”). (19). The questionnaire explores the mother’s beliefs, attitudes and intentions around their infant’s PA using a 24-item questionnaire with a 4-point Likert-type scale (0 = strongly disagree to 3 = strongly agree) (106). There are 6 factor variables including PA knowledge, views on children’s PA, PA optimism, self-efficacy for promoting PA, future expectations around infant’s PA and TV viewing, and floor play concerns. Each factor’s score was generated by calculating the mean score within each factor, where a higher score indicated higher agreement with the factor variable (106). The 6-factor variable totals were added together to form a total continuous score. The categories and maximum scores are listed in Table 9.

Table 9: Maternal Beliefs Questionnaire categories and respective score ranges

Maternal Beliefs	Max Score
Physical activity knowledge	30
Views on physical activity	12
Physical activity optimism	9
Future expectations	6
Floor play concerns	6
Self-efficacy for physical activity	9
Total	72

Assessing Children's Active and Sedentary Pursuits

This questionnaire was also adapted from the Melbourne INFANT programme (18) to be more language and context specific in Soweto (19). The questionnaire has two parts; 1) Mothers are asked to report the amount of time (minutes) their infant spent in various activities, on an average day and, 2) asked to report, using a 4 point Likert-type scale, whether their child had access to, or was likely to have access to age-specific toys and equipment (such as balls, push toys, bicycles, etc.) in the home or at nearby facilities within the next year (106).

For part 1, all activities were presented as hours and minutes per day but were recoded as total minutes during data cleaning. Activities were pooled together into sub-groups to report on time spent sedentary/restrained (e.g. in highchair, cot, on mother's back, etc), time spent watching TV, a combined score of time spent being sedentary/restrained and watching TV, or time spent free to engage in active play. Continuous data were truncated based on what was considered feasible when adding up the time sleeping, being active, and sedentary in 24 hours. As the 24-hour movement guidelines suggest that 12 month-old children should have a minimum of 11 hours of sleep, this allows for a maximum of 13 hours (780 minutes) to be either physically active or sedentary/restrained (27). The 12 month PA and sedentary/restrained sub-groups were therefore truncated to a maximum range of 780 minutes. Both the raw and truncated scores were reported.

For part 2, each response was coded as “3” if mothers responded that they had the equipment already, “2” if they were very likely to get it within the next year, “1” if mothers responded they would possibly get the equipment in the next year, and “0” if mothers responded that they were unlikely to get the equipment within the next year. A sum of the responses for each item was created, with a higher score indicating better access to equipment or intention to provide access, and a lower score indicating no access and/or less intention to provide access (106).

Opportunities for Active Play Score

A new score, “Opportunities for active play”, was created for each participant. The 12 month Maternal Belief Score was recoded “1” if the participant scored above the total combined group mean, or “0” if they score below the mean. The Assessing Sedentary and Active Pursuits subgroups were categorized based on the truncated scores detailed above. As the 24-hour movement guidelines suggest that children, 12 months and older, should be engaging in a minimum of 3 hours (180 minutes) of active play per day, participants in the PA sub-group were recoded as “1” for scores equal to or higher than 180 minutes and “0” for scores less than 180 minutes. As 12 month-olds should not watch any TV in 24 hours, participants were coded as “1” for 0 minutes of watching TV and “0” if they recorded any number of minutes watching TV. As the movement guidelines suggest that infants and toddlers should not be restrained for more than 1 hour at a time, this measure was used to measure sedentary time (27). All participants who were restrained in one or more activities for more than an hour per day were given a score of “0” and all participants who were not restrained for longer than an hour, and therefore free to move, were given a score of “1”.

Lastly those with an “adequate” amount of the AHEMDS physical space sub-scale (calculated as a score higher than 5, the minimum score for “adequate” physical space – see Table 1) were recoded as “1” and those scoring lower than 5 were recoded as “0”. All categorical scores were added together, creating a maximum score value of 5. A lower total score indicated fewer opportunities for active play and a higher score indicated more opportunities for active play.

6.3.5. Statistical analysis

STATA (version 18) was used to analyse all quantitative data. The baseline sample was the same sample used to measure the primary outcome in Chapter 5. Age, SES, house density, number of children in the home, infant sex, maternal education, employment status and relationship status were included to describe the characteristics of the sample. Sociodemographic data were summarized and reported using N (%) for categorical data and means (SD) for continuous data. Missing data were imputed using a multiple imputation method. Student t-tests (for normally distributed data), Wilcoxon rank tests (for data not normally distributed) and chi-squared (for categorical data) were carried out to determine whether there was a statistically significant difference in each respective outcome measure between the control and intervention groups, to provide the average treatment effect of the intervention.

Linear regression analyses were performed with the respective outcome measure scores regressed on group membership to determine the individual treatment effect. Logistic regressions were performed with all categorical outcome scores. As the baseline data was different between the two groups at 6 months, each regression was adjusted to include the respective 6 month score as a confounder to provide a more accurate estimate of the relationship between the group membership and the respective outcome score, while controlling for the influence of the baseline data. A new “change” score variable was generated for each participant to determine the change in each of the secondary outcome measure scores between 6 and 12 months by subtracting the respective 6 month total scores from the 12 month total scores. Chi squared tests were performed using the categorical change variable to determine where there was a significant change in the respective outcome measure scores in the intervention group compared to the control group, where 0 equalled no change in score, -1 equalled a reduction in score and +1 equalled an increase in score. Student t tests or Wilcoxon rank tests were used to determine whether there was a significant change between the two groups over time, using the change variable scores. 95% confidence intervals were calculated, with a p-value <0.05 assumed for statistical significance.

6.3. Results

6.3.1. Participant characteristics

The baseline characteristics for this sample have been described in Chapter 5 but are reported again in Table 10.

Table 10: Social demographics of total number of participants (n=132), stratified by intervention (n=67) and control group (n=65)

	Whole sample (n=132)	Intervention group (n=67)	Control group (n=65)
Maternal age , mean (SD)	29.2 (6.0)	28.6 (5.7)	29.7 (6.2)
SES , mean (SD)	8.1 (2.1)	8.2 (2.1)	8 (2.2)
Density , median (IQR)	2.3 (0.75; 6.0)	2.3 (1.0; 6.0)	2.2 (1.0; 5.0)
No. of children in home , median (IQR)	2 (1.0; 5.0)	2 (1.0; 5.0)	2 (1.0; 5.0)
Infant sex , n (%)			
Female	52 (39.4)	25 (48.1)	27 (51.9)
Male	80 (60.6)	42 (52.5)	38 (47.5)
Education , n (%)			
Not completed High School	47 (35.6)	24 (51.1)	23 (48.9)
Completed High School	62 (47.0)	31 (50.0)	31 (50.0)
Completed Postgraduate	23 (17.4)	12 (52.2)	11 (47.8)
Employment , n (%)			
Never been employed	42 (31.8)	21 (50.0)	21 (50.0)
Currently employed	57 (43.2)	28 (49.1)	29 (50.1)
Looking for employment	33 (25.0)	18 (54.5)	15 (45.5)
Relationship status , n (%)			
Single	84 (63.6)	39 (46.4)	45 (53.6)
In a relationship	48 (36.4)	28 (58.3)	20 (41.7)

6.3.2. Maternal Beliefs Questionnaire

While the average scores were slightly higher in the intervention group, they were not significantly different between the two groups at 12 months (Table 11). However, the change in Maternal Beliefs score from 6 to 12 months was significant ($p=0.00$), with the intervention group's scores increasing on average, 35.44 points compared to an average of 25.7 points in the control group (Table 11). Although not significant, the linear regression (Table 12) showed a positive effect of the intervention on the

Maternal Beliefs Score (coefficient = 0.79, 95% CI [-1.42; 2.99], p=0.48). Participants in the intervention group had an average increase of 0.79 units in the Maternal Beliefs score compared to the control group.

Table 11: Maternal Beliefs Questionnaire scores at 12 months, and total change over time from 6-12 months

Maternal Beliefs Questionnaire Scores (n= 132)	Intervention (n=67)		Control (n=65)		
	Median/ Mean	IQR/ SD	Median/ Mean	IQR/ SD	P-value
Physical Activity knowledge (median; IQR)	28	(20; 30)	28	(20; 30)	0.81
Views on Physical Activity (mean; SD)	8.53	1.94	8.33	2.21	0.58
Physical Activity optimism (median; IQR)	9	(6;9)	9	(6;9)	0.01*
Future expectations (mean; SD)	2.69	1.54	2.48	1.81	0.48
Floor play concerns (mean; SD)	3.05	1.91	2.59	1.97	0.18
Self-efficacy for physical activity (median; IQR)	9	(6;9)	9	(6;9)	0.98
Total Maternal Beliefs score (mean; SD)	57.41	5.46	56.66	6.39	0.47
Change in Maternal Beliefs 6-12 mths (student's t-test)	35.44	8.44	25.7	6.8	0.00*
* significant					

Table 12: Maternal beliefs Questionnaire Scores at 12 months linear regression

Maternal beliefs scores 12 months	Coefficient	Standard Error	t-value	p-value	[95%Confidence	Interval]
Intervention group	0.79	1.11	0.71	0.48	-1.41	2.99
Control group	0.00	(base)				
Constant	56.70	0.79	71.97	0	55.14497	58.26
Number of obs	122					
F-test	0.5					
R-squared	0.0041					
Root MSE	6.1535					
Probability>F	0.48					
Adjusted R-squared	-0.00					

6.3.3. Assessing children's active and sedentary pursuits

Table 13 highlights that while the intervention group, on average, engaged in more time doing PA and less time being sedentary/ restrained or watching tv (or both), than the control group, this difference was not significant. However, when the PA score was truncated, the average time in the control group (501.4 minutes) was higher than the average time (482.14) in the intervention group (although not significant).

Table 13: Assessing Children's Active and Sedentary Pursuits at 12 months (continuous scores)

Assessing Children's Active & Sedentary Pursuits (n=132)	Intervention (n=67)		Control (n=65)		
	Median/mean	IQR/ SD	Median/ mean	IQR/ SD	P-Value
Physical activity (minutes)(med/ IQR)	530	(240; 1030)	520	(300; 930)	0.98
Physical activity (truncated)(mean/ SD)	482.14	139.93	501.40	130.27	0.41
Sedentary or restrained (minutes) (med/ IQR)	190	(45; 480)	210	(75; 390)	0.15
Time watching TV (minutes)(med/IQR)	15	(5;30)	30	(5;30)	0.44
Sedentary or restrained & TV combined (minutes) (med/ IQR)	210	(155; 282)	235.41	(175;315)	0.13
Pursuits for next year (med/ IQR)	22	(13; 31)	22.17	(14; 35)	0.70

When using the raw PA score, although there was a positive relationship between being in the intervention group and an increase in time spent engaging in PA, this was not shown to be significant (Table 14). After adjusting for the score at 6 months, the linear regression (Table 15) showed a positive effect of the intervention on the time spent engaging in PA, but this was not significant (coefficient = 1.04, 95% CI [-83.24; 85.33], $p=0.88$). Participants in the intervention group had an average increase of 1.04 minutes engaging in PA compared to the control group, at 12 months.

Table 14: Assessing Children’s Active and Sedentary Pursuits “Physical activity” sub-group at 12 months
linear regression

Physical Activity 12 months	Coefficient	Standard Error	t-value	p-value	[95%Confidence	Interval]
Intervention group	6.07	40.41	0.15	0.88	-73.87	86.01
Control group	0	(base)				
Constant	554.63	28.79	19.27	0	497.67	611.58
Number of observations	132					
F-test	0.02					
R-squared	0					
Root MSE	232.09					
Prob>F	0.89					
Adjusted R-squared	-0.01					

Table 15: Assessing Children’s Active and Sedentary Pursuits “Physical activity” sub-group at 12 months
linear regression adjusted for 6 month scores

Physical Activity 12 months, adjusted for 6 months	Coefficient	Standard Error	t-value	p-value	[95%Confidence	Interval]
Intervention group	1.04	42.6	0.02	0.98	-83.24	85.32
Control group	0	(base)				
Phys Activity 6 months	0.01	0.02	0.38	0.7	-0.03	0.05
Constant	548.24	33.33	16.45	0	497.67	611.58
Number of obs	132					
F-test	0.08					
R-squared	0.01					
Root MSE	232.09					
Probability>F	0.92					
Adj R-squared	-0.01					

When using the truncated PA score, although there was a negative relationship between being in the intervention group and time spent engaging in PA, this was not shown to be significant (coefficient = -19.26, 95% CI [-65.85; 27.32], $p=0.42$) (Table 16). Similarly, after adjusting for the score at 6 months, the linear regression (Table 17) showed a negative effect of the intervention on the time spent engaging in PA (coefficient = -18.07, 95% CI [-70.38; 37.25], $p=0.52$), however, this was not significant. Participants in the intervention group had an average decrease of 19.26 minutes engaging in PA compared to the control group, at 12 months.

Table 16: Assessing Children's Active and Sedentary Pursuits at 12 months linear regression (continuous truncated scores)

Physical Activity 12 truncated	Coefficient	Standard Error	t-value	p-value	[95%Confidence	Interval]
Intervention group	-19.26	23.55	-0.82	0.415	-65.85	27.32
Control group	0	(base)				
Constant	501.4	16.78	29.89	0	468.21	534.6
Number of obs	132					
F-test	0.67					
R-squared	0.01					
Root MSE	135.26					
Probability>F	0.41					
Adjusted R-squared	0					

Table 17: Assessing Children's Active and Sedentary Pursuits at 12 months linear regression, adjusted for 6 month scores (continuous truncated scores)

Physical Activity 12 truncated adjusted for 6 months	Coefficient	Standard Error	t-value	p-value	[95%Confidence	Interval]
Intervention group	-18.07	23.55	-0.82	0.415	-65.85	27.32
Control group	0	(base)				
Physical Activity 6 months	0.08	0.09	-0.08	0.94	-0.19	0.17
Constant	503.21	16.78	29.89	0	468.21	534.6
Number of obs	132					
F-test	0.34					
R-squared	0.01					
Root MSE	135.78					
Probability>F	0.72					
Adjusted R-squared	-0.01					

Table 18 shows that there was a non-significant negative relationship between being in the intervention group and time spent being restrained or being sedentary (coefficient = -17.89, 95% CI [-57.63; 21.85], $p=0.38$). When adjusting for the 6 month data (Table 19), although not significant, those in the intervention group spent on average 25 minutes less than those in the control group being restrained or sedentary (coefficient = -25.73, 95% CI [-67.32; 15.86], $p=0.22$).

Table 18: Time spent sedentary or restrained sub-group at 12 months linear regression

Sedentary or Restrained 12 months	Coefficient	Standard Error	t-value	p-value	[95%Confidence	Interval]
Intervention group	-17.89	20.09	-0.89	0.38	-57.63	21.85
Control group	0	(base)				
Constant	223.81	14.31	15.64	0.00	195.5	252.18
Number of obs	132					
F-test	0.79					
R-squared	0.01					
Root MSE	115.38					
Probability>F	0.37					
Adjusted R-squared	-0.00					

Table 19: Sedentary or restrained sub-group linear regression adjusted for 6 months

Sedentary or Restrained 12 months adjusted for 6 mths	Coefficient	Standard Error	t-value	p-value	[95%Confidence	Interval]
Intervention group	-25.73	21.02	-1.22	0.22	-67.32	15.86
Control group	0	(base)				
Sed or Rest 6 mths	0.10	0.08	1.24	0.22	-0.06	0.26
Constant	209.93	18.15	11.57	0.00	195.5	252.18
Number of obs	132					
F-test	1.17					
R-squared	0.02					
Root MSE	115.14					
Probability>F	0.31					
Adjusted R-squared	-0.00					

Although not significant, the linear regression in Table 20 showed a negative effect of the intervention on the time spent watching TV (coefficient = -9.75, 95% CI [-27.01; 7.51], $p=0.27$). Participants in the intervention group had an average decrease of 9.75 minutes watching TV compared to the control group. When adjusted for 6 month data, Table 21 highlights the decrease to 12.11 minutes (coefficient = -12.11, 95% CI [-29.66; 5.44], $p = 0.17$), although also not significant.

Table 20: Time watching TV sub-group at 12 months linear regression

Total Min watching TV 12 months	Coefficient	Standard Error	t-value	p-value	[95%Confidence	Interval]
Intervention group	-9.75	8.72	-1.12	0.27	-27.01	7.51
Control group	0	(base)				
Constant	39.14	6.22	6.30	0.00	26.84	51.43
Number of obs	132					
F-test	1.25					
R-squared	0.01					
Root MSE	50.11					
Probability>F	0.27					
Adjusted R-squared	-0.00					

Table 21: Time watching TV sub-group linear regression, adjusted for 6 months

Total Min watching TV 12 months	Coefficient	Standard Error	t-value	p-value	[95%Confidence	Interval]
Intervention group	-12.11	8.87	-1.37	0.17	-29.66	5.44
Control group	0	(base)				
Watching TV 6 mths	0.06	0.04	1.35	0.18	-0.03	0.14
Constant	37.44	6.32	5.92	0.00	24.93	49.95
Number of obs	132					
F-test	1.54					
R-squared	0.02					
Root MSE	49.95					
Probability>F	0.22					
Adjusted R-squared	-0.01					

Similarly, the linear regression in Table 22 reported a negative, non-significant effect of the intervention on the combined time spent being sedentary or restrained and watching TV (coefficient = -27.64, 95% CI [-77.83; 22.55], p=0.28). Participants in the intervention group had an average decrease of 27.64 minutes being sedentary or restrained and watching TV compared to the control group. When adjusted for the 6 month data, Table 23 shows a further decrease to 42.05 minutes (coefficient = -42.05, 95% CI [-95.08; 10.98], p=0.12), although also not significant.

Table 22: Sedentary or restrained sub-group and time watching TV sub-group combined linear regression

Combined Sedentary and TV 12 months	Coefficient	Standard Error	t-value	p-value	[95%Confidence	Interval]
Intervention group	-27.64	25.37	-1.09	0.28	-77.83	22.55
Control group	0.00	(base)				
Constant	262.95	18.07	14.55	0.00	227.2	298.71
Number of obs	132					
F-test	1.19					
R-squared	0.01					
Root MSE	145.71					
Probability>F	0.28					
Adjusted R-squared	0.00					

Table 23: Sedentary or restrained sub-group and time watching TV sub-group combined linear regression, adjusted for 6 months

Combined Sedentary and TV 12 months, adjusted for 6 months	Coefficient	Standard Error	t-value	p-value	[95%Confidence	Interval]
Intervention group	-42.05	26.8	-1.57	0.12	-95.08	10.98
Control group	0	(base)				
Combined sedentary and TV 6 months	0.12	0.08	1.59	0.115	-0.03	0.27
Constant	242.64	22.06	11	0	199	289.28
Number of obs	132					
F-test	1.86		Probability>F	0.16		
R-squared	0.03		Adjusted R-squared	0.01		
Root MSE	144.87					

When considering the number of participants who were restrained for one or more hours per day and those who were restrained for less than an hour (or not at all), more participants were constrained for longer than an hour in the intervention group at 6 months, compared to the control group, however the difference was not significant ($p=0.23$). At 12 months this changed, and fewer were constrained for more than 1 hour in the intervention group compared to the control group, however this was also not significant ($p=0.47$). As a result, there was a higher positive change in the intervention group from 6-12 months, however this was also not significant (0.14) (Table 24).

Table 24: Time restrained for more or less than an hour per day at 6 months, 12 months and change from 6 – 12 months, respectively

Time participants spend restrained at 6 months	Intervention group (n=67)	Control group (n=65)	chi square	p-value
more than 1 hour or more per day	41	33	1.46	0.23
less than 1 hour per day	26	32		
Time participants spend restrained at 12 months				
More than 1 hour or more per day	35	38	0.52	0.47
less than 1 hour per day	32	27		
Change from 6 to 12 months				
1(reduction in score)	10	19	4.01	0.14
0 (no change)	41	32		
1 (increase in score)	16	14		

6.3.4. Affordances in the Home Environment for Motor Development Infant Score (AHMDS-IS)

When comparing the affordances in the home environment sub-scales and total score, Table 25 highlights that there was no significant difference between the intervention and control group, except for a higher Physical Space score ($p=0.004$) (particularly outdoor space ($p=0.03$)) and change in AHMDS between 6 and 12 months, in the control group compared to the intervention group ($p=0.00$).

Table 25: Affordances in the Home for Motor Development (AHEMDS) at 12 months and total change over time from 6-12 months

AHEMDS 12 mths (n=132)	Intervention (n=67)		Control (n=65)		
	Median/ Mean	IQR/ SD	Median/ Mean	IQR/ SD	P-value
Gross Motor Toys	2.27	(1;5)	2	(1;5)	0.56
Fine Motor Toys	2.72	(1;7)	3	(1;6)	0.67
Physical Space	5.22	(3;8)	6	(4;8)	0.004*
Inside	3	(0;4)	3	(0;4)	0.08
Outside	2.4	1.3	2.89	1.28	0.03*
Variety of Activities	5	(4;5)	5	(4;5)	0.46
Total AHEMDS	16	(11;21)	16	(12;22)	0.18
Change in AHEMDS over time from 6-12 mths (Wilcoxon sum rank test)	-5	(-8;-2)	-2.9	(-5;-1)	0.00*
*Significant					

The linear regression (Table 26) showed a negative (non-significant) effect of the intervention on the AHEMDS score (coefficient = -0.75, 95% CI [-1.97; 0.47], p=0.22). When adjusted for 6 months, participants in the intervention group showed a significant decrease of 1.53 units in the AHEMDS score, compared to the control group, at 12 months (Table 27).

Table 26: AHEMDS 12 month linear regression

AHEMDS 12 mths	Coefficient	Standard Error	t-value	p-value	[95%Confidence	Interval]
Intervention group	-0.7540984	0.616344	-1.22	0.224	-1.974417	0.4662199
Control group	0	(base)				
Constant	16.42623	0.435821	37.69	0	15.56333	17.28912
Number of obs	122					
F-test	1.5					
R-squared	0.0123					
Root MSE	3.4039					
Prob>F	0.2235					
Adj R-squared	0.0041					

Table 27: AHEMDS 12 month linear regression, adjusted for 6 months

AHEMDS Total 12 months, adjusted for 6 months	Coefficient	Standard Error	t-value	p-value	[95%Confidence	Interval]
Intervention group	1.53	0.59	-2.62	0.01	-2.69	-0.38
AHEMDS 6 months						
1	-0.11	1.01	-0.11	0.91	-2.11	1.90
2	-0.3	1.02	-0.29	0.77	-2.31	1.72
3	0.6	1.05	0.58	0.57	-1.47	2.67
4	2.34	1.08	2.17	0.03	0.21	4.47
5	3.38	1.32	2.57	0.01	0.78	6.00
6	0.98	1.65	0.59	0.55	-2.29	4.25
7	5.49	3.30	1.67	0.10	-1.01	11.99
Constant	16.04	22.06	11.00	0.00	199.00	289.28
Number of obs	132					
F-test	2.59		Probability>F	0.01		
R-squared	0.14		Adjusted R-squared	0.09		
Root MSE	3.155					

6.3.5. Opportunities for active play

When considering the combined opportunities for active play at 6 months, Table 28 shows that those in the control group had significantly higher scores ($p=0.00$), and therefore, more opportunities for active play than those in the intervention group at baseline. When considering the scores at 12 months they were similar, and the difference between the groups was not significant ($p=0.343$). When looking at the change in opportunities for play from 6 to 12 months, there was a significant ($p=0.001$) difference between the intervention and control group, with 27 participants (40%) in the intervention group increasing between 1 and 3 points (compared to 8% in the control group) and 43 participants (42%) of the control group decreasing between 1 and 4 score units (compared to 31% in the intervention group). The linear regression (Table 29) showed a negative but non-significant effect of the intervention on the opportunities for active play score (coefficient = -0.11, 95% CI [-0.88; 0.66], $p=0.78$).

Table 28: Opportunities for active play at 6 months, 12 months and change from 6-12 months

	No of opportunities	Intervention (n=67)	Control (n=65)	Chi2	P value
Combined opp for play 6 mths	2	30	2	43.96	0.00*
	3	24	18		
	4	8	35		
	5	5	10		
Combined opp for play 12 mths	1	7	2	4.36	0.36
	2	16	18		
	3	25	28		
	4	14	15		
	5	5	2		
Change in combined opp for play 6-12 mths	-4	0	1	25.31	0.001*
	-3	3	2		
	-2	4	12		
	-1	14	28		
	0	19	17		
	1	19	4		
	2	6	1		
	3	2	0		
*significant					

Table 29: Change in opportunities for active play at 12 months logistic regression

Change in opp for active play 12 months	Coefficient	Standard Error	z	p> z	[95%Confidence	Interval]
Intervention group	-0.11	0.39	-0.28	0.78	-0.88	0.66
Control group	0	(base)				
Constant	1.04	0.28	3.68	0.00	0.48	1.59
Number of obs	132					
F-test	0.79					
R-squared	0.01					
Root MSE	115.38					
Probability>F	0.37					
Adjusted R-squared	-0.00					

6.4. Discussion

The overall aim for this chapter was to determine whether the intervention aimed at improving health literacy (in Chapter 5), increased the participants' opportunity for active play at 12 months in the intervention group compared to the control group, and whether there was a change in opportunity for active play from 6 to 12 months. At 12 months, the intervention group showed a significantly higher maternal beliefs score and time spent being physically active, compared to the control group. However, those in the control group were found to have greater affordances in the home environment for motor development over time, compared to the intervention group. Overall, there was a significant increase in the opportunities for active play score from 6 to 12 months in the intervention group. Other studies have had similar outcomes. PA measurement in infants and toddlers lacks standardization, making comparisons across studies challenging (137,138). The early years are crucial for establishing healthy movement behaviors, highlighting the need for consistent measurement protocols and targeted interventions to promote PA and reduce sedentary time in young children (137,138). Early childhood interventions targeting PA and sedentary behavior show mixed results. A randomized controlled trial including antenatal information and postnatal activity groups found little effect on PA at age 2 despite high initial participation (139). However, a systematic review and meta-analysis of interventions for 0-5

year olds reported significant reductions in screen time and sedentary time (140). Longer interventions (≥ 6 months) in community settings were most effective for reducing screen time, while interventions targeting PA were more effective at reducing sedentary time (140). A New Zealand based RCT which aimed to increase family PA and decrease time restrained in infants through a home-based intervention, found no difference between the two groups when comparing infant PA and time restrained (141). The study authors suggested that competing priorities such as sleep problems and infant crying could be more important to caregivers in this age group (141). A study aiming to increase tummy time and unrestrained floor time, and reduce restrained time in low-income settings after receiving parenting sessions and information pamphlets, found that the intervention group was more likely to practice tummy time and unrestrained time compared to the control group, however there was no difference between the two groups for overall time in movement-restricted devices (142). In this same study, parental health literacy had no effect on the outcome in the intervention group, but increased attendance (dosage) was associated with increased tummy time and floor time (142). A study which did find positive cognitive and motor outcomes in the intervention group compared to control group included physical therapist led weekly groups (143). All activities at home were closely monitored and focused on postural and locomotor tasks as well as being taught how to make toys out of recycled materials found at home, which does suggest that a more structured programme with initial training may be needed to improve outcomes in this population and setting (143).

An interesting and important observation is that despite there being fewer affordances in the home for motor development in the intervention group, particularly with regards to physical outdoor space, there was still an increase in opportunities for active play over time. Many of the activities and information included as part of the intervention content focused on providing opportunities for active play within small indoor living spaces and with limited resources. Examples included encouraging safe crawling on the floor or supervised on a bed, as well as how to make toys, which encouraged active movement out of recycling e.g. standing blocks, shakers, etc. This provides some evidence to suggest that the intervention did have a positive impact on the mothers' maternal beliefs, infants' time spent being active and therefore opportunities for active play, despite living in environments that are not usually conducive for promoting active play. This finding has important implications for policy and practice, where future

interventions with caregivers of infants should focus on shaping maternal beliefs around activity, as well as teaching caregivers how to use the space and resources that they have, without needing expensive toys or equipment to encourage active play and development.

However, conversely, it is important to consider the reason as to why no effect was seen in the secondary outcomes. As the intervention was focused on improving health literacy as a mediator for providing more opportunities for play, and the findings from Chapter 5 showed that the intervention did not increase the health literacy of the intervention group, one assumption is that the limited change in health literacy resulted in a limited effect on the secondary outcome measures. Although, on the other hand, the intervention content could have been too heavily focused on play and development and increasing activity through play, and further work or analysis would need to be done to tease this out further. Lastly, the SmartPlay study was embedded within the PLAY Study intervention, which had a component of measuring and providing feedback on movement behaviours and encouraging adherence to the 24-hour movement guidelines, which could have influenced the SmartPlay Study outcomes. Future analyses are required to attempt to disentangle how these two studies impacted each other.

Limitations

As the data collection and management procedures were the same as the health literacy data, the secondary outcome data had similar limitations to those discussed in chapter 5. However, there were limitations specific to the secondary outcome data. Firstly, the physical activity (PA) and sedentary/restrained sub-groups were measured using self-reporting instead of an objective measurement device such as an accelerometer. When using self-reporting, participants are more likely to report higher levels of activity (PA) and lower levels of time being sedentary/restrained, with one study finding that on average, participants under-reported their time being sedentary when compared to a device measurement by 1.74 hours per day (144). The data may have been more reliable using accelerometers; however, these resources were not available as these outcomes were not primary outcomes for the overall trial. Secondly, as the opportunities for play score was created as a measure for this specific study, this has not been validated elsewhere and therefore the cutoff/categorization of each category may

need to be refined and tested if using it in another study or setting. Assessing adherence to the movement guidelines also proved to be a challenge, as the movement guidelines are not very specific or quantifiable (especially around sedentary time) and the data were not collected in a way that would allow for accurate measurement of each component of the guidelines (as this was not the primary objective).

6.5. Conclusion

Mother and infant dyads who received the intervention were found to have higher maternal beliefs and increased time spent being physically active, compared to the control group, as well as an increased change in opportunity for active play from 6-12 months, compared to those who did not. Many of the activities and information included as part of the intervention content focused on providing opportunities for active play within small indoor living spaces and with limited resources. Interventions that provide activities that can be implemented in small spaces with resources available at home, can be effective in promoting active play for infants in low resources settings. Policy makers and health promoters need to focus on providing simple, cost effective and practical activities for caregivers with young children to engage with at home, using the space and resources that they have, without needing expensive toys or equipment, to encourage participation in age-appropriate active play starting from birth.

PART 3: INTEGRATED DISCUSSION AND CONCLUSION

Chapter 7: Integrated discussion and conclusion

This chapter consolidates the main objectives and corresponding findings from the previous chapters in the thesis. The themes that have arisen in the thesis, specifically the methodological and empirical themes, are considered. Lastly, ideas for future research are proposed and the implications of this research and limitations are discussed.

7.1. Key findings

Table 30: Summary of Key findings of SmartPlay Study

Chapter	Research Question	Hypothesis	Results	Conclusion
3	1. What are the challenges and barriers that a group of Soweto mothers experience when facilitating play with their young infants?	The hypothesis for this chapter was that after understanding the needs and barriers around play and development and co-creating an intervention, the mothers from the CAG would find the	The main barriers/ challenges discussed were: • The lack of consistent information provided by health workers as well as from family, peers and those in the community • Crowded living spaces and lack of safety in physical environment (indoor and outdoor), limiting opportunities for active play • Mothers not having enough time to engage in play due to work, chores or engaging in leisure activities	The main barriers when facilitating play are the lack of consistent information, limiting environments and lack of time to engage in playful activities. The prototype activities were found to be acceptable to participants. Suggestions were given

	2. After presenting a prototype of intervention activities and content – What are the perceptions as to how the activities and content may improve health literacy (thereby encouraging participation in play)? How should the intervention be presented?	intervention acceptable	• Using the Acceptability component constructs, participants reported liking and understanding the content and did not see it as a burden. • Overall, the participants perceived the proposed prototype activities to be acceptable and useful for improving health literacy. • Participants did not mind if the videos were in English, as long as there were subtitles accompanying the audio, moving slowly across the screen. • Participants suggested having actors who were more representative of the Sowetan Community when it came to their race and culture.	by participants regarding implementation, which, together with the prototype feedback, assisted with developing the intervention for the SmartPlay Study.
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	3.How acceptable is the intervention prototype after being tested by the mothers in Soweto?		• All participants found the intervention content acceptable in all the constructs. • However, Of the fourteen participants, just over half (eight) of the participants found it very easy to find the resources to make the toys at home, five participants found it easy to find the resources and one participant found it difficult. • When it came to how and when the intervention content should be presented, 97% of the participants preferred being shown a video instead of it being presented in person, so that they could watch in their own time, slow down and pause the video, and could refer back to it as needed.	
4	1. How feasible and acceptable was an intervention aimed at improving	The hypothesis for this chapter was that participants would find the intervention	• The health literacy content was found to be highly acceptable in the questionnaire and FGDs. • Most of the participants (70%) could access the intervention content over the 12 months of the PLAY Study.	While the intervention was considered feasible within the setting and highly acceptable to participants, barriers related to external

	maternal health literacy around infant play and development?	content feasible and acceptable and that they would find the study questionnaires easy to understand and relate to.	• Of those who could access the content, 59% looked at content more than once a week and 10% every day. Less than a quarter only looked at the content sporadically. • Access was impacted by technical difficulties attributed to using inconsistent external service providers.	management of the app resulted in some issues with accessibility. Interventions which provide meaningful, clear and easily accessible information around play and development in infants, created through community engagement and feedback, would be useful and well received by mothers and caregivers in similar settings, and show potential for effectiveness in improving health literacy around play and development.
	2. What was the participants' understanding and perceived relevance of the study outcome questionnaires, taking into account the context in which they live?		• Participants found the assessments relatable and wanted to find out more about the assessment topic after the session was completed. • Participants learned more about the stages of development and what behaviours were appropriate at the different stages from questionnaires about milestone attainment. • The questions encouraged participants to reflect on their home and outdoor environments, particularly related to where their infant could play safely. • The questions encouraged participants to think about what type of toys their infants were	

			playing with, and when they should play with different types of toys, according to their stage of development.	
5	The primary objective: Did 12 months of a co-created intervention result in higher health literacy scores in the group that received the intervention, compared to the group that did not.	The hypothesis for this chapter was that those in the intervention group would have higher health literacy scores at 12 months compared to the control group. Furthermore, it was hypothesized that the change in health literacy from 6-12 months would be greater in the intervention group	• There was no significant difference between the intervention and control group HLQ scores at 12 months, yet there was a significant difference between the two groups at 6 months, with those in the control group having higher HLQ scores than those in the intervention group. • Being in the control group was associated with having a higher HLQ score compared to the intervention group, however this association was not significant ($p=0.295$).	The health literacy intervention did not have a significant effect on those who received the intervention, compared to those who did not, but there was a significant increase in health literacy scores in the intervention group over time. This change was most significant in the mothers' ability to actively manage their child's health, their social support for health, and their ability

		compared to the control group.		to identify good information and reliable sources of information. Developing and using a health literacy questionnaire that is more appropriate for postpartum mothers in low resource settings well as increasing the dosage of the intervention, and providing better access to the app, may result in a greater effect in future studies.
	The secondary objective: Was there a greater change in health literacy scores from 6 to 12 months in the intervention group compared to the control group.		• The scores at baseline were relatively high, showing a limited potential for change over time. • After recoding the HLQ continuous scores according to the categorical cutoff, it was found that being in the intervention group was associated with a significant change in HLQ scores from 6 to 12 months ($p=0.01$). • Out of the 44 questions in the HLQ questionnaire, there were 5 questions which showed as significant change over time, between the two groups. These fell into 3 categories, namely: 1) Actively managing my (child's) health, 2) Social support for health and, 3) Appraisal of health information.	
6.	1. Was there a difference in	The hypothesis for this study was that	• While the average scores were slightly higher in the intervention group, they were not	Mother and infant dyads who received the

	maternal beliefs around PA between the intervention and control group at 12 months? Was there a change in beliefs from 6 to 12 months?	there would be higher maternal beliefs, motor affordances in the home, time spent active and less time sedentary at 12 months, in the intervention group compared to the control group. This would then result in more opportunities for play in the intervention group compared to the control group.	significantly different between the two groups at 12 months. • The change in Maternal Beliefs score from 6 to 12 months was significant ($p=0.00$), with the intervention group's scores increasing on average, 35.44 points compared to an average of 25.7 points in the control group. • Although not significant, the linear regression (Table 5) showed a positive effect of the intervention on the Maternal Beliefs Score (coefficient = 0.79, 95% CI [-1.42; 2.99], $p > 0.05$). Participants in the intervention group had an average increase of 0.79 units in the Maternal Beliefs score compared to the control group.	intervention were found to have an increased opportunity for active play compared to those who did not. Interventions that provide activities that can be implemented in small spaces with resources available at home can be effective in promoting active play in infants in low resources settings.
	2. Was there a difference in time engaging		• While the intervention group, on average, engaged in more time doing PA and less time being sedentary/ restrained or watching tv (or	

	in PA, time spent being sedentary/restrained and time spent watching tv in the intervention and control group at 12 months?		both), than the control group, this difference was not significant. • Although not significant, the linear regression in Table 13 showed a negative effect of the intervention on the time spent watching TV (coefficient = -9.75, 95% CI [-27.01; 7.51], $p > 0.05$). • Participants in the intervention group had an average decrease of 9.75 minutes watching TV compared to the control group. When adjusted for 6 month data, this decreased to 12.11 minutes (coefficient = -12.11, 95% CI [-29.66; 5.44], $p > 0.05$), although also not significant.	
	3.Was there a difference in affordances in the home environment for promoting motor development		• When comparing the affordances in the home environment sub-scales and total score, there was no significant difference between the intervention and control group, except for a higher Physical Space score ($p=0.004$) (particularly outdoor space ($p=0.03$))	

	in the intervention and control group at 12 months? Was there a change in these affordances from 6 to 12 months?		• There was a significant change in the AHEMDS between 6 and 12 months, in the control group compared to the intervention group ($p=0.00$). • The linear regression showed a negative (non-significant) effect of the intervention on the AHEMDS score (coefficient = -0.75, 95% CI [-1.97; 0.47], $p > 0.05$). When adjusted for 6 months, participants in the intervention group showed a significant decrease of 1.53 units in the AHEMDS score, compared to the control group, at 12 months.	
	4. Was there a difference in opportunities for active play in the intervention and control group at 12 months? Was		• When considering the combined opportunities for active play at 6 months, Table 22 shows that those in the control group had significantly higher scores ($p=0.00$), and therefore, more opportunities for active play than those in the intervention group. • The scores at 12 months were similar, but the difference between the groups was not significant ($p=0.343$).	

	there a change in these opportunities from 6 to 12 months?		When looking at the change in opportunities for play from 6 to 12 months, there was a significant ($p=0.001$) difference between the intervention and control group, with 34% of the intervention group increasing by a point and 46% of the control group decreasing by a point.	
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7.2. Emerging themes

7.2.1. Methodological Themes

7.2.1.1. Developing and evaluating an intervention within a larger study

This section describes the strengths and weaknesses of using the respective methods in each phase of the study and well as the implications and impact of the SmartPlay study being embedded within the PLAY study on these methods. Each phase was evaluated through the lens of the conceptual framework for implementation fidelity (61).

Phase 1: Intervention Development

The strengths and weaknesses of using co-creation, FGDs and use of a questionnaire to measure acceptability of the prototype specifically with regards to the SmartPlay study are further explained in Table 31.

Table 31: Strengths and Weaknesses of Phase 1 Methodology

	Co-creation	Focus Group Discussions (Qualitative)	Acceptability Questionnaire (Quantitative)
Strengths	• Participants provided valuable input regarding how the intervention should be implemented which	• Provided insight into the participants' lives, which helped to understand their context and	• Provided objective measure which considered each aspect (construct) of acceptability

	helped increase feasibility of intervention • Added validity to choice of activities used for intervention as participants had physically completed the activities at home and provided feedback	environmental constraints • Participants found the prompts helpful to discuss topics that they were not very familiar with (e.g. how the home environment impacts play)	• Created by researcher using simple language - easier to administer
Challenges	• True co-creation should start with all stakeholders conceptualizing, planning and delivering the intervention together. As the prototype had already been planned according to literature, only minimal changes could be made when meeting with the CAG.	• Due to the nature of the topics discussed, the FGDs required an experienced facilitator to guide and contain conversations – at times some of the concepts were not adequately explored. • Due to the participants all having young babies with them, there were multiple interruptions, resulting in longer FGDs and participant fatigue.	• Although some language could be changed, some was difficult to relay to English 2nd language audiences without changing the meaning and nature of the component • It was difficult to create enough nuance in each question to ensure each component of acceptability was assessed

Implications of being embedded in the PLAY study

These FGDs were conducted as part of the PLAY study, which meant that there were other topics being explored as part of the series of FGDs. As there was another student also based in Cape Town, we planned two FGDs together, with the first part of the FGD discussing the SmartPlay study and the other part discussing nutrition. At times this led to confusion between the two topics, both with the facilitator and participants. In retrospect, if I had to plan this phase again, I would have conducted these FGDs on separate days and perhaps included other forms of qualitative data collection such as behavioural mapping, to encourage the participants to think “out of the box”.

Furthermore, if the financial and time resources were available, it would have been useful to have had a longer time to co-create higher fidelity content with the CAG. As the CAG participants discussed their preference for seeing people “who looked like them” in the intervention content, it would have been preferable to either have them in the content videos/ infographics or have more time and resources to create animated representatives of the group in the content videos. However, due to the resource limitations (including my physical location not being in Johannesburg and limited time due to my own personal lack of funding), I had to create the content videos and infographics myself with amateur software and skills, which was not always in line with what the CAG initially suggested, and may have limited the acceptability of, and engagement with the intervention content. Similarly, as the PLAY study already had a structure that would be followed, there was only a certain amount of participant input that we could incorporate, to allow the whole study to feasibly move forward e.g. some participants may have wanted to receive breastfeeding content more often than play and development content, but all content had to be delivered in a uniform way, which was not dependent on the topic. Despite these limitations, I thought that we did well to have a good combination of participant preferences with our own knowledge from literature, whilst sticking to the PLAY study structure.

Phase 2: Intervention implementation

The strengths and weaknesses of using a mobile application for the SmartPlay Study are further explained in Table 32.

Table 32: Strengths and weaknesses of the intervention mode of delivery

	Using a mobile application
Strengths	• Participants received information through a variety of mediums e.g. infographics, videos, etc, keeping participants engaged and allowing for different learning styles (i.e. audio, visual, etc) • Could tailor the content to be specific to the participants and their context • As I created the content, costs could be kept to a minimum
Challenges	• Feasibility issues as discussed in Chapter 4 (i.e. lack of access to data, electricity for charging and how often mobiles are lost/ stolen) • As I created the content, it was not produced at a professional level • Similarly, as I do not have lived experience of living in Soweto, it was difficult to ensure all content was completely context specific.

Implications of being embedded in the PLAY study

As I would not have had the funds to implement my own mobile app intervention if the SmartPlay Study was not embedded in the PLAY study, this was a significant benefit of embedding this intervention in the PLAY study. It was also incredibly helpful to have an established app that was initiated and managed by the PLAY Study Primary Investigator, where my only role was to create and upload the content to the shared database. However, as the play and development health literacy content was not the only content being delivered via the app, this led to multiple people being in contact with the developers, creating confusion in communication at times. This also led to a reduction in the dosage of the intervention, which is discussed in more detail below.

Phase 3: Intervention evaluation

The strengths and weaknesses of using the HLQ as the primary outcome measure as well as the FGDs and questionnaire to measure feasibility of the SmartPlay study are further explained in Table 33.

Table 33: Strengths and weaknesses of Phase 3 methodology

	HLQ questionnaire	Focus Group Discussions (Qual)	Feasibility Questionnaire (Quant)
Strengths	• Provided a holistic measure of the different components of health literacy • Fairly easy for second language speakers to understand	• Provided really good insight into how the intervention positively impacted the participants, despite this change not being reflected in the quantitative data.	• Provided objective measure of acceptability of the intervention content • Provided objective data related to access and usage of content.
Challenges	• Volume of questions together with other secondary measure questionnaires created room for error due to time constraints • Was difficult to find a health literacy questionnaire which could accurately capture the sample's baseline	• No real challenges experienced other than the usual challenges of facilitating FGDs	• Difficult to know how much the content was engaged with, even when it was accessed and participants looked at it, i.e. how much did their health literacy change because of engagement with the content itself?

	and change in health literacy		
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Implications of being embedded in the PLAY study

As previously mentioned, apart from its own outcome measures, the PLAY study also comprised of 3 sub studies, which resulted in there being numerous outcome measure tools that were administered at each follow-up point. It was therefore difficult for me to ensure quality control at all follow-ups (although this was also impacted by me not consistently being in Johannesburg). Independent of the PLAY study, despite the HLQ being recommended for LMICs, this measure was not appropriate for this study and context. Some of the questions, for example, around having a Health Care Worker (HCW) that you know by name, were not appropriate for a public health context where health users see different health providers each time they access services. The PLAY study, and therefore the SmartPlay study, was an ambitious, complex intervention, which had a limited budget and timeline. It was initially proposed that the PLAY Study intervention and follow-ups would begin at birth and continue to 24 months, however this timeline was not found to be feasible with the available resources and was then changed to 12 months. While the evidence does show the importance of active play in children from as early as the first 6 weeks, since most children start walking around the age of 12 months, a further 12 months of the intervention may have seen a larger effect on the opportunities for active play at 24 months. Lastly, because of the complexity of the study, each objective included a variety of methodologies, intervention components and outcome measures. While this allowed for a rich and in depth understanding of all the components of the study, some of the nuance may have been missed when attempting to summarise and fit all of the findings and analyses into one thesis. For example, one of the main anecdotal findings from my experienced and involvement with the participants and research process, was the immense positive impact of the social support gained from the participants being part of this study. This in turn, may have had an impact on their ability to provide nurturing care and opportunities for play, however this was not measured and therefore its true impact remains unknown.

7.2.2. Empirical Themes

Why was there no effect?

From the discussion above, regarding the methods used in each phase of the study, one has to determine whether the lack of effect was due to the choice of methodology or due to other circumstances such as the pathways to impact. While there were some significant weaknesses in some of the methods chosen for the study, most of these were outweighed by the strengths, and the lack of effect could not be attributed solely to these weaknesses. As a result, we can presume that the main contributor to the lack of effect was due to a combination of some methodological weakness as well as other pathways to impact, which acted as potential moderators. Many of these “moderators” have been discussed in detail in Chapter 5 and 6, however, Figure 22 provides a broader picture of what potential moderators impacted study implementation, both in the development and implementation phase. Access to the app (due to difficulties with software providers in providing data free content and uploading users’ profiles) and limited dosage of the intervention (due to the health literacy content being received together with other content as well as app access issues) were all potential moderators which impacted the potential for participants to improve their health literacy in the designated intervention period. Furthermore, using participants still in the PLAY study at 6 months as the SmartPlay baseline sample potentially impacting the sample size, and choosing the HLQ as the outcome measure, as well as the lack of quality control with questionnaire administration may have had an impact on the quality of data collected and statistical strength of the sample.

The concept of dosage is particularly important with regards to health literacy. If we go back to Figure 1 and the WHO’s description of how health literacy is impacted by information, environments, resources and supports, apart from the information received, individuals require strong supportive environments to enable increased health literacy. The qualitative findings provided insight into how the participants did not receive consistent resources or support from their health care providers and families and as a result, would need to lean heavily on the information provided in the intervention content. If the dosage of the health literacy content was limited, this provides further insight into why the intervention did not

have any significant effect. Similarly, if the content was diluted because of the heavy focus on promotion of play and development, it may have been more impactful to focus more on the constructs of health literacy e.g. how to know if information is reliable online, how to ask health care providers questions, etc.

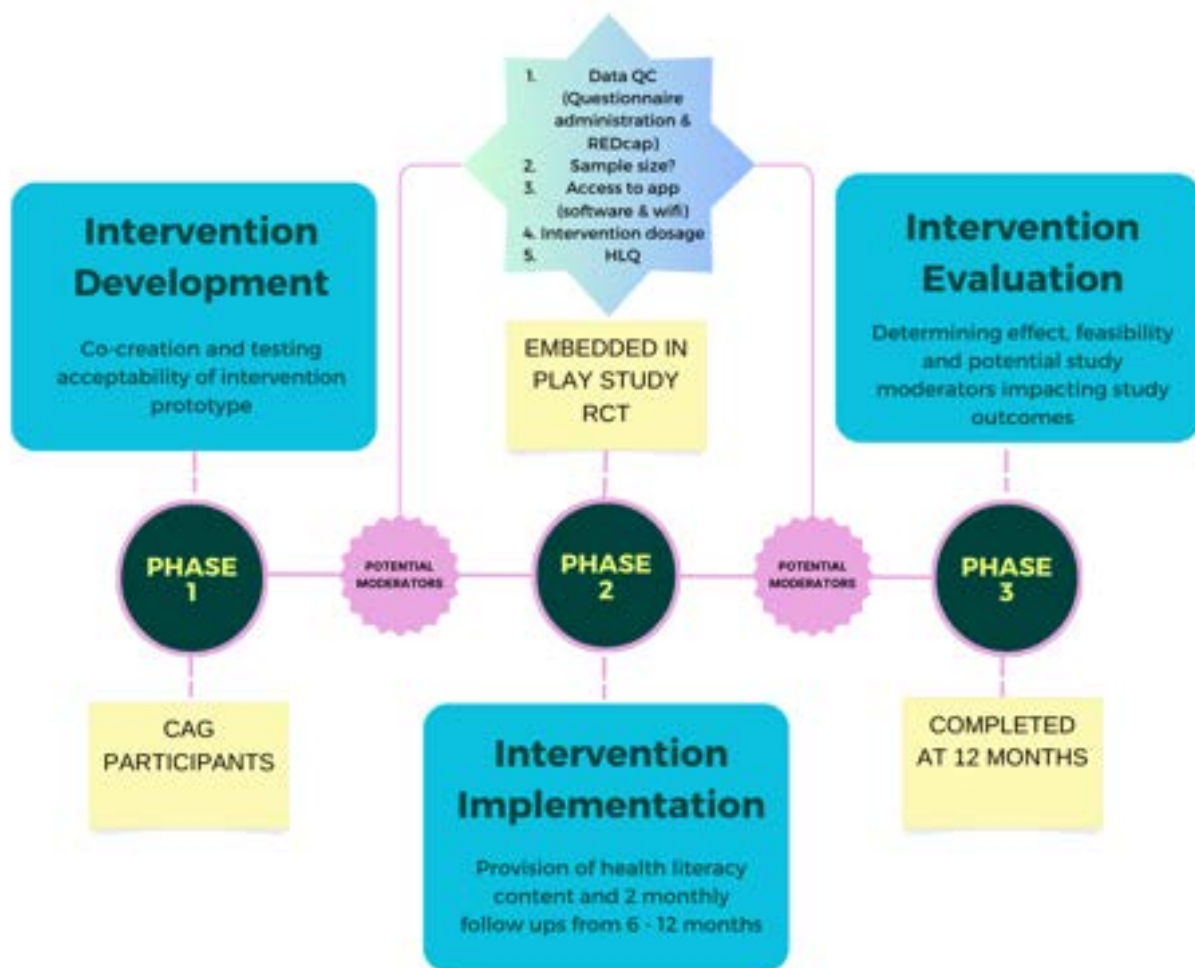


Figure 22: The 3 phases/ components of the SmartPlay Study, including potential moderators

If the study were to be repeated, I would use a similar development process but increase the dosage of the intervention by having a longer implementation timeframe (minimum 12 months) and focus solely on providing health literacy content, without being embedded in a larger study. I would also focus on determining the true baseline levels of health literacy in the sample before measuring health literacy outcomes, using a more appropriate tool that has been validated in similar contexts.

7.3. Conceptual Frameworks

7.3.1. The Behaviour Change Wheel in intervention development and implementation

As seen in Figure 23, the original conceptual framework based on the Behaviour Change Wheel assumed that by focusing equally on improving the caregivers' capability, motivation and opportunity through increased health literacy, this would result in the desired behaviour i.e. an increase in participation in (active) play.

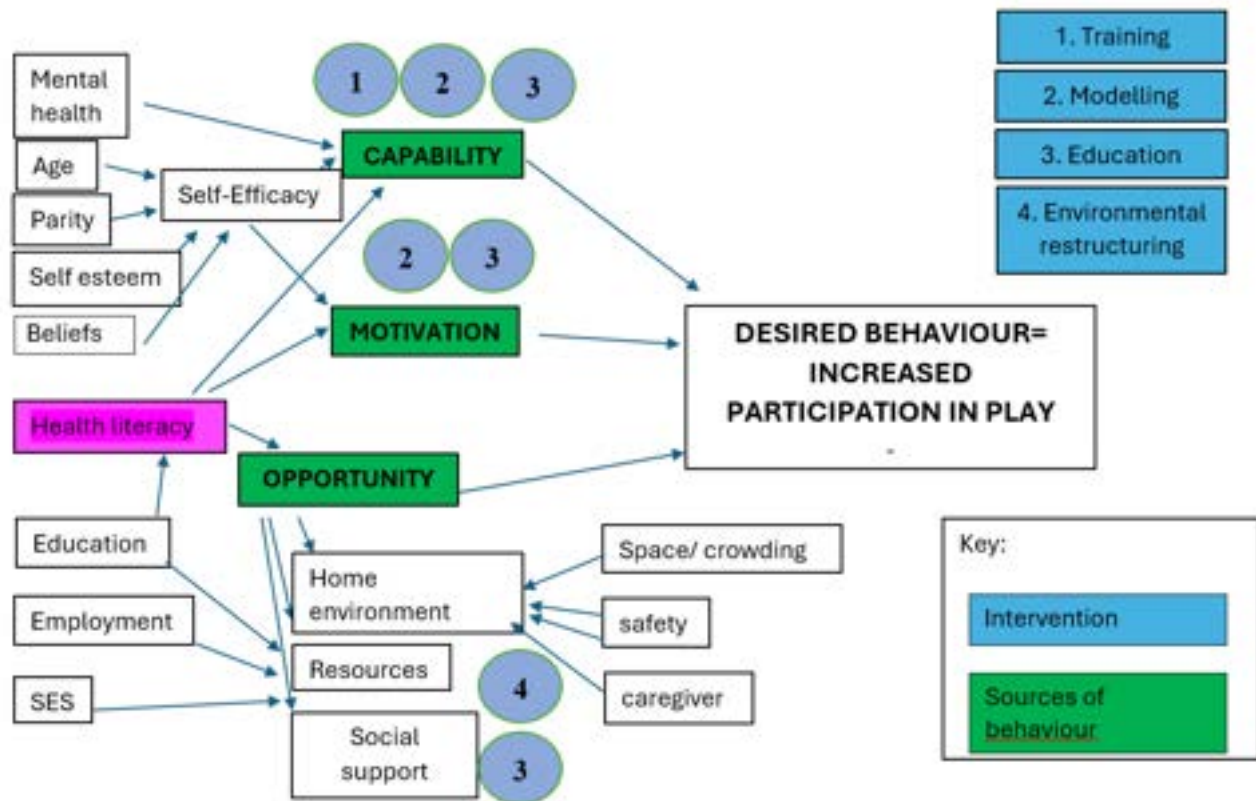


Figure 23: Original conceptual framework (based on behaviour change wheel) (51)

However, this was not found to be the case in our population. Throughout the thesis themes around how the differing levels of support, or lack thereof, in the caregivers' social and physical environment impact their ability to provide nurturing care to their infants. Therefore, there cannot be an equal focus

on the three components and the framework needs to be looked at from a hierarchical perspective. Other research conducted in low resource settings has found that family characteristics such as household size and low income have a direct impact on maternal stress and self-efficacy (145). Caregivers who do not have the opportunity to provide greater participation in play, won't have the motivation to increase their capability to do so. In this context, caregivers need to be provided with further opportunities to increase their SES, earn an income through employment, receive greater social support from their community and to live in safer environments with adequate housing and access to recreational activities. However, these factors won't change overnight and while it is well known that factors influencing SES are not easily modifiable, there are modifiable parent characteristics, such as self-efficacy and knowledge, that can increase opportunities for healthier developmental outcomes in children, through the provision of adequate support (146). The qualitative work in the SmartPlay study provided excellent insight into the barriers faced by mothers in this community, and was useful in developing the intervention. However, the theme around lack of support persisted throughout the study and it is clear that this barrier needs to be at the forefront of policy makers and implementers working with new mothers in low-income settings. Once these opportunities for support become available, there is a shift from a feeling of despair or hopelessness to hope and potential for change, thereby increasing motivation, and encouraging a desire to increase individual capabilities (such as levels of health literacy) which may lead to greater behaviour change. The change points in the framework should be around providing opportunities in the social and community environment, which will then cascade down to the individual change in behaviour, as proposed in Figure 24.

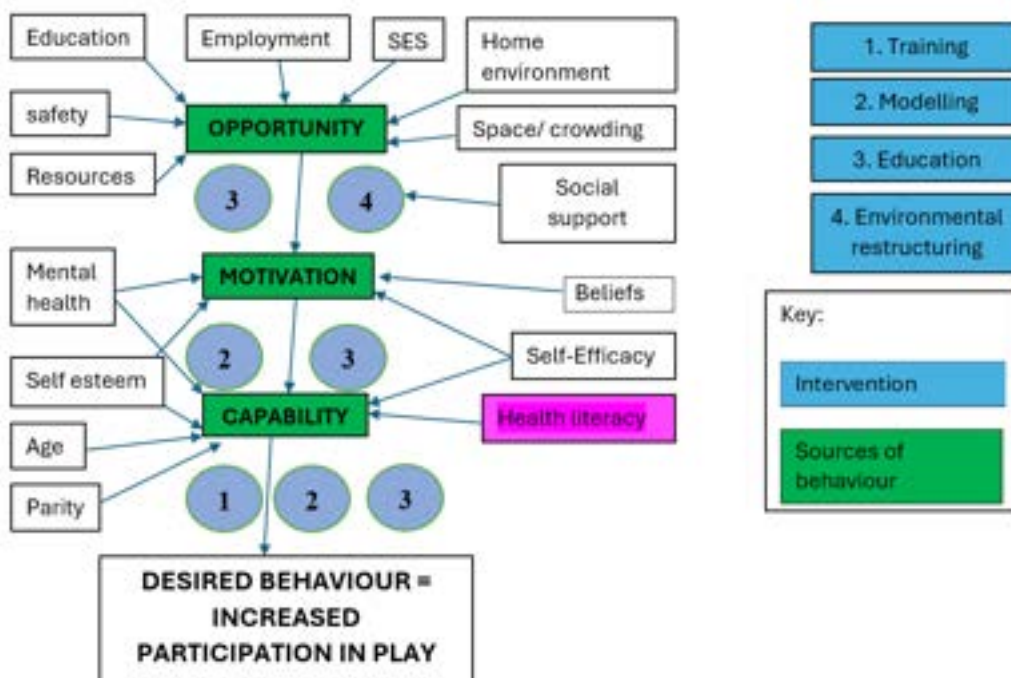


Figure 24: Revised hierarchical conceptual framework (based on behaviour change wheel) (51)

7.3.2. Acceptability framework

The acceptability framework created by Sekhon et al. was chosen as the framework to determine the acceptability of the initial prototype (discussed in chapter 3) and the play and development intervention content (discussed in chapter 4). While this was a useful way to determine the components of acceptability and to have a concrete measure of acceptability, it was difficult to determine whether each component truly captured what it was intended to measure, largely due to a) the complexity of the concept of each component, b) the similarity between some of the components, and c) the potential language barrier. An example would be the “ethicality” component or the “extent to which the intervention has good fit with an individual’s value system”. While in theory this is an important concept, it was difficult to ask in a way that was understood by the participants from our local context. However, this was not specific to our context alone. My colleague and I were asked about how our participants handled the ethicality concept when we presented at the 2024 International Society for Behavioural

Nutrition and Physical Activity (ISBNPA) conference, as the individual asking the question had found it difficult to communicate with individuals from low-income communities in the United States.

7.3.3. UK MRC framework for developing and evaluating complex interventions

The UK MRC framework for developing and evaluating complex interventions was a very helpful and appropriate framework to use for developing, implementing and evaluating the SmartPlay intervention (48). However, as the SmartPlay Study was embedded within an even more complex trial, the PLAY Study, it was difficult to consistently revisit the core elements of the framework throughout the process (described in Figure 2). However, the PI of the PLAY study, as well as the DPHRU in which the study was based, had extensive experience of working in Soweto and had a good understanding of the context in which the study was conducted. Another strength was setting up and engaging with stakeholders, i.e. the CAG, when developing the study and throughout, to make sure the intervention was acceptable and feasible within the context. I personally focused on considering the economic context in which the participants lived, by promoting play through the use of recycled materials and common objects found at home. However, due to the SmartPlay Study being embedded in a larger study, it was difficult to refine the intervention as we went along, as there were certain structures that were in place to ensure consistent provision of the content. However, these learnings can be used for future implementation studies using the same framework.

7.4. Research Implications

7.4.1. Methodological implications

While this thesis set out to determine whether an intervention aimed at improving maternal health literacy had an effect, it has instead provided valuable learnings around methodology used for intervention development, implementation and evaluation. These findings show the importance of using suitable methodological frameworks right through from conception of the intervention to evaluation, which consider the context and engage with stakeholders, ideally through co-creation. Furthermore,

while an intervention can be 100% acceptable and feasible, the desired effect may never be achieved due to external factors that need to be fully understood and considered by researchers before implementation begins. These findings also show the importance of using an implementation fidelity framework to evaluate reasons and identify external factors that may hinder behaviour change, so as to not repeat similar mistakes in future work and to provide guidance to other researchers implementing complex interventions in similar settings. Furthermore, it is important to determine the baseline levels of the outcome being measured, to avoid seeing no change in behaviour due to an incorrect hypothesis (which may have been the case in this population due to their high baseline health literacy scores).

7.4.3. Implications for the field

The findings of this thesis are an important contribution to the scientific community as they provide important recommendations around encouraging behaviour change in mothers with infants, who are heavily impacted by their social, physical and fiscal environments, thereby reducing their agency and resources available for providing opportunities for play, development and growth of their children. It was clear that this study's intervention was highly acceptable to the participants, however it is important that future interventions consider the feasibility issues discussed in this thesis before implementing a similar intervention, particularly if using a mobile app. With regards to health literacy, future interventions need to consider having a large enough "dosage" of information and content to see significant change over time.

7.4.4. Implications for policy or public health practitioners

One of the main themes that has emerged from this work is how an infant and their caregiver are part of a much larger environment which impacts the caregiver's ability to provide nurturing care. Therefore, focusing solely on the caregivers' individual capabilities and skills cannot ensure that the needs of infants and young children will be sufficiently met (24). In the FGDs with the CAG and intervention group mothers, the same theme was consistently discussed: the caregivers' significant need for more support from their family, friends, community and service providers.

At a facility level (e.g. primary health care clinics in Soweto), it is imperative that these findings are disseminated to the HCWs working with caregivers and new mothers, many of whom are caregivers themselves. While HCWs experience high volumes of patients, low resources and at times, burnout, there needs to be a collective effort supported by management and the DOH to encourage supportive and judgement free health care and advice to caregivers seeking more information. Providing empathic, patient centred care also needs to be incorporated into HCW training.

In South Africa, the Children's Act mandates various interventions which aim to support positive parenting (147). At a national level, the South African National Integrated ECD Policy (NIECD Policy) highlights the importance of parenting support as part of a comprehensive package of ECD services for young children (24). Therefore, in theory, there is sufficient focus on providing support to caregivers in the various policies which aim to encourage nurturing care in ECD environments. However, in practice there are barriers to implementation which need to be addressed before these policies can take full effect. For example, previous research in South Africa has shown that a lot of focus is on keeping children safe, which may result in harsh parenting practices instead of encouraging engagement in safe play as a family (24). Similarly, due to concerns around safety, most South African children play inside the house, where historically children played outside and were 'raised by the community' and relied less on adults to provide opportunities for play (24). This is further reiterated by the WHO's enabling environments for nurturing care framework (figure 25), which shows that by providing comprehensive support, through improving capabilities, empowering communities, providing supportive services and implementing enabling policies, only then will it be possible for caregivers to provide nurturing care for their young children (24) (75).



Figure 25: WHO enabling environments for nurturing care (24)

7.4.5. Implications for caregivers

A continuous theme that is often mentioned in the literature is the importance of providing maternal and child health services which are supportive, consistent, acceptable, appropriate and accessible to all individuals who need them, particularly in the South African public sector where this is often reported to not being the case. As many caregivers do not have high levels of health literacy, HCWs and ECD providers need to adapt their service provision to ensure that caregivers have reliable and simple information to promote growth and development in their infants. As supported in the 2025 Child Gauge, ECD policies need to be integrated across sectors to see meaningful changes in South African child health (24). While important advances have been made in encouraging nurturing care and support in the early years, the results of this thesis provide further practical examples of supporting caregivers e.g. making toys, encouraging active play in small spaces, in providing optimal care which will see positive results in the years to come.

7.5. Future research plans

One of the important findings from this thesis is that there is a need for a valid and reliable maternal health literacy questionnaire that can be used in low- and middle-income settings, with individuals who have lower functional literacy levels and where English is not the predominant first language. Similarly, the development of a measure determining an infant/ small child's opportunities (and barriers) for active play would also be of benefit within this same population group.

To create the health literacy questionnaire, we (the research team) will search the literature for all health literacy questionnaires validated for use with a) mothers and/or b) in low literate population and use similar questions to create our questionnaire. This will need to be checked by an expert in the field before piloting it ourselves (to check grammar, understanding of questions, etc.) (148). The questions will then be piloted with a sample from the target population, cleaned and entered into Stata where a Principal Component Analysis (PCA) can be done to determine which factors are being measured by the questions, after which these questions can be grouped together (148). The internal validity of the questions will be tested using Cronbach's Alpha. The questionnaire can then be piloted again to complete the validation process (148). A similar process will be used when creating an "opportunities for active play" score, however this may take a bit longer to refine as this is a fairly novel concept and there is limited literature to draw from.

7.6. Limitations

While the limitations of each component of the study have been discussed in detail, there are some limitations that are specific to this PhD in particular. The PLAY study was a complex intervention with many different components needing to be delivered/ administered at each study visit. Having two RAs working on each group would have allowed greater capacity to carry out all the intervention components and troubleshoot difficulties with accessing the app, etc., however the budget did not allow for further human resources to be added as the study progressed. Furthermore, I was unable to source salary support during my PhD, which would have allowed me to complete the PhD full time and to spend more

time in Johannesburg conducting data collection. However, due to COVID and my age, options for PhD funding were limited and I completed the PhD whilst working full time in Cape Town.

7.7. Personal Reflections

While a PhD is known to be a challenging experience, there are a number of personal lessons learned from the whole process. As I have not had a “linear” route to where I am now, before starting the PhD I was often despondent about my roles as research coordinator and manager, as they were seen as a means to an end, however when I started my PhD I realized that I had developed many skills required for managing a research project and this allowed me to focus primarily on the “academic” part of the research e.g. research analysis, writing, etc. This has helped me to “trust the process” more, knowing that all skills can be used at some point, even if you are not where you are wanting to be in your career at that very moment.

I have always had an interest in mobile health, as my main research interest started with finding out how to increase access to healthcare after seeing so many barriers in my clinical work in South Africa. However, this project gave me valuable insight and experience in what is feasible and acceptable in a low resource setting and digital health has now become one of my main focuses in my current role as a socio-behavioural researcher. Lastly, this project has provided experience in planning, executing and evaluating behaviour change interventions, something that I now routinely use in my current role, and presume will continue to use in my future work.

7.8. Conclusion

While using theory to plan and develop interventions is important, researchers should not underestimate the potential challenges faced during the implementation phase of the intervention. It is imperative for researchers conducting complex interventions to pilot and test an intervention with a participant group from the same context, to attempt to counteract issues around adherence, outcome measure tools, dosage and acceptability, prior to implementing an intervention. Lastly,

adequate budgeting for a study can be one of the key factors determining whether it is a success or failure. One can have a perfect plan, but without the required funding, this can impact data collection, findings and most importantly, the outcome in populations which would stand to benefit the most from the intervention.

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9. Appendices

Appendix A: PLAY Study Informed Consent Form (ICF)



V2.1 20/10/2022

Play Love And You (PLAY) Study: Information Sheet for Participants

Hello, my name is Dr Alessandra Prioreshi, and I am a Researcher in the Department of Paediatrics at the University of Witwatersrand. I work in the Developmental Pathways for Health Research Unit (DPHRU) at Chris Hani Baragwanath Academic Hospital. Together with other colleagues from the University, we are conducting research to support new mothers in caring for their babies. We are going to be providing support for breastfeeding, mental health, bonding with your baby, and playing with your baby so that your baby can grow and develop to their full potential.

Before you decide if you want to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is The PLAY Study?

The PLAY Study is a study designed to support women in Soweto with caring for their baby from when the baby is born, until they are 2 years old. The support we are providing is about being a mother and caring for your baby, helping your baby learn, breastfeeding, and your own mental health. The aim of The PLAY Study is to see if the support we provide to you can assist with your baby's growth and development.

What is involved if I decide to take part in The PLAY Study?

We will first ask you to finish reading this information sheet. If you are happy to participate in the research, we will ask you to sign a consent form.

There are two different programmes designed to support mothers in Soweto. Both programmes involve having regular (every 2 months) contact with our research team for one year in which you will receive information and material designed specifically to support mothers in Soweto. The material and the way this material is delivered to you will be different in the two groups.

Group A – will receive material through:

- face-to-face meetings when we first enroll you
- mobile phone conversations or home visits
- messages and referrals from a trained health helper.

Group B – will receive material through:

- face-to-face meetings when we first enroll you
- mobile phone conversations or home visits
- messages and referrals
- The PLAY Study mobile app
- in-person assessments from a trained health helper.

How will it be decided which group you go into?

You will randomly be placed in Group A or B and you will have an equal chance of going into Group A or Group B. You will not be able to decide which group you want to go into and will stay in the same group for the full study period. We will give each person a unique identifying number, and will use a computer system to randomly link your identifying numbers into either Group A or Group B.

What is involved for Group A and Group B?

For everyone (Group A and Group B)

- Everyone who enrolls in this study will receive the standard Road to Health booklet as well as the Side-by-Side services which are provided for all mothers who have had a baby, whether they are in the study or not.
- Additionally, a trained health helper will spend time explaining the Road-to-Health book to you and teach you about some of the important things to know as a new mother.
- You will also be contacted telephonically or in person every 2 months to check in on how you and baby are doing, and if you need extra support, you will be referred to the required health care facilities or available community services. We may also ask you some questions about you and your baby during these conversations.
- At 4 and 8 months we will measure your baby's movement and play, their growth, their development, and your interactions with your baby. We will also measure your physical activity, and your height and weight.
- You will be expected to fill in a few questionnaires and take measurements when you enroll in the study, after 12 months and again after 24 months.
- We will ask you if you are currently living with a family matriarch (mother, grandmother, mother-in-law, aunt or other influential maternal figure), and if so, if she would be interested in enrolling in our "Matriarch sub-study".

For Group B only

If you are assigned to Group B, you will additionally receive:

- Access to The PLAY Study mobile App which will provide you with information and resources to help you care for your baby and will allow you to communicate with us and receive extra information from us. This information

and the resources will be about breastfeeding, play and development, your mental health, and bonding with your baby.

- When we do your telephonic or in person check in every 2 months, we will provide you with more information and support. From 0-6 months this support will be about breastfeeding, and from 6-12 months this support will be about play, development, and bonding.
- At 4 and 8 months we will share the information with you about your baby's movement and play, their growth, their development, and your interactions with your baby, as well as your physical activity, and your height and weight. We will explain this information to you, as well as provide recommendation on how to improve bonding, growth, development, play, and physical activity.
- When we enroll you, we will ask you to fill out some questions to assess your mental health after having your baby. If you need further support, we will provide you with a free assessment with a trained counselling psychologist, who will support you and refer you if necessary.
- We will do an assessment on your baby once or twice in the first two months, and give you feedback on this and provide information to help you learn to communicate with your baby.

When and where will measurements take place?

Besides the programme material we will be providing you with, everyone will also have certain measurements done at the beginning of the study, after 6 months, after 12 months, and again after 24 months. When possible, we will come to do assessments at your home, or telephonically. For some measurements after 12 months and after 24 months, you may need to come to our offices (DPHRU) at the Baragwanath Hospital and you will always be reimbursed (R200 in cash) for your transport to our offices.

What measurements will be taken?

Basic measurements

When you join the study, and again after 12 and 24 months, we will be measuring your height and weight in a private setting. We will also measure your baby's weight and length and the circumference of their head and arms. This will take about 10 minutes. These measures will be repeated every 4 months.

Questionnaires

When you join the study, and again after 12 and 24 months, one of our interviewers will ask you a series of questions, which will take about 60 minutes to complete. These are the questionnaires we would like to go through with you:

- Questionnaires about your home environment
- Questionnaires about your general health

- Questionnaires about your mental health
- Questionnaires about food, and how you feed your baby
- Questionnaires about how confident you feel about looking after and breastfeeding your baby
- Questionnaires about sleep, screen time, activity and play
- Questionnaires about your health literacy
- Questionnaires about your baby's development

About 2- and 4 months after you join the study, one of our interviewers will phone you or visit you and ask you some questions. The questionnaires we would like to go through include:

- A questionnaire about how you feed your baby
- A questionnaire about how confident you feel about breastfeeding your baby
- A questionnaire about your baby's development

About 6-months after you join the study, one of our interviewers will phone or visit you and ask you some questions. The questionnaires we would like to go through include:

- A questionnaire about how you feed your baby
- A questionnaire about how confident you feel about breastfeeding your baby
- A questionnaire evaluating the breastfeeding support you received (if you were in Group B)
- A questionnaire about the support you received from your influential female family member
- A questionnaire about your mental health and bonding
- A questionnaire to assess your health literacy
- A questionnaire about your baby's play and development and your home environment

Headcam videos

After 4, 8, 12 and 24 months, we will ask you and your baby to wear a small camera on an elastic headband while at home together. You will be asked to take the cameras away with you for a week and use them at least 5 times for a few minutes each whilst interacting with your baby (playing or feeding). We will give you a sheet to record what days and times you used the cameras. We will then collect them back approximately one week later.

These cameras will record video footage which will be used to understand your behaviours when playing and interacting with your baby. We will watch the video second by second and record what is happening. We will always

use a study ID code when looking at your videos, and never your personal information (such as your name). We are only interested in looking at the behaviours between you and your baby and will ignore anything else.

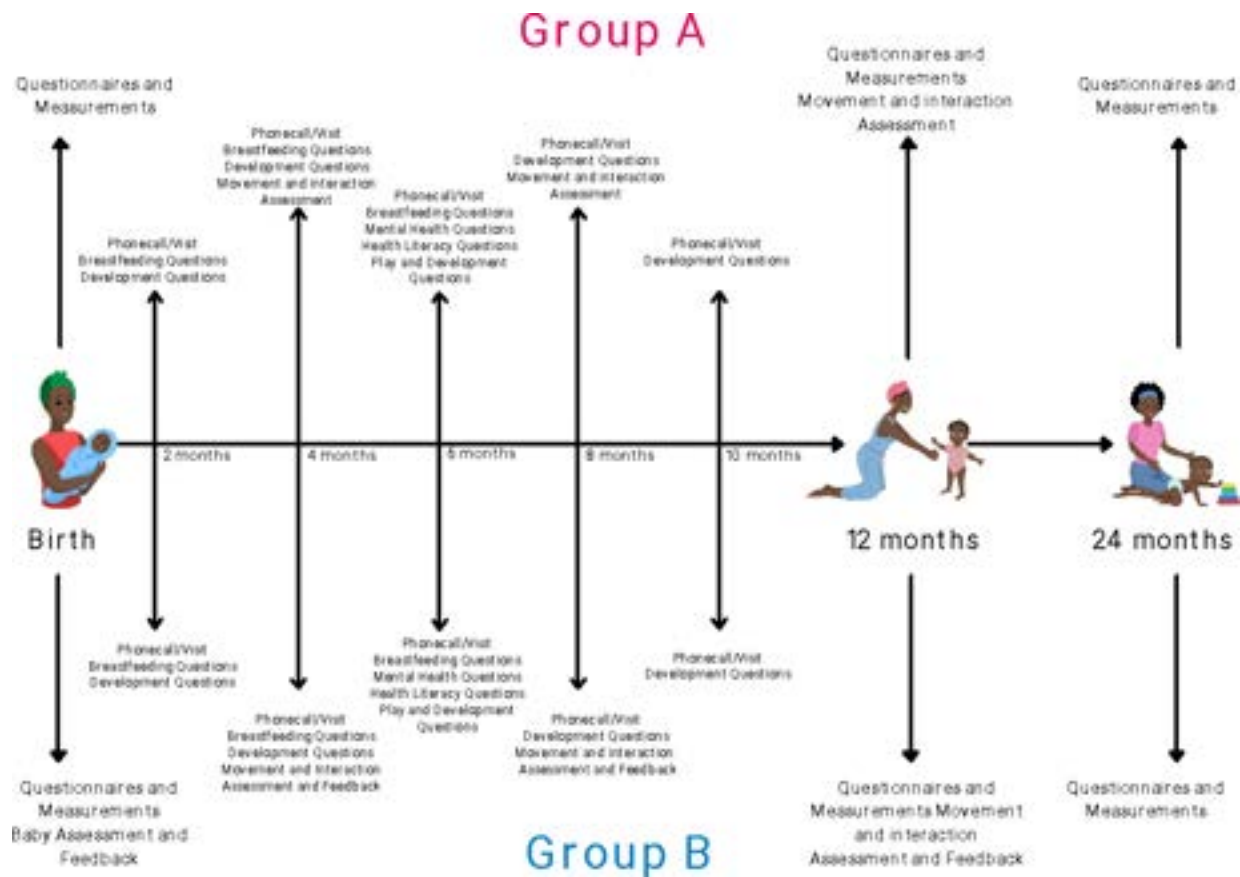
Play and physical activity

After 4, 8, 12 and 24 months, we will measure how much movement you and your baby do using a small device called an accelerometer. You will both wear the device on your wrist for one week, and then we will collect it from you. It will be placed within a strap to prevent swallowing and should not be removed for any reason. You will be asked to record any time that you remove the device.

Body composition

After 12 and 24 months, we will be measuring body fat, muscle and bone health on you and your baby using a special x-ray machine called DXA. The whole-body scan takes 10 minutes to complete and has very low radiation exposure and is not thought to cause any health risks. A trained technician will explain what you need to do during the procedure. Briefly, you will need to lie very still on a bed while your whole body is scanned. Before the scan you will be asked whether you are pregnant. If there is any possibility that you may be pregnant, please inform the technician so that we do not expose you to the scan. We have urine pregnancy tests available onsite to confirm pregnancy status.

To summarise when we will do questionnaires, measurements and assessments see the figure below:



What are the benefits of being involved in the study?

There is no direct benefit to you from participating in this study. This study will contribute to a better understanding of healthy childhood growth and development in South Africa and will help us understand how to help more babies and mothers in the future. There will be no financial compensation for your participation to the trial.

What are the risks of being involved in the study?

There is a small risk that your child may become upset by the head camera or by the device used to measure play. If this happens you can just remove the device. You can try again another day or simply return the devices to us. These devices are made of hard plastic and so there is a small risk of your child injuring themselves in some way. Although this is unlikely, we ask that you do not leave your child unattended with the devices.

Some of the questions may cause psychological distress. If this is noticed by the interviewer or if you report any experience of distress to us, you will be offered an appointment within the next week with a professional registered Psychologist at the research unit at Baragwanath hospital to receive counseling as required. The Psychologist will be able to talk to you to try to address the causes of your distress and has a network of referral bodies for further management of any issues that may arise. You will be free to choose not to respond to any questions, or to stop the interview at any time. The contact details

for the psychologist are as follows: Mrs Sarah Cantrell, Psychologist, Telephone number 0824649381 or by email at sarahcantrellphd@gmail.com.

Headcams, photos and videos:

Confidentiality cannot be completely maintained due to the nature of the photos, and headcam video recording. A number of preventative measures have thus been put in place to ensure that confidentiality is maintained as much as possible, and that you have complete control over your footage:

1. All photos and videos will be labelled using a study ID only, and the footage will only be used for the behaviour coding described in the methods.
2. You will be given the option to request that any portion of a recording (or an entire recording) or photo be deleted, and this will be done without investigators viewing the photo or video beforehand and without any question.
3. It is a possibility that other family members or visitors to the home may appear in the photos and footage. We ask that you alert any people in the home to the fact that you will be recording or taking photos at certain times, and obtain permission if family members may be in the room at the same time. If there are any other family members in the home who appear in any of the recordings, you will have the option to delete any portion of the video, or the entire video. If family members do not request their data to be deleted, we will still ignore any portions of video where they appear. All faces in photos will be blurred out. Recordings will only be done at home, and so external parties will not be recorded.
4. You will be able to take photos and turn the cameras on and off as you wish, and so you can choose when you would like to record or not.
5. The photos and videos are viewed on special software and the data is password protected, so that if devices are lost other people will not be able to view your videos.
6. Your images will not be published (unless separate consent is obtained).
7. The Principal Investigator will keep all footage, and de-linked files on a password protected computer and encrypted university server.

Do I have to participate in this study?

Participation in this study is completely voluntary, and lack of participation will not have any negative consequences. You can choose to not complete any activities and assessments, fill in any questionnaires or talk to anyone on the phone if it will make you feel uncomfortable. You are able to withdraw at any point during the study and without giving a reason. Withdrawing from the study at any stage will not affect the standard of care you receive from your clinic or hospital.

Will I be paid to take part in this study?

You will not be paid to be part of this study, however we will provide you with R200 in cash to cover your transport expenses for your travel to the research unit when we ask you to come in for a visit.

Will my taking part in this study be kept confidential?

Personal information will be handled with strictest confidentiality. For this study we may be making video recordings, as mentioned above and we ask that you only use the cameras in your own home and when only your immediate family is present. This will prevent us seeing anyone who has not consented to be involved. As part of the consent process, we will ask your permission to record yourself, and your child. As soon as the cameras are returned to us the recordings matching the dates and times on your schedule will be downloaded and stored securely, the camera footage will then be erased to protect confidentiality. The videos can only be viewed using special software, so if you do lose your cameras other people would not be able to view the footage.

Your video recordings will be seen by the researcher who will code what they see; this researcher will have no other information about you while they are coding. All information will be identified by your unique code at all times. There may be more than one researcher viewing different videos from you. We also need to send the videos to our study partners in the United Kingdom for coding. These videos will be sent in a protected format, or hand delivered, and will always be anonymous using only your unique study ID. All researchers are bound by ethical guidelines when analysing your videos and will not break your confidentiality.

Data sharing

The data that we collect as part of this study may be shared with other researchers, including researchers in the United Kingdom, for analysis of the data. In all cases, confidentiality will be maintained as per the processes outlined in this information sheet. All of your data will be anonymous except for the video data, which will show your face and your baby's face but will not be linked to your name or other personal details. All data we collect from you is stored with a unique ID number. Researchers do not need, and will never be given access to your name, address or date of birth. We will never share your details with anyone else except in exceptional circumstances where we feel there is a risk to the safety of your child or someone related to them. We are required by law to report any instance of child abuse which may come to our attention to the authorities.

What if I change my mind?

Participating in this study is entirely voluntary. You may change your mind about taking part in this study at any point in time. If you change your mind, you must contact the research staff to let them know that you no longer want to participate in the study. Changing your mind and withdrawing from the study will not affect the standard of care you receive at your hospital or clinic.

What will happen with the results of this study?

The results of this study will be published in medical journals and may be presented at scientific meetings. You may also view the results of this study on our website after the study is finished (www.theplaystudy.co.za). No individuals will be specifically identified in any one of our publications or in any one of our presentations. Upon completion, we will be pleased to provide a summary of the study results on request, free of charge.

Who has reviewed this study?

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee"). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Dr Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

If you are happy to take part in the study, please read and sign the attached consent form. Thank you for your time and attention.

Kind regards

Dr Alessandra Prioreshi February 2022



University of the Witwatersrand, Johannesburg

Developmental Pathways for Health Research Unit

Department of Paediatrics and Child Health

Play and Love in the eArly Years (PLAY): Information Sheet for the Community Advisory Group
(Mothers)

Hello, my name is Dr Alessandra Prioreschi, and I am a Researcher in the Department of Pediatrics at the University of Witwatersrand. Together with other colleagues from the University we are conducting research to understand how to support mothers in caring for their babies. We are interested in understanding what the home environment is like in Soweto, who helps look after babies, and how we can support mothers in breastfeeding, and teaching them how to play and bond with their babies.

We would like to invite you to be part of this study because

- a) you have a baby aged between 0 months and 3 months
- b) you are a Soweto community member
- c) you are the primary caregiver for your baby

What is involved in the study?

If you are happy to participate in the research we will first ask you to read this information sheet and sign the consent form. You will then become one of our Community Advisors!

In the first month

At first, you will be invited to take part in a small discussion with the other Community Advisors (12-15 mothers from Soweto) to answer some questions and discuss your ideas about parenting in Soweto. These discussions will take place at the DPHRU research unit, within Baragwanath Hospital. This first discussion session should not last longer than two hours.

In months 2-4

We will then use the information you give us to design a study to help women in Soweto with breastfeeding, and caring for their baby. Once we have designed the study (about 2 months later), we would like to speak with you again and show you what we have developed, and get your feedback on whether you think it is helpful, and whether you think it will work. Your advice will be important for us to get the study right, and make sure we can help other mothers like you! We may ask you to test out some of the tools, either by using them with us at DPHRU, or taking the tools home to use with your baby.

Months 6-24

After we have agreed on the study, you may also be asked to attend more of these sessions over the course of the next 2 years as our study continues, so that we keep developing tools that will be useful for mothers as their babies (and yours) get older.

Benefits:

There is no direct benefit to you from participating in the study. You will, however, contribute to what we know about caring for, playing with and breastfeeding infants and toddlers, and how we may be able to help improve these behaviours in the Soweto community.

Risks:

Our discussions will be audio recorded so that we can transcribe your responses in your own words. Therefore, your information and feelings shared will not be anonymous at first; However the tapes will only be heard by the researchers, and only for the purposes of this study, and will be kept in the strictest confidence. The recordings will be stored on the researcher's computer (password protected) and destroyed after five years following the completion of the project. Direct quotes from you may be used in a published paper, however, your name and other identifying information will always be kept anonymous.

Some of the questions may cause psychological distress. If this is noticed by the interviewer or reported to us by yourself, we will assign you an appointment within the next week with a professional registered nurse at the research unit at Baragwanath hospital in order to receive counseling as required. The registered nurse has more than 15 years of experience in research and counselling, and also has a network of referral bodies for further management of any issues that may arise. You will be free to choose not to respond to any questions, or to stop the interview at any time.

Participation is voluntary:

Participation in this study is completely voluntary, and lack of participation will not have any negative consequences. You can choose not to answer any question(s) which make you feel uncomfortable. You are able to withdraw at any point during the study.

Reimbursement:

You will not be paid to be part of this study, however we will provide you with R200 to cover your transport expenses for your travel to the research unit.

Confidentiality:

Personal information will be handled with strictest confidentiality. Due to the nature of these interviews, it is not possible to keep your responses completely anonymous when analysing the results. The note-takers and interviewers will be present in the focus group, and a research assistant will transcribe the information from the voice recordings and notes taken. We will use the name you give us for our own notes, and your voice will appear on our recording, but only the research team has access to these notes and recordings. We like to record because we can't write fast enough to capture the whole conversation. In our analysis, we give each person a number that is in no way linked to your name. We are only looking at general trends, and we will not be reporting on or publishing about individual opinions. Your answers will therefore be linked to your name (first name only), but only the researchers and the research team will have access to this data. If results are published, they will not include any names or personal details that can lead to individual identification, and all published data will be completely anonymous.

Further information:

If you require any further information or have any questions/complaints about the study please contact the Human Ethics Committee of Witwatersrand 011 717 71234 or zanele.ndolvu@wits.ac.za

If you are happy to take part in the study please read and sign the attached consent form and we will commence with the questions.

Thank you for your time and attention

Kind regards

Dr Alessandra Prioreshi

Appendix C: CAG Focus Group Discussion Guide



Play and Love in the eArly Years (PLAY) Study

Focus group discussion guide: Development & Co-Design Phase

Purpose of the focus group:

To explore how mothers in Soweto, South Africa, feel about and experience playing, caring for and breastfeeding their infants and young children, and what they feel would be important to consider when planning and developing an intervention to support mothers in playing with, caring for and breastfeeding their babies.

Date: _____ Starting Time: _____ Ending Time: _____

Please fill out and attach the participant register.

Name of Facilitator: _____

Name of Note Taker: _____

Name of Observer: _____

DIRECTIONS: The qualitative focus group begins with open-ended questions that point to starting a dialogue. The interviewer should encourage the study participants to do most of the talking but should use the questions listed here as a guide. After you ask each question, wait for the study participants to respond and go on to the next question when you are satisfied with the answer. If it seems as though the study participants did not understand a question, then repeat it or ask it in another way. If the study participants go on talking without much prompting, then let them guide the conversation. Bold indicates major questions and probes are in parentheses or listed below. Mentally check off these questions as they are asked so you do not repeat a question if it has been discussed previously.

Remember to audio record each focus group. Use a backup recorder to prevent technological problems.

Note to the Facilitator:

Introduce yourself at the beginning of the session, explain who you work with, why you are here, and introduce everyone on the team who is with you observing, taking notes, or helping in anyway.

Introduction: Hello, my name is _____. I am working with researchers at the Developmental Pathways to Health Research Unit (DPHRU) to develop a study on caregiver-infant interactions and the influences on infant movement, play and feeding, as well as growth and development. We are interested in getting your views on caring for, playing with and feeding your babies. We would like to ask you some questions about your experiences and an intervention that may support you. This should not take more than one hour. Do not worry; there are NO right or wrong answers. Your experiences and ideas are very important to us and you should feel free to express whatever you are thinking. Your responses are confidential and will not be shared outside of this group. Please feel free to ask for clarification if you do not understand a question

(Introduce the others on the team) Do we have your permission to continue?

Note to Note-Taker: Try to capture the major ideas and always note the specific question that the facilitator and participants are referring to. If the facilitator asks a question that is not on the guide, note the question as it is asked and try to capture the answers.

Play/ development

1. What are your perspectives and experiences of play, feeding and bonding
2. What are the barriers and/ or opportunities for play in home environment (social/ physical/ resources, etc)
3. Can you provide a description of a 'day in the life'/ your routines/ normal activities with your child
4. What is your understanding and/ or questions around play and development

Feeding

1. How do you feel about Breastfeeding? / what has your experience around breastfeeding been?
2. What experiences / difficulties / challenges in your daily life do you experience that complicate breastfeeding?
3. Who do you ask for advice when it comes to breastfeeding your baby? / Who supports you with your breastfeeding related questions?
4. What role do you think breastfeeding plays in the growth and development of your baby?

5. What kind of advice / information have you heard about Breastfeeding?
6. Do you have any experiences you'd like to express or questions to ask about breastfeeding?

Intervention

We would like to develop an app-based intervention to support you with caring for, playing with and feeding your baby.

1. When it comes to playing with, caring for and feeding your child, what information do you feel should be included?
2. What information would you benefit from/ What information would you find helpful?
3. How would you like information to be presented to you?
 - Videos?
 - Alerts?

Acceptability and feasibility of using the Intervention:

1. How was your experience of using the Intervention tool(s) / app?
2. What did you like about the intervention tool(s)? What did you not like?
3. What made the tool(s) easy to use? What did you find difficult?
4. What about the tool helped and/or made it difficult for you to understand when it should be used?
5. What in the content/ information did you find was helpful to you? What wasn't helpful?
6. What information do you think should be added to the intervention tool(s) and what do you think should be taken out?

Methodology tools

We would like you to use different ways of finding out information and would like to know what works best

1. What did you like/ not like about this tool?
2. Tell us about your experience using it

2

Final questions/comments:

1. Are there any other experiences or feelings that you would like to express about the intervention tool(s) / app or their use?
2. Do you have any other questions you would like to ask us?

Appendix D: CAG Acceptability Questionnaire



Acceptability Questionnaire (CAG) (Telephonic)

CAG Participant ID: _____

Date: _____

Age of child: _____

In your last Focus Group Discussion, you were asked to go home and play some of the games and make a sensory square and/or the shaker, which were discussed in the group.

We are going to ask you a few questions about your experience at home. There is no right or wrong answer and it's fine if you didn't manage to do as much as you would have liked but please do be as honest as possible as your answers will help us to make the activities as easy as possible to use with other mothers in future.

1. Which of the activities did you manage to do at home?	
1.a. Sensory Square	Yes/ no
1.b. Shaker	Yes/no
1.c. Game 1 – whisper a secret	Yes/no
1.d. Game 2 – touch and tickle	Yes/no
1.e. Game 3 – rolling around	Yes/no
1.f. Game 4 – shake some noise	Yes/no
1.g. Game 5 – trying new smells	Yes/no
2. If no to all above, why?	

GAMES QUESTIONS					
3. Did you and your baby enjoy engaging in the games? a. What did you like about them? b. What did you not like about them?	<table border="1"> <tr> <td>yes</td> <td>no</td> </tr> </table>	yes	no		
yes	no				
4. Did you find the games difficult or easy to do? a. Please explain	<table border="1"> <tr> <td>yes</td> <td>no</td> </tr> </table>	yes	no		
yes	no				
5. Did you understand how to do the games? a. Were the instructions clear? i. b. If no, was there anything else that could have been added to make it easier?	<table border="1"> <tr> <td>yes</td> <td>no</td> </tr> </table> <table border="1"> <tr> <td>yes</td> <td>no</td> </tr> </table>	yes	no	yes	no
yes	no				
yes	no				
6. Did you have enough time to fit them into your schedule? a. If no, can explain what made it difficult to find time to do it? b. What would help to remind you or help you find time to include the games in your day?	<table border="1"> <tr> <td>yes</td> <td>no</td> </tr> </table>	yes	no		
yes	no				

7. Do you think the games are beneficial for you and the baby?	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center; padding: 2px 10px;">yes</td> <td style="width: 50%; text-align: center; padding: 2px 10px;">no</td> </tr> </table>	yes	no		
yes	no				
a. Why?					
8. Were you confident that you knew how to do the activity and were doing it correctly?	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center; padding: 2px 10px;">yes</td> <td style="width: 50%; text-align: center; padding: 2px 10px;">no</td> </tr> </table>	yes	no		
yes	no				
a. How do you think you could become more confident in it?					
SENSORY SQUARE + SHAKER QUESTIONS					
9.a. What did you like about the square and/or shaker?					
9.b. What did you not like about them?					
10.a. How easy was it to find the resources that you needed to make it, in your house (or from a friend/ family member)?					
<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td style="width: 25%; padding: 2px 10px;">Very easy</td> <td style="width: 25%; padding: 2px 10px;">Easy</td> <td style="width: 25%; padding: 2px 10px;">Difficult</td> <td style="width: 25%; padding: 2px 10px;">Very difficult</td> </tr> </table>		Very easy	Easy	Difficult	Very difficult
Very easy	Easy	Difficult	Very difficult		
10.b. Did you have to buy any of the resources?	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center; padding: 2px 10px;">yes</td> <td style="width: 50%; text-align: center; padding: 2px 10px;">no</td> </tr> </table>	yes	no		
yes	no				

10.c. If yes, what did you buy?			
11.a. Were the toys easy to make?			
<table border="1"> <tr> <td>yes</td> <td>no</td> </tr> </table>		yes	no
yes	no		
11.b. Did you prefer having the video or watching someone show you how to make them in person?			
<table border="1"> <tr> <td>In person</td> <td>video</td> </tr> </table>		In person	video
In person	video		
11.c. Why?			
12.a. Did the toy-making take up a lot of your time?			
<table border="1"> <tr> <td>yes</td> <td>no</td> </tr> </table>		yes	no
yes	no		
12.b. If yes, why do you think it did?			
13. How often would you like us to send instructions to make a new toy?			
14. Do you have any other comments/ suggestions about any of the activities we asked you to do at home?			

Thank you for your time.

Appendix E: 12 Month Focus Group Discussion guide



Focus group discussion guide: Intervention Feasibility

Purpose of the focus group:

To further explore the feasibility of the PLAY study intervention with mothers in the PLAY study intervention group.

Date: _____

Starting Time: _____ Ending Time: _____

Please fill out and attach the participant register.

Name of Facilitator:

Name of Note Taker:

Name of Observer:

DIRECTIONS: The qualitative focus group begins with open-ended questions that point to starting a dialogue. The interviewer should encourage the study participants to do most of the talking but should use the questions listed here as a guide. After you ask each question, wait for the study participants to respond and go on to the next question when you are satisfied with the answer. If it seems as though the study participants did not understand a question, then repeat it or ask it in another way. If the study participants go on talking without much prompting, then let them guide the conversation. Bold indicates major questions and probes are in parentheses or listed below. Mentally check off these questions as they are asked so you do not repeat a question if it has been discussed previously.

Remember to audio record each focus group. Use a backup recorder to prevent technological problems.

Note to the Facilitator:

Introduce yourself at the beginning of the session, explain who you work with, why you are here, and introduce everyone on the team who is with you observing, taking notes, or helping in any way.

Introduction: Hello, my name is _____. I am working with researchers at the Developmental Pathways to Health Research Unit (DPHRU) , as you will know, are carrying out a study on caregiver-infant interactions and the influences on infant movement, play and feeding, as well as growth and development. You would have been asked to complete a questionnaire recently about your thoughts on the study intervention. This group is to discuss those questions further so that we can fully understand your experience of using the intervention content.

This should not take more than one hour. Do not worry; there are NO right or wrong answers. Your experiences and ideas are very important to us and you should feel free to express whatever you are thinking. Your responses are confidential and will not be shared outside of this group. Please feel free to ask for clarification if you do not understand a question

(Introduce the others on the team) Do we have your permission to continue?

Note to Note-Taker: Try to capture the major ideas and always note the specific question that the facilitator and participants are referring to. If the facilitator asks a question that is not on the guide, note the question as it is asked and try to capture the answers.

Question guide (based on findings from 12 month acceptability questionnaire):

App:

- How much time did it take to look at the info on the app? If it did take a long time, why do you think so? (e.g. too much info, was too busy, etc)
- How would you describe your experience of working with the study team?

- Were staff knowledgeable about play and development?
- Could they explain the content?
- Did this impact their implementation of the content?
- Were they respectful, friendly, non-judgemental, did you feel valued?
- Did they explain all info?
- did they listen, answered questions?
- were they caring?
- explained in your language?
- Many said that you liked looking at and reading the play and development information on the app – can you tell me a bit more what you liked about it? What did you not like about it?
- In the questionnaire, many said that you liked speaking to the team over the phone or at the visits about play and development, can you tell us why you preferred speaking in person?
- Explore likes and dislikes of 1)infographics, 2) videos and 3) in person
- Many of you said that you thought the information was relevant to mothers in Soweto? Is there any info that you think wasn't relevant? (scroll through app) Was there any information that you didn't understand?
- Is there any of the information that you read or looked at and thought that you didn't really agree with?
- Is there any other information that wasn't provided that you think should have been provided? If so, what was missing?

Play & Development specific questions:

- Did you find it took effort to look at the play & Development videos and read the information on the app?
 - What about talking to the study team? Did this take effort?
- What were the benefits of reading the info or looking at the videos?
 - What did you learn?
- How did the information on the app impact on how you played with your baby?

- How did the information on the app affect your confidence as a mother?
 - How did the information on the app affect your confidence in helping your baby to develop?
- How often did you use the information that you read or watched?
- How did watching or reading the information on the app affect your day?

Feedback:

- What did you like or dislike about receiving feedback on yours and your baby's movement?
- What did you like or dislike about receiving feedback on yours and your baby's videos?
- How did you find the experience of wearing the accelerometer for measuring movement for you and your baby?
- How did you find the experience of wearing the video cameras while playing with your baby?
- Were you able to play naturally with your child when wearing the cameras?
- What were your thoughts about the information you got while receiving the feedback?
- How did you feel watching the videos of you and your baby?
- How did you feel seeing the graphs of yours and your baby's movement?
- How did the feedback you received affect your confidence as a mother?
- How did the feedback you received change the way you play or interact with your baby?

Mental Health:

- Did you feel your mental health was supported during this study? In what way?
- How did this support impact your experience of being a mother?
- How did this support impact your confidence as a mother?
- If you received support around your mental health (a phonecall, a flyer or a

referral), how did you feel about this support?

- What made it difficult to engage with the mental health support you received?
- What made it easy to engage with the mental health support you received?

Appendix G: 12 Month Feasibility Questionnaire



Feasibility Questionnaire (Intervention group)

CAG Participant ID: _____

Date: _____

Child DOB: _____

Access to intervention content	
Average number of monthly app logins	
Number of telephonic interviews over 12 months	

Feedback from Participants (Telephonic)

We are going to ask you a few questions about your experience of using the PLAY study app and using the activities to play with your child. There is no right or wrong answer, we would just like to know what worked and didn't work as well as expected.

Access to intervention content			
1.	Did you login to the app at least once?	Yes	No
2.	Did you participate in one or more telephone calls?	Yes	No
3.	Did you understand the activity instructions?	Yes	No
	Please explain:		
4.	Was there anything that made it difficult to get onto or use the app?	Yes	No
	Please explain:		

5.	Do you have any more comments/ suggestions about using the app?		
Participation in intervention			
6.	How often did you do the suggested activities (choose below)?		
	always	often	sometimes
7.	Did you have enough time to do the activities?	yes	no
8	If you answered 'no' to Q7, please explain what made it difficult to find time?		
9	Did you have enough space at home to complete the activities?	yes	no
10	If you answered 'no' to Q9, please explain what made it difficult about your space at home to engage in the activities?		
11.	Were there any other factors which made it difficult to complete the activities?	yes	no
12	If you answered 'yes' to Q11, please explain further:		
13	Did you find that you already had some resources at home that helped you to participate in the activities?	yes	no
	If you answered 'yes' to Q13 please explain what you had at home:		

Intervention impact			
14	Do you think the intervention content helped you to understand more about play and development with your baby	yes	no
15	Could you explain more about why you answered yes or no in Q14?		
16	Did the content help you to make changes in your home to play more with your child?	yes	no
17	If you answered 'yes' to Q16, could you explain how it helped and what changes you made?		
18	If you have any suggestions/ comments about the app or content based on your experience, please write them below:		

Thank you for your time.

Appendix H: Parent Health Literacy Questionnaire (HLQ)

Participant ID

Understanding Health and Healthcare Questionnaire

Thank you for taking the time to complete this questionnaire. We hope the results will help us to improve the way we provide care for our community.

We want to learn about how you find, understand and use health information regarding your child's health, and how you manage your health and interact with doctors and other healthcare workers.

In this questionnaire, the term **healthcare providers** means doctors, nurses, physiotherapists, dieticians and any other health worker you seek advice or treatment from.

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Information about this questionnaire and how to fill it in

This questionnaire contains two parts.

In **Part 1** you are asked to indicate how strongly you **disagree** or **agree** with a set of statements.

In **Part 2** you are asked to indicate how **difficult** or **easy** you find a set of tasks. For each statement or task check the box that **best describes you now**.

Please ensure that you **check a box** for **every** statement or task.

An example



Strongly disagree
Disagree
Agree
Strongly agree

1. The Earth is flat

Ms Jane Citizen has indicated that she **strongly disagrees** with this statement.

Part 1 of the questionnaire starts here

Please indicate how strongly you **disagree** or **agree** with each of the following statements. Remember to check only **one** box for each statement.

Check a box by crossing it like this:



- | | | |
|---|--|---|
| 1 | I feel I have good information about my child's health | ☐ ☐ ☐ ☐ |
| 2 | I have at least one healthcare provider who knows my child well. | ☐ ☐ ☐ ☐ |
| 3 | I can get access to several people who understand and support me | ☐ ☐ ☐ ☐ |
| 4 | I compare health information from different sources | ☐ ☐ ☐ ☐ |
| 5 | When my child is ill, the people around me really understand what I am going through | ☐ ☐ ☐ ☐ |
| 6 | I spend quite a lot of time actively managing my child's health | ☐ ☐ ☐ ☐ |
| 7 | When I see new information about health, I check up on whether it is true or not | ☐ ☐ ☐ ☐ |
-

Part 1 continued

Please indicate how strongly you **disagree** or **agree** with each of the following statements. Remember to check only **one** box for each statement.

		Strongly disagree	Disagree	Agree	Strongly agree
8	I have at least one healthcare provider I can discuss my child's health problems with	☐	☐	☐	☐
9	I make plans for what I need to do to for my child to be healthy	☐	☐	☐	☐
10	I have enough information to help me deal with my child's health problems	☐	☐	☐	☐
11	If I need help, I have plenty of people I can rely on	☐	☐	☐	☐
12	I always compare health information from different sources and decide what is best for my child	☐	☐	☐	☐
13	Despite other things in my life, I make time to keep my child healthy	☐	☐	☐	☐
14	I am sure I have all the information I need to manage my child's health effectively	☐	☐	☐	☐
15	I have at least one person who can come with me to my child's medical appointments	☐	☐	☐	☐
16	I know how to find out if the health information I receive is right or not	☐	☐	☐	☐
17	I have the healthcare providers I need to help me work out what I need to do	☐	☐	☐	☐
18	I set goals for my child's health	☐	☐	☐	☐
19	I have strong support from family or friends	☐	☐	☐	☐
20	I ask healthcare providers about the quality of the health information I find	☐	☐	☐	☐
21	There are things that I do regularly to improve my child's health	☐	☐	☐	☐
22	I can rely on at least one healthcare provider	☐	☐	☐	☐
23	I have all the information I need to look after my child's health	☐	☐	☐	☐

Please continue to the next page.

Part 2 of the questionnaire starts here

Please indicate how **difficult** or **easy** the following tasks are for you **now**. Remember to check only **one** box for each statement.

Check a box by crossing it like this: 

		Cannot do or always difficult	Usually difficult	Sometimes difficult	Usually easy	Always easy
1	Find the right health care	☐	☐	☐	☐	☐
2	Make sure that the healthcare providers understand your child's problems properly	☐	☐	☐	☐	☐
3	Find information about health problems	☐	☐	☐	☐	☐
4	Feel able to discuss your concerns about your child's health with a healthcare provider	☐	☐	☐	☐	☐
5	Confidently fill medical forms in the correct way	☐	☐	☐	☐	☐
6	Find health information from several different places	☐	☐	☐	☐	☐
7	Have good discussions about your child's health with doctors	☐	☐	☐	☐	☐
8	Get to see the healthcare providers your child needs	☐	☐	☐	☐	☐
9	Accurately follow instructions from healthcare providers	☐	☐	☐	☐	☐
10	Get information about health so you are up to date with the best information	☐	☐	☐	☐	☐
11	Decide which healthcare provider your child needs to see	☐	☐	☐	☐	☐
12	Read and understand written health information	☐	☐	☐	☐	☐

1 Make sure you find the right place to get the healthcare your child needs

□ □ □ □

3

Part 2 continued

Please indicate how **difficult** or **easy** the following tasks are for you now. Remember to check only **one** box for each statement.

		<i>Cannot do or always difficult</i>	<i>Usually difficult</i>	<i>Sometimes difficult</i>	<i>Usually easy</i>	<i>Always easy</i>
1	Get health information in words you understand	☐	☐	☐	☐	☐
4						
1	Discuss things with healthcare providers until you understand all of what your child	☐	☐	☐	☐	☐
5	needs					
1	Find out which healthcare services your child is entitled to	☐	☐	☐	☐	☐
6						
1	Read and understand all the information on medication labels	☐	☐	☐	☐	☐
7						
1	Get health information by yourself	☐	☐	☐	☐	☐
8						
1	Work out what the best care is for your child	☐	☐	☐	☐	☐
9						
2	Ask healthcare providers questions to get the health information you need	☐	☐	☐	☐	☐
0						
2	Understand what healthcare providers are asking you to do	☐	☐	☐	☐	☐
1						

Thank you for completing this questionnaire.

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Appendix I: Maternal Beliefs Questionnaire – 6 & 12 months

MATERNAL BELIEFS QUESTIONNAIRE

The following instructions were used for each of the questions:

Any questions that start with a C6: (e.g. C6b) “The following statements ask about your views regarding babies’ and toddlers’ (0-2 years of age) physical activity. Please indicate how much you agree or disagree with each statement by ticking one response for each statement.”

Any questions that start with a C9 (e.g. C9j): “The statements below ask about your views on a number of things around children’s activities. Please indicate how much you agree or disagree with the statements by ticking one response for each statement.”

Any questions that start with a C7 (e.g. C7b): “The following questions ask about what you think will happen with your baby’s play time in the coming months. Please indicate how much you agree or disagree with the statements by ticking one response for each statement.”

Any questions that start with a B9 (e.g. B9k): How confident are you that you will be able to do the following things with your baby over the next year? (Please *tick one response for each statement*)

Scale for all the above items:

Strongly agree (0), agree (1), disagree (2), strongly disagree (3)

Factor		Score
Physical activity knowledge	C6b- Physical activity is important for babies’ and toddlers’ health and the way they grow and learn	
	C6c- Parents need to make their babies and toddlers be active	
	C6d- Babies need some planned moving and playing every day	
	C6e- Parents need to help and make sure their babies explore the space around them	
	C6f- The time babies are in places that do not let them move properly should be little	
	C6g- Babies and toddlers need a safe space where they can move freely and explore	
	C6h- Babies need to be active and move so that they can learn skills like crawling and walking	

	C9j- The toys and games I give my baby to play with will affect his/her learning movements and being active in the future	
	C9l- Babies are more likely to enjoy sports and active play if they see their parents doing them	
	C9m- Babies need help and encouragement to be active	
Views on physical activity	C9d- I don't know what activities and games I should play with my baby to help his/her learning and growth	
	C9e- An active baby would be too difficult for me to manage	
	C9f- I think it's safer for my baby to be kept in a highchair/play area/baby chair than on the floor	
	C9g- A calm baby that does not move a lot would be easier to look after than an active one that moves a lot	
Physical activity optimism	C7b- I think that my baby will be naturally active and move a lot	
	C7f- I think it will be easy for my baby to get plenty of playing and moving time every day	
	C7g- Overall, I think my baby will have plenty of chances to be active and move enough for healthy growth, learning and development	
Future expectations	C7o- I think that when s/he is older, my baby will have similar activity/exercise levels to my own	
	C7p- I think that when s/he is older, my baby will watch similar amounts of TV to me	
Floor play concerns	C9a- I am worried that my baby might hurt him/herself if I leave him/her lying on the floor	
	C9b- I am worried that my baby will get too tired and fret if I leave him/her lying on the floor	
Self-efficacy for physical activity	B9k- Provide my baby with a lot of movement and playing options over the next year	
	B9l- Get my baby to do enough movement and playing to be healthy over the next year	
	B9n- Play with my baby	

Appendix J: Affordances in the Home Environment for Motor Development Infant Scale (AHEMDS-IS) – 3-18 months



Note: Validation (for research purposes) and development of a scoring system for the AHEMDS-IS is currently in progress. However, the instrument in its current form is quite useful for individual home assessment.

AHEMD affordances in the home environment for motor development INFANT SCALE Questionnaire (3 – 18 months)

Dear Parents (Guardians),

This questionnaire has been developed to evaluate the opportunities for motor development (movement and play) that your family and home environment make available for your baby. Because you know your baby very well, you are the best person to provide this kind of information.

It is important that you fill out the questionnaire as accurately as possible, thinking about what you have available, such as toys, or what happens in your home to encourage your baby's movement and play. We hope that information from this questionnaire helps you learn to stimulate the development of your baby.

The questionnaire is composed of an initial section with questions about your baby and your family, followed by three sections that address: Physical Space in the Home, Daily Activities, and Play Materials.

Instructions: Read each question carefully and mark the box that best reflects your answer:

I. PHYSICAL SPACE OUTSIDE AND INSIDE		YES	NO
1.	OUTSIDE your home is there a <i>safe, adequate, and large</i> space for your child to play and move freely (crawl, walk, roll)? (<i>backyard, front yard, garden, playground, etc.</i>)	☐	☐

If you answered YES please proceed with the next set of questions, if you answered NO, go to question number 6.

In this **OUTSIDE SPACE**, is there...

		YES	NO
2.	More than one type of ground texture? (<i>grass, dirt, concrete, wood, sand, etc.</i>)	☐	☐
3.	One or more sloped surfaces? (<i>varied degrees and types of inclines or gradual slopes, i.e. ramps, angles, slides</i>)	☐	☐
4.	Any type of equipment in which your child can pull herself/himself up to a standing position and/or walk? (<i>gate/fence, tables, bench/chairs, blocks, cubby house, toddler plastic steps, etc.</i>)	☐	☐
5.	Steps or stairs? (<i>e.g. steps to front or back door, steps up a slide</i>)	☐	☐

In your home's **INSIDE SPACE**, is there...

		YES	NO
6.	Enough space for your child to play or move around freely?	☐	☐
7.	More than one type of floor texture? (<i>carpet, wood, tile, linoleum, etc.</i>)	☐	☐

8.	Any furniture or equipment for your child to pull up to a standing position and/or walk? (<i>table, chair, couch, objects, etc.</i>)	☐	☐
9.	Steps or stairs?	☐	☐
10.	A special place for toys where your child can choose what to play with and get it without help? (<i>toy bins, drawers, boxes, shelves</i>)	☐	☐

DAILY ACTIVITIES

During the day - but ONLY referring to the time spent in your home:

YES NO

11.	My/Our child regularly (at least twice a week) plays with other children.	☐	☐
12.	I/We usually have a daily time for playing (interacting) with our child.	☐	☐
13.	My/Our child regularly (at least twice a week) plays (interacts) with adults, other than the parent(s).	☐	☐
14.	I/We regularly (at least twice a week) play games with my/our child to practice learning about body parts. (<i>e.g., where is your hand?</i>)	☐	☐
15.	I/We regularly (at least twice a week) play games with my/our child to practice movements, such as "clap hands", "wave", "crawl", "walk", etc.	☐	☐

PLAY MATERIALS

Instructions:

With each toy group listed below, please check the box for the number of equal or SIMILAR toys you use in your house to play with your baby.

Please read each group's general description carefully before deciding if you have this type of toy.

14. Toys suspended above or to the side of the baby, mobiles, ornaments.

Examples are:



How many of these toys do you use to play with your baby at home?

None ☐ One - two ☐ Three - four ☐ Five or more ☐

15. Hand (graspable) toys: simple rattles, mouthable toys (teethers), graspable mirrors, cars

Examples are:



How many of these toys do you use to play with your baby at home?

None ☐

One - two ☐

Three - four ☐

Five or more ☐

16. Stuffed toys, squeeze-squeak toys, cloth toys, water (floating, sponges) toys.

Examples are:



How many of these toys do you use to play with your baby at home?

None ☐

One - two ☐

Three - four ☐

Five or more ☐

17.. Infant swings, seats,, johnny jumpers.

Examples are:



How many of these toys do you use to play with your baby at home?

None ☐

One - two ☐

Three - four ☐

Five or more ☐

18. Educational toys e.g. pop-up, spinning toys., blocks, balls, shape sorters

Examples are:



How many of these toys do you use to play with your baby at home?

None ☐

One - two ☐

Three - four ☐

Five or more ☐

19. Books for babies (cloth, cardboard or plastic).

Examples are:



How many of these toys do you use to read and play with your baby at home?

None ☐ One - two ☐ Three - four ☐ Five or more ☐

20. Materials that encourage movement e.g. walkers, mats, climbing equipment

Examples are:



How many of these toys do you use to play with your baby at home?

None ☐ One - two ☐ Three - four ☐ Five or more ☐

21. Musical materials: instruments, music boxes hand-cranked by the child.

Examples are:



How many of these toys do you use to play with your baby at home?

None ☐ One - two ☐ Three - four ☐ Five or more ☐

ATTENTION:

- If your baby's age is between 03 and 11 MONTHS, STOP here and do not answer additional questions. The following toys are not recommended for infants YOUNGER than 12 MONTHS OF AGE.
- If your baby is 12 months of age or older please CONTINUE answering the questionnaire.

22. Educational e.g Shape sorters, stacking and nesting toys

Examples are:



How many of these toys do you use to play with your baby at home?

None ☐ One - two ☐ Three - four ☐ Five or more ☐

23. Dolls and other play figures with accessories.

Examples are:



How many of these toys do you use to play with your baby at home?

- None ☐ One - two ☐ Three - four ☐ Five or more ☐

24. Home activity toys: telephone, kitchen utensil sets, tool sets.

Examples are:



How many of these toys do you use to play with your baby at home?

None ☐ One - two ☐ Three - four ☐ Five or more ☐

25. Puzzles (2-6 pieces).

Examples are:



How many of these toys do you use to play with your baby at home?

None ☐ One - two ☐ Three - four ☐ Five or more ☐

26. Materials that encourage standing and movement e.g. Pull or Push toys, standing tables, bikes

Examples are:



How many of these toys do you use to play with your baby at home?

None ☐ One - two ☐ Three - four ☐ Five or more ☐

Appendix K: Assessing Children's Active and Sedentary Pursuits Questionnaire



Maternal reported physical activity and Home environment questionnaire adapted from the Melbourne INFANT Program questionnaire

ASSESSING CHILDREN'S ACTIVE AND SEDENTARY PURSUITS – 6 & 12 MONTHS OF AGE

QC5 On an average day about how much time does your child spend doing the following activities? For example an hour and a half would be recorded as 1 hour and 30 minutes. (Please write a response on each line)

Hours	Minutes
a. Playing games with an adult (e.g. block building, clapping games)?	_____ & _____
b. Being physically active with you (e.g. chasing, playing with a ball, dancing)?	_____ & _____
c. In a pushchair?	_____ & _____
d. In a car chair?	_____ & _____
e. In a cot or bed during the day?	_____ & _____
f. In a high chair or other chair?	_____ & _____
g. In a play area?	_____ & _____
h. Free to move about?	_____ & _____

i. Playing alone (supervised but no interaction)? _____ &

j. With other children of a similar age? _____ &

k. With older children? _____ &

l. Watching or in front of the television? _____ &

m. Outside? _____ &

n. Strapped to an adults back? _____ &

ASSESSING CHILDREN'S HOME ENVIRONMENT – 12 MONTHS OF AGE

QC8 Thinking about the *next year*, how likely do you think it is that you will provide the following things in your home for your child? (Please tick one response on each line)

	We already have	Extremely Likely	Very Likely	Possibly	Unlikely
a. balls	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b. trolley/toy for child to push while walking	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c. climbing toy/ jungle gym	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
d. swings	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
e. slide	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

f. sand pit	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
g. trampoline	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
h. bike	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
i. sit down push-along toy	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
j. TV in my child's bedroom	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
k. a safe and secure play-space inside	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
l. a safe and secure play- space outside	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
	We already	Extremely Likely	Very Likely	Possibly	Unlikely

Appendix L: HREC clearance certificate PLAY Study (M220217)



R49 Dr A Pioreschi

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL) CLEARANCE CERTIFICATE NO. M220217

NAME:
(Principal Investigator)

Dr A Pioreschi

DEPARTMENT:

School of Clinical Medicine
Department of Paediatrics and Child Health
Developmental Pathways for Health Research Unit
Chris Hani Baragwanath Academic Hospital

PROJECT TITLE:

The PLAY study trial protocol: an intervention to improve infant growth and development by encouraging responsive caregiving through interactive play

DATE CONSIDERED:

2022/02/25

DECISION:

Approved unconditionally

CONDITIONS:

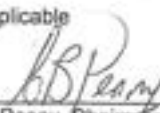
NOTE:

If contact information regarding student study participants is required, please contact the Registrar's office - <Nicoleen.Potgieter@wits.ac.za>

SUPERVISOR:

Not applicable

APPROVED BY:


Dr CB Penny, Chairperson, HREC (Medical)

DATE OF APPROVAL:

2022/05/05

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 February and therefore reports and re-certification will be due in the month of February each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator

Date

Appendix M: HREC clearance certificate CAG (M210846)



R49 Dr A Pioreschi

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL) CLEARANCE CERTIFICATE NO. M210846

NAME: Dr A Pioreschi
(Principal Investigator)

DEPARTMENT: School of Clinical Medicine
Department of Paediatrics and Child Health
Developmental Pathways for Health Research Unit
Chris Hani Baragwanath Academic Hospital

PROJECT TITLE: PLAY Study (Play and Love in the eArly Years)
Community Advisory Group

DATE CONSIDERED: 2021/08/27

DECISION: Approved unconditionally

CONDITIONS:

NOTE: If contact information regarding student study participants is required, please contact the Registrar's office - <Nicoleen.Potgieter@wits.ac.za>

SUPERVISOR: Not applicable

APPROVED BY: 
Dr CB Penny, Chairperson, HREC (Medical)

DATE OF APPROVAL: 2022/02/25

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, Philip 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 **August** and therefore reports and re-certification will be due in the month of **August** each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator

Date

Appendix N: HREC clearance certificate (M22084)



R49 Ms F Bennin

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL) CLEARANCE CERTIFICATE NO. M220844

NAME:
(Principal Investigator)

Ms F Bennin

DEPARTMENT:

School of Clinical Medicine
Department of Paediatrics and Child Health
Developmental Pathways for Health Research Unit
Medical School
University

PROJECT TITLE:

The home environment and play: the co-creation of an intervention aimed at increasing participation in infant play in a low-income community in Johannesburg, South Africa.

DATE CONSIDERED:

2022/08/26

DECISION:

Approved unconditionally

CONDITIONS:

The HREC (Med) requires sight of a Materials Transfer Agreement before data is shared with collaborators outside of South Africa

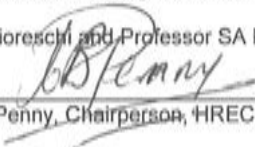
NOTE:

If contact information regarding student study participants is required, please contact the Registrar's office - <Nicoleen.Potgieter@wits.ac.za>

SUPERVISOR:

Dr A Priesch and Professor SA Norris

APPROVED BY:


Dr CB Penny, Chairperson, HREC (Medical)

DATE OF APPROVAL:

2022/10/25

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 **August** and therefore reports and re-certification will be due in the month of **August** each year. Unreported changes to the study may invalidate the clearance given by the HREC (Medical).

Signature of Principal Investigator

Date

Appendix O: HREC PLAY Study Sub-study clearance certificate (M220886)

R14/49 Ms Fiona Bennin

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M220886

NAME: Ms Fiona Bennin
(Principal Investigator)
DEPARTMENT: Paediatrics and Child Health
PROJECT TITLE: The home environment and play: The co-creation of an intervention aimed at increasing participation in infant play in a low-income community in Johannesburg, South Africa
DATE CONSIDERED: Ad hoc
DECISION: Approved unconditionally
CONDITIONS: Sub-study under M210846 and M220217
SUPERVISOR: Dr A. Prioreschi
APPROVED BY: 
Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL: 15/09/2022

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 the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. 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 resubmit the application to the Committee. I agree to submit a yearly progress report. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **August** and will therefore be due in the month of **August** 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

Appendix P: HREC acceptability and feasibility amendment approval (M220217)



24 April 2023

Dr Alessandra Prioreschi
Developmental Pathways for Health Research Unit
Department of Paediatrics and Child Health
University of the Witwatersrand
Johannesburg

Sent by email to: alessandra.prioreschi@wits.ac.za

Dear Dr Prioreschi

Re: Protocol Ref No: M220217
Protocol Title: *The PLAY study trial protocol: an intervention to improve infant growth and development by encouraging responsive caregiving through interactive play*
Principal Investigators: Dr A Prioreschi
Protocol Amendments

Thank you for the letter dated 31/03/2023.

This letter serves to confirm that the Chairman of the Human Research Ethics Committee (Medical) has approved the amendments for the above-mentioned protocol including sub-studies M220827 and M220844 to add Focus Group Discussions (FDGs) in a sub-sample of participants at 6 and 12 months.

The following documents were received:

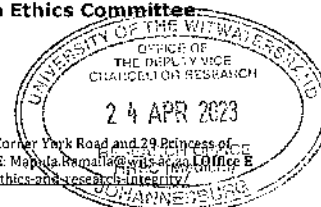
- Summary letter.
- Acceptability questionnaires.
- FGD guide to assess acceptability and feasibility at 6 and at 12 months.
- Participant information sheet and consent form for the 6/12 months FGD.

Thank you for keeping us informed.

Yours Sincerely,

Ms M Ramaila, Administrative Officer
Human Research Ethics Committee
(Medical)

Dr CB Penny, Chairperson
Human Research Ethics Committee
(Medical)



Research Office Secretariat: Faculty of Health Sciences, Phillip Tobias Building, 3rd Floor, Office 302, Corner York Road and 29 Princess of Wales Terrace, Parktown, 2193 Private Bag 3, Wits 2050 | T+27 (0)11-717-1234/2656/2700/1252 E: Mapula.Ramaila@wits.ac.za Office E
HREC-Medical: ResearchOffice@wits.ac.za | Website: www.wits.ac.za/research/about-our-research/ethics-and-research-integrity/

Appendix Q: Co-Author's Declaration

Declaration: Student's contribution to article(s) and agreement of co-author(s)

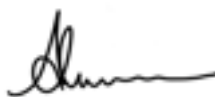
I, Fiona Bennin, student number [2589983], declare that this Thesis/Dissertation/Research Report is my own work and that I contributed adequately towards research findings published in the article(s) stated below which are included in my Thesis.



Signature of Student

Date: 01/02/2025

Name of Primary Supervisor: Dr Alessandra Prioreshi

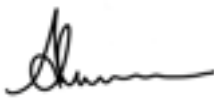
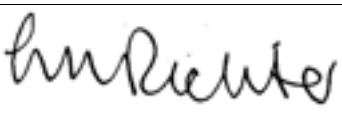


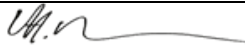
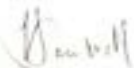
Signature of Primary Supervisor **Date** 24/03/2025

Agreement by co-authors: By signing this declaration, the co-authors listed below agree to the use of the article(s) by the student as part of his/her Thesis/Dissertation/Research Report. 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 his/her degree purposes.

Article 1: Title: Protocol for the PLAY Study: a randomised controlled trial of an intervention to improve infant development by encouraging maternal self-efficacy using behavioural feedback

Journal name, year, volume and page numbers: BMJ Open, 2023, 13(3).

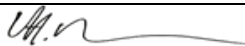
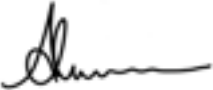
Authors	Name	Signature	Date
1 st author	Prioreshi, A		18/12/2024
2 nd author	Pearson, R		4/02/2025
3 rd author	Richter, L		6/02/2025

4th author	Bennin, F		01/02/2025
5th author	Theunissen, H		02/01/2025
6th author	Cantrell, S.J		02/01/2025

Comments by primary supervisor: Please see attached document with signatures for article 1 included

Article 2: Title: Determining the perceived acceptability of an intervention designed to improve health literacy around developmentally appropriate play during infancy, with a community advisory group of mothers, in Soweto, South Africa

Journal name, year, volume and page numbers: PLOS Global Public Health, 2024, 4, e0002233

Authors	Name	Signature	Date
1st author	Bennin, F		01/02/2025
2nd author	Theunissen, H		02/01/2025
3rd author	Norris, S		
4th author	Prioreschi, A		18/12/2024
5th author			
6th author			

Appendix Q: Paper 1 – Determining the perceived acceptability of an intervention designed to improve health literacy around developmentally appropriate play during infancy, with a community advisory group of mothers in Soweto, South Africa

PLOS GLOBAL PUBLIC HEALTH

RESEARCH ARTICLE

Determining the perceived acceptability of an intervention designed to improve health literacy around developmentally appropriate play during infancy, with a community advisory group of mothers, in Soweto, South Africa

Fiona Bennin^{*}, Helene Theunissen, Shane A. Norris, Alessandra Pioreschi

SA MRC/Wits Developmental Pathways for Health Research Unit, Department of Paediatrics, Faculty of Health Sciences, School of Clinical Medicine, University of the Witwatersrand, Johannesburg, South Africa

^{*} fionabennin@gmail.com



OPEN ACCESS

Citation: Bennin F, Theunissen H, Norris SA, Pioreschi A (2024) Determining the perceived acceptability of an intervention designed to improve health literacy around developmentally appropriate play during infancy, with a community advisory group of mothers, in Soweto, South Africa. *PLOS Glob Public Health* 4(8): e0002233. <https://doi.org/10.1371/journal.pgph.0002233>

Editor: Julia Robinson, PLOS, PUBLIC LIBRARY OF SCIENCE, UNITED STATES OF AMERICA

Received: June 1, 2023

Accepted: August 5, 2024

Published: August 29, 2024

Peer Review History: PLOS recognizes the benefits of transparency in the peer review process; therefore, we enable the publication of all of the content of peer review and author responses alongside final, published articles. The editorial history of this article is available here: <https://doi.org/10.1371/journal.pgph.0002233>

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Data Availability Statement: All data can be found in the manuscript and [Supporting Information files](#).

Abstract

Children require opportunities to participate in unstructured, unrestricted active play as infants, to encourage positive health, socioemotional and developmental outcomes in life. Certain social and environmental factors in the home setting can limit participation in play, particularly in low resource settings. As caregivers are their infants' first teachers, they have the important role of providing opportunities and space for children to learn through play. This mixed methods, cross-sectional study aimed to test the acceptability of an intervention developed to improve health literacy around play and development with mothers from Soweto, South Africa. Fifteen mothers with infants aged 0–3 months were included to form a Community Advisory Group (CAG). Two rounds of focus group discussions (FGDs) were conducted to explore the understanding of, and barriers to play and development, and to determine the acceptability of an intervention prototype. The prototype included developmentally appropriate activities presented in video format, demonstrations of how to make toys, infographics and other educational material which would be delivered to participants as part of the intervention. A further questionnaire was administered to participants one week after the FGD to determine the acceptability of intervention activities which the participants completed at home, with their infants. Participants reported several barriers to play, including limited options for safe outdoor play, overcrowding, insufficient time, limited resources, and conflicting information. Participants suggested that the intervention content be delivered every 1–2 weeks, through a data-free app. Overall, the prototype activities tested at home were deemed acceptable. The reported barriers, together with reduced motivation and self-efficacy observed in the participants, guided the researchers to develop intervention content focused on improving health literacy in play and development, delivered in the form of an interactive mobile app. Future research will develop and test the efficacy of this intervention in a low resource setting in South Africa.

Funding: This work was supported by the National Institute for Health Research (NIHR) (using the UK's Official Development Assistance (ODA) Funding) and Wellcome [222007/2/20/2] under the NIHR-Wellcome Partnership for Global Health Research. The views expressed are those of the authors and not necessarily those of Wellcome, the NIHR or the Department of Health and Social Care. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. AP received funding for this work from the National Institute for Health Research (NIHR) (using the UK's Official Development Assistance (ODA) Funding) and Wellcome [222007/2/20/2] under the NIHR-Wellcome Partnership for Global Health Research. JB received no specific funding for this work. HT received no specific funding for this work. SAN received no specific funding for this work. Dr Alessandra Proveschi received a salary from the Wellcome Trust from the same fund.

Competing interests: The authors have declared that no competing interests exist.

1. Introduction

Early childhood is one of the most important timeframes in life, due to the rapid growth and development of the brain and body during this time [1]. Children are particularly receptive to their environment in the first 1000 days of life, making it an important time for developing healthy behaviours, which encourage positive outcomes later in life [1]. In South Africa, obesity is a major public health concern, with 13% of South African children under 5 years being overweight in 2020 [2], making it important to start encouraging physical activity as soon as infants are born [3]. It is imperative for early movement behaviours (for example, 'tummy time') to be encouraged within the first days after birth, as these activities have been consistently shown to be associated with advanced gross motor and personal-social development over time [4].

In the early months of life, infants require access to unstructured, unrestrictive play at home to encourage development and increased physical activity [5]. This is evident in the poor developmental outcomes seen in children who spend too much time in a supine position as infants, constrained in infant seats, walkers, or in small playpens [5]. Unstructured outdoor play is particularly important as it allows space and opportunities for playful activities, which encourage development of gross motor skills (e.g. kicking and throwing balls, climbing on play equipment, etc.) and higher intensity physical activity required to meet daily movement guidelines [6]. Children need to be provided access to, and opportunities to engage in unstructured play by their caregivers, which highlights the importance of caregiver education and modelling when encouraging more unstructured play with children. By focusing on increasing participation in play from birth, infants and toddlers will naturally be more physically active, helping to reduce the risk of developing obesity and other non-communicable diseases later in life [7].

There are a number of social and environmental factors in the home setting that can limit participation in play, particularly in low-middle income settings such as South Africa. Examples of environmental factors include outside areas which are not considered safe to play (e.g. exposure to violence, heavy traffic, pollution, unsanitary conditions, etc.) as well as inside areas which may be very small or overcrowded with no limitations on screen time and other similar sedentary behaviours [8]. Social conditions that impact play include lack of resources available for toys or books, low maternal health literacy, and poor maternal mental health [8, 9].

As caregivers are their infants' first teachers, they have the important role of providing opportunities and space for children to learn through play [10]. Empowerment and provision of support for caregivers is therefore essential, to allow facilitation of playful learning in day-to-day activities in the home environment and community [10]. This is particularly important in a setting such as South Africa, where caregivers have expressed a lack of motivation and knowledge in how to promote development, particularly through play [8]. Therefore, increasing caregiver health literacy is key to developing a greater understanding of the importance of play and development in the early months [11].

In light of the above, this study aimed to test the acceptability of an intervention developed to improve health literacy around play and development with mothers from the Soweto community in South Africa. The researchers hypothesized that increased health literacy in mothers would improve capability, motivation and opportunity, thereby ultimately resulting in greater participation in infant play. The specific objectives in this paper were:

1. To understand the challenges and barriers that a group of Soweto mothers experience when facilitating play with their young infants.

2. To present a prototype of intervention activities and content, discuss perceptions as to how the activities and content may improve health literacy (thereby encouraging participation in play), and how best to present the intervention.
3. To determine the acceptability of the intervention prototype after being tested by the mothers in Soweto.

2. Methods

2.1. Study setting and participants

This study was nested in the larger Play Love and You (PLAY) study, which was developed with the overriding theme that all that infants need is Play (opportunities for movement and development), Love (responsive and interactive caregiving) and You (the mother herself) [11]. The PLAY study had three aims. The current study was part of the third aim, namely, "To test the efficacy, feasibility and acceptability of providing content, and increasing opportunities for early learning through play to promote literacy" [12].

In order to develop the intervention, a Community Advisory Group (CAG) was established with the intention of testing the acceptability of the intervention before implementing it in the PLAY Study [12]. Twenty mothers from Soweto with infants aged 0–3 months were recruited in April 2022 to form the CAG. Participants were recruited by approaching women at the taxi rank outside Chris Hani Baragwanath Academic Hospital (CHBAH) to ask whether they would be interested in participating. Mothers were eligible for recruitment if i) they were 18 years of age or older with an infant aged 0–3 months ii) of whom they were the primary caregiver, and iii) were living in Soweto for the duration of the study. Mothers were ineligible if infants were born preterm or if the infant had any disabilities, impairments or disease that would limit movement or impair normal development. 0–3 month old infants were included as this was the age group that would be included in the PLAY study, and as a result of the evidence showing that an increase in movement and play in very young infants is associated with advanced gross motor and personal-social development later in childhood and beyond [4].

Ethics statement. Ethical approval was obtained from the University of the Witwatersrand Human Research Ethics Committee (Sub-study M220886 under main study M210846). Written, formal informed consent was obtained from all participants, for participation in the focus group discussions (FGDs) and questionnaires, and for each FGD to be recorded. All participants were reimbursed for travel costs and provided with refreshments.

2.2. Data collection

Two rounds of Focus Group Discussions (FGDs) (named "Round 1" and "Round 2", respectively) were conducted for each participant, approximately two weeks apart in April 2022. All FGDs were conducted at CHBAH in Soweto, Johannesburg by staff trained in qualitative research data collection. Although questions were asked in English, participants could speak in their home language and conversations progressed in the vernacular. This was later translated into English if the response was in a different language, and transcribed for analysis. Lastly, Round 3 of data collection, a telephonic questionnaire, was conducted approximately one week after the completion of the FGDs with the same group of participants. All FGDs and telephone calls were audio recorded with the participants' consent and transcribed into English verbatim.

Round 1. Round 1 comprised of three FGDs, conducted over 3 days with 8 participants in the first FGD, 6 participants in the second FGD and 6 participants in the third FGD (total

N = 20). All participants started the session by providing socio-demographic information in a questionnaire. The aim of the Round 1 FGDs was to understand the challenges and barriers that the CAG members experienced when facilitating play with their infants. Participants were given a detailed explanation of what the PLAY study was, including the study's aims and objectives, themes, contact points between the different arms of the trial, as well as examples of the types of assessments and interventions that would be included in the study [12]. The theme in the PLAY study that participants were asked to focus on, was around interactive play and promotion of early learning. As a result, discussions were largely around the participants' understanding of play and development, as well as the effect of their home environment on participating in play with their infants. As part of this discussion, participants were shown a number of photos/ pictures depicting different home environments, which invoked a discussion around which environments enabled or discouraged active play. The stock photos were chosen to show a variety of home environments that would be similar to those found in Soweto, including single roomed homes, shacks and hostels, as well as different settings where children may play e.g. on the side of the road, in a yard, etc. Participants also had a general discussion around the delivery of the intervention, e.g. the preferred means of contact and how often participants should be contacted.

Round 2. All participants from Round 1 FGDs were invited back for Round 2, approximately two weeks later, however, five of the twenty participants did not attend. Round 2 comprised of two FGDs conducted on the same day, with seven and eight participants in each respective FGD (fifteen in total, n = 15). Round 2 was primarily focused on a discussion around the acceptability of the play and development aspect of the content to be included in the study intervention. Drawing from the themes which emerged in Round 1 as well as previous research conducted in this same population group, we created a 'prototype' or an example of intervention content appropriate for infants aged 0–3 months, which was introduced to the groups in Round 2. This content was in the form of developmentally appropriate activities, which would be delivered to participants as part of the intervention. The content included videos (for example, singing games, clapping hands, rolling games etc), demonstrations of how to make toys from recycling materials (S1 Fig), as well as infographics and other educational material (such as monthly developmental milestones). Participants were asked to give feedback based on their perceptions as to how the activities and content may improve health literacy, as well as how best to present the intervention. Participants were then asked to engage in and complete three specific activities at home. The first activity was based on videos consisting of games to play with baby and trying different tummy time positions. The second activity was for the participants to make a sensory toy, which was demonstrated in person. The last activity was to determine the potential acceptability of the content in the home setting from the perspective of the caregiver. They were encouraged to pick a few that they liked and try those, instead of attempting to complete all of them. The videos were sent to the participants via Whatsapp.

Round 3. The participants from Round 2 (n = 15) were then contacted a week later by the study team to complete an acceptability questionnaire, comprising of 24 questions over the phone (see S3 Appendix). The first question determined which prototype activities (sensory square, shaker and five games) had been completed at home. The rest of the questions focused on determining whether the participants found the prototype activities "acceptable" after testing them at home [12]. The acceptability of the activities was determined by asking questions specifically based on the seven component constructs of acceptability by Sekhon et al. [12], which were used to measure acceptability in this study. Examples of questions included, "Were the instructions clear?" (measuring intervention coherence), "Do you think the games are beneficial for you and the baby?" (measuring perceived effectiveness), etc. Each component



Fig 1. Definition of acceptability and the seven constructs of acceptability [12].

<https://doi.org/10.1371/journal.pgph.0002233.g001>

construct (namely, affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness, and self-efficacy) is described further in Fig 1.

Fig 2 shows a summary of all three data collection points.

2.3. Data analysis

All participants' identities were protected by assigning a unique identifier to each participant, making all qualitative data non-identifiable during the analysis. The quantitative data were de-

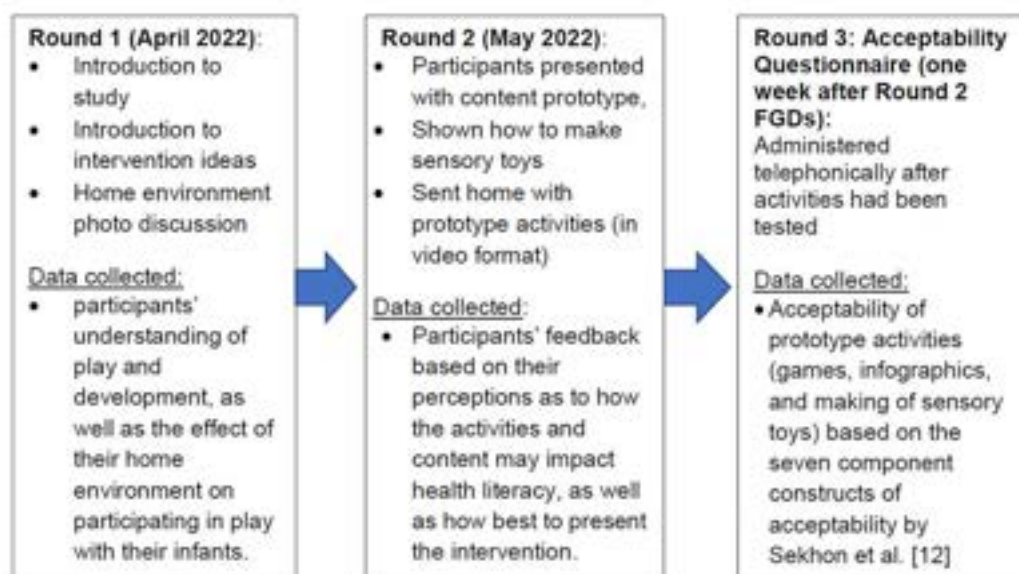


Fig 2. Summary of data collection.

<https://doi.org/10.1371/journal.pgph.0002233.g002>

identified at the point of data entry, using the study ID number, so that the researchers could not link the participants to their data. The data used in analysis only had a study ID number, without names or any other identifying information available. The qualitative data were analysed using thematic networks analysis [13]. Meaningful statements and ideas were coded and then grouped into themes. Similar themes were then grouped and placed in thematic networks, which were subsequently summarised and discussed in relation to the original research question. The three transcripts from Round 1, and two transcripts from Round 2 were divided among three researchers who assigned codes to each statement and grouped the codes into themes. The researchers then swapped transcripts to cross-check all the identified themes and codes, which were further checked by a fourth researcher. Thereafter, all researchers met as a group to discuss and refine the themes until no new themes emerged. Means, medians and ranges were calculated on Microsoft Excel and used to describe the demographics of the participants and the quantitative data from the acceptability questionnaire.

3. Results

The average (mean) age of the twenty participants was 24 years old and the median was 23.5, ranging from 18 to 43 years old. Eighty percent of the participants described themselves as single, while the other twenty percent reported themselves to be married, engaged or in a relationship. Seventy percent of the participants were unemployed while thirty percent had some form of employment. The majority (sixty percent) of the mothers had completed their Matric (final year of secondary school), while thirty five percent had not completed secondary school. Only one participant had a tertiary degree. Six of the participants were first time mothers. There was a fairly equal distribution of male and female infants, with half being female, forty five percent male, and one infant whose mother preferred not to say. The youngest baby was new-born, and the oldest baby was 5 months old, with the average infant age being 2 months and the median age being 3 months old. The time between enrolling participants and the first FGD was just over a month, which explains why some infants were older than the 3 months inclusion criteria.

Round 1 & 2

The following eight themes emerged from Round 1 FGDs: 1) Being a mother, 2) Environment, 3) Play and Development, 4) Intervention, 5) Physical Wellbeing, 6) Health Literacy, 7) Breastfeeding, and 8) Mental Health. "Being a mother" included discussions around the challenges and joys that motherhood brings, while the "Environment" theme gave insight into factors in the participants' home and residential areas which impacted their activities, support (or lack thereof), safety and movements. The participants discussed their knowledge and perceptions of the importance of "play and development" in their infants, while the "Intervention" theme largely focused on preferences around the delivery of the intervention. The "Physical Wellbeing" theme explored how the participants manage their infants' and own physical health, and the "Health Literacy" discussion focused on access to information and ability to understand information provided. The "Breastfeeding" theme was a prominent discussion exploring reasons for breastfeeding (or not), factors impacting continuation of breastfeeding, support available, etc. Lastly, "Mental Health" explored all factors impacting the participants' mental health as mothers. The Health Literacy, Environment, and Play and Development themes were relevant to this study, while the rest are discussed in papers currently in review.

During the second round of FGDs, the three themes which emerged from Round 1 (Health Literacy, Environment and Play and Development) that were pertinent to this study, were discussed again and expanded upon further. Furthermore, one new theme emerged, namely

Acceptability of the intervention prototype content, which was the primary focus of the discussion. The themes were further divided into subthemes and are discussed below.

Health literacy. *Clinics/ healthcare workers.* The participants relayed a sense of distrust in the health workers at the clinics. Many reported that they are provided with minimal information around the importance of play or how to encourage normal development, and health workers can be rude or make new mothers feel ashamed for asking certain questions.

"No you know at the clinic they don't explain anything, they just give you Road to Health [booklet] (a booklet given to parents by clinic staff when children are born which keeps record of the child's growth and other key developmental milestones, as well as providing the parent with information on nutrition, loving & bonding, protection of the child including immunisation schedule, basic health care e.g. treating common illnesses and "extra care" for those living with HIV, disabilities, etc) [14] after giving birth to the baby. You will figure out when you get home when to take the baby in for the three day check-up, and when you have to take them in for six weeks. They don't explain anything. You just have to give yourself time and read the Road to Health book because at the back they have symptoms that explains the things to watch out for in a child. They don't explain. You have to sit and read that book."

(Round 1, grp 2).

Family/ peers/ other sources. A few of the participants expressed an interest in receiving additional information on how and when to play with their infants as they did not have access to family and/ friends who could provide them with advice when it came to their infants' development. Participants expressed that even when they did have family members involved, they often did not know who to trust and would prefer objective information from a trusted source. However, they did not tend to trust and/ or understand the objective information given to them (such as the Road to Health Booklet), or did not see its relevance, but did not discuss what/ who they would trust.

"My mother is there to help me about the baby but I take care of most of the things because my mother loves going out. So most of the time I have to look after the baby so I have to know a lot of things. To clean the belly button and things like that."

(Round 1, grp 2).

"I would be happy [to receive this intervention], because when you go to the Road to Health [booklet], there are some things which are different, if you go to some pages, they talk about SASSA (An agency that aims to provide comprehensive social security services against vulnerability and poverty) and I don't understand what SASSA has to do with Road to Health."

(Round 1, grp 2)

Environment. The discussion around the photos of children playing in different settings evoked various thoughts around safety, space and the effect on the child.

Physical safety. The participants were quick to point out that they felt there was a risk of children being kidnapped or subjected to abuse when an area was not enclosed or when there were many men around. There was also mention of children needing to be kept inside or in an enclosed yard to avoid them being involved in motor vehicle accidents.

"The house is not in a busy part of the township, but you need to keep the gate closed as there is a small child. A car can come and drive over the baby if the baby gets out of the yard"

(Round 1, Grp 3)

"You know, to be honest, these days, you saw how the first picture was [picture of children playing on the street] ... I won't feel free if my child lives in a place like that. A girl especially, not only a girl, because sometimes boys do get raped as well, you understand, I won't feel happy".

(Round 1, grp 2)

Effect on development. Many felt that it was important for children to be around other family members such as grandmothers. This was so that they could also look after the child when the mothers were not able to, without the child experiencing separation anxiety. The participants were also aware of the importance of playing with other children and being around other people for their children's social development. However, there was minimal mention of how the lack of space and outdoor play areas would impact their children's gross or fine motor play and development.

"For me, I think it is something good [for a child to play freely], ... I did not want him to play outside with other kids. ... so when you close a child up, he can't communicate with other people. I saw right now at school, to get [him] to understand a lot of things, it is hard for him, so I think [you need] to give a child the freedom to play. Yeah, it is a good thing.

(Round 1, grp 2)

In the house: Occupants and space. The participants were of differing opinions when it came to the condition of a home and how this may impact the child. Many identified that some of the photos showed unsafe conditions for children, such as exposed wires, potential for injury from kettles/ stoves, lack of running water, etc. Others felt that while certain conditions in their own home were unsanitary or unsafe, they were used to living that way (and taking appropriate precautions) as they had always lived in these conditions. It was suggested that any accident that may occur as a result of the home environment was due to the parent/s' negligence.

"As she says that there is no ideal place where a child can be raised. I feel that the mother can be careless and put water in a dish and not be mindful of the child. If the child falls in the dish and drowns, I feel it would be the mother's negligence, not that the place is not safe for the child".

(Round 1, Grp 3).

Some participants reported that they live in one room houses where the bedroom and kitchen would be combined and felt that the space constraints did have an effect on what activities they were able to do with their children. However, those with bigger houses also expressed difficulties with space due to overcrowding.

"So did you see the games that you showed us, did you see them, they need open space. I said last time, we live in a four room [house], there are a lot of us. There is no time to do these sort of things. When you are sitting like this, you are sitting like this, and that is the end of it.

When you move, you don't have space anymore. When you go to the bedroom, they follow you. So the time that you get is when you go outside and sit under a tree and sit on the grass, and play. When it is raining, we are not playing we will just be sitting in the house only".

(Round 2, grp 2)

Factors hindering play. The main reasons for respondents not engaging in play with their children included lack of time due to having to go to work, doing chores, and spending time on social media. Some felt that there were no hinderances as they liked to play with their infants, especially as they did not need toys in the first few months.

"Maybe [you don't play] when you are on the phone and on WhatsApp. Sometimes I am on the phone and when the baby is crying I am like wait a bit you, it is WhatsApp. It is when I am looking at statuses".

(Round 1, grp 2)

"The chores is what I can say when I think about something that is stopping me, because most of the chores are looking at me at home."

(Round 1, grp 2)

Play and development. *Activities with infants.* As all the participants had infants below six months of age, they tended to engage in activities which were appropriate for this age range, such as singing and dancing. Some participants also liked to talk to their infants, massage their feet and laugh with them. After seeing a video about ways to engage in "tummy time" with their infants, some participants mentioned that they were not aware that they could put their infant on their tummies in so many different positions.

"For me, I play with him by singing, and he laughs and enjoys it."

(Round 1, grp 2)

"... I play with my child by talking to him. I will talk to him and then sometimes the child shows reactions. He laughs a bit, and then sometimes when I am playing with him, he will look at me but when my other [child] is playing with him, he will laugh."

(Round 1, grp 2)

Maternal beliefs. Many of the participants were aware of what the term "development" meant, and some were aware that "milestones" were indicators of how their infant was developing. Some felt that play was good for monitoring how their infant was growing and some had insight into the effect of play on motor development.

"She develops muscles if she plays and you also see the change in her body".

(Round 1, Grp 1)

One of the main beliefs discussed in Round 2 was around tummy time and sleep. Most participants believed that infants slept better when they slept on their stomachs and were not aware of the dangers associated with this.

"When a baby is sleeping on their tummy, they become better than when they are in other positions and when they're sleeping on their tummy they sleep".

(Round 2, grp 1).

Acceptability. The main purpose of Round 2 FGDs was to determine the acceptability of the prototype and therefore, this theme was only introduced in Round 2.

The acceptability concept was introduced with a general discussion around the intervention activities, specifically how often the content should be delivered and whether it should be delivered through an app or WhatsApp. Access to mobile data (or lack thereof) for delivery purposes was also explored. All of the participants requested a data free option, and some preferred WhatsApp, while others preferred the idea of using an app. The frequency of the content delivery varied, ranging from daily to weekly and bi-weekly (app content).

Regarding the app content, participants did not mind if the videos were in English, as long as there were subtitles accompanying the audio, moving slowly across the screen. As many of the videos available on the internet are usually North American/ Eurocentric, many of the participants suggested using local videos or having actors who were more representative of the Sowetan Community when it came to their race and culture.

"It should be maybe it could be a black person. You see?"

Sometimes we as people, we say these things are done by white people."

(Round 2, Grp 1)

After being presented with the prototype activities, the participants further discussed their thoughts and perceptions of each activity. Subthemes were then created to align with the seven acceptability component constructs as described in Sekhon et al. [12] and the discussion points were placed into each subtheme, accordingly. Table 1 expands on subthemes and their supporting quotes.

Round 3

Acceptability questionnaire. The percentage of participants participating in each respective activity is shown in Fig 3. The results of the acceptability questionnaire and participant's free responses, (separated into each component structure) are reported below.

One participant was not contactable and therefore only fourteen participants completed the telephonic questionnaire. This participant's data were excluded from the final quantitative analysis. The number of participants completing each respective activity is represented in Fig 3. The discrepancy in the number of mothers completing the activities is due to the mothers only being instructed to pick a few activities to complete at home (i.e. they were not required to complete all of them in the week).

Every participant reported that they liked playing the games with their infants, largely due to both the baby and participant's enjoyment, seeing their baby's development and because it encouraged bonding with their infants.

"Well I like them a lot because I could see that the baby was developing and I was able to see what he likes and what he thought he did not like and he was smiling and showing me that he was enjoying it. That's why I was able to see that he was enjoying the rolling because for me it seemed like the most uncomfortable one but he was enjoying it. And my son is very picky so I

Table 1. Subthemes and supporting quotes from Round 2 FGDs.

Component constructs	Supporting Quotes
Affective attitude (How the individual feels about an intervention)	
Overall, the participants liked the content that was shown to them. They liked that it showed them something they did not know, that it included fathers, that it would help their children grow.	"What do you think about this paper in front of you, this one of milestones?" "I feel like it's right, it helps". (Round 2, grp 1) "And I also like that they included the father, father figure on the video. . . To show that parenting is not only for the mother, it is for fathers." (Round 2, grp 2)
Burden (The perceived amount of effort that is required to participate in the intervention)	
The participants felt that the activities (games and crafts) would not take up too much of their time and that they would find time in the day to do the activities with their infants.	"It won't waste our time. For me it won't waste my time because I also like to teach my baby how we are supposed to play, it won't waste my time." (Round 2, grp 1) "Me too I don't see it as something difficult because sometimes you find that you finished cleaning at about eleven, you have nothing to do, I can do it." (Round 2, grp 1)
Ethicality (the extent to which the intervention has good fit with an individual's value system)	
This subtheme was not explored as much as the other subthemes, but participants did not show any reason for the content not fitting in with their individual value system.	"Okay I see that it's right because it's the way we live, the way at home, at the location we live like that, I mean in one room. (Round 2, grp 1) "It is reliable." (Round 2, grp 2)
Intervention Coherence (The extent to which the participant understands the intervention and how it works)	
The participants understood the prototype activities shown and understood why they were important.	"It is important to have knowledge about your baby that when they are one month what does your baby do, two months what does your baby do. (Round 2, grp 1) "I am going to do it more often because I only did that during my time, it was very informative." (Round 2, grp 2)
Opportunity Costs (The extent to which profits, benefits or values must be given up to engage in the intervention)	
The participants did not seem to mind that there may be opportunity costs as they tended to see the benefit outweighing the "cost".	"There's nothing that takes time, it's your baby who is important at that time, when they're still young you need to play with them you need to do that, you must. (Round 2, grp 1)
Perceived effectiveness (The extent to which the intervention is perceived to achieve its purpose)	
As this discussion took place before engaging in the activities it was difficult to determine how effective the participants perceived the prototype to be in the FGDs, but some did acknowledge that the content had been effective in teaching them how to play more with their infants.	"It helps us, it teaches us new things that we can do with our babies, we did have others, but they also add [to this]." (Round 2, grp 1)
Self-efficacy (The participant's confidence that they can perform the behaviour(s) required to participate in the intervention)	
Similarly with self-efficacy, it was difficult for the participants to judge their level of self-efficacy in completing the activities in the FGDs, but most seemed confident that they would be able to complete them independently at home.	"But do you think that that is something that you could make?" "Yes, it sounds easy." (Round 2, grp 2)

<https://doi.org/10.1371/journal.pgph.0002233.t001>

was surprised when he enjoyed rolling. The thing about the games basically you are interacting with your baby and bonding in the time we do these games so I don't think there is anything that I did not like about the games."

—participant with baby aged 5 months.

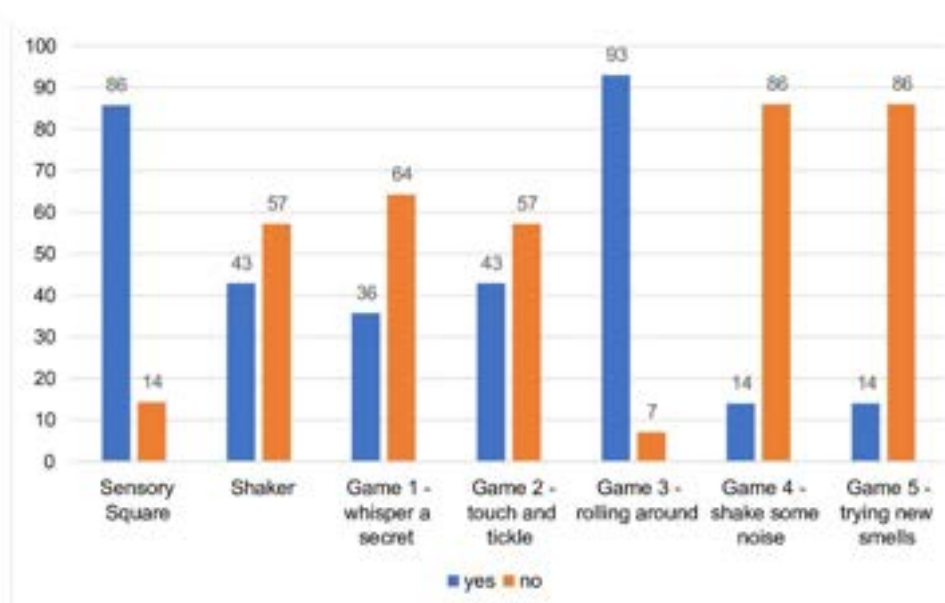


Fig 3. Percentage (%) of participants completing the sensory toys and video activities at home.

<https://doi.org/10.1371/journal.pgph.0002233.g003>

"They make her strong, I can see that she is getting used to them. I am also teaching her the tummy to tummy and I have started doing it a lot. She also likes the games but I can also see that some are helping her with development. She can see and follow sounds, that shows me that there is something that she likes and enjoys. There's a lot that I enjoyed about the games".

-participant with baby aged 2 months.

Only one participant mentioned that they did not like the sensory square because it was too loud for them even though the baby enjoyed it. Otherwise, the rest of the participants stated that they liked the sensory toys because the infants liked the noise, the colours, and holding the square. Other reasons for liking the toys included: using the toys to calm the infant down when they cried, making the infant happy, and encouraging further learning.

"They make the baby to be more playful when they touch their toys especially the one with the plastic inside [sensory square] it makes the baby so happy"

- participant with baby aged 4 months.

"I loved everything about it, my baby loves it, I can also see that she can hear it and she wants to hold it"

- participant with baby aged 4 months.

"I loved the sound that it make because now that she is used to it when she cries it calms her down".

- participant with baby aged 1 month.

Every participant felt that the activities were beneficial. Reasons for finding them beneficial included: enjoying the bonding time, both mom and infant (and family) being happy when engaging in the activities, learning and development for both mom and infant, and safety.

"[It is beneficial] because they help me to understand my baby and they help her to develop and to learn many things."

- participant with baby aged 2 months.

"[It is beneficial] because when I saw the baby smiling and laughing I was also happy so I am happy that they don't only benefit the baby but myself as well"

- participant with baby aged 1 month.

"[It is beneficial] because the games are safe"

- participant with baby aged 2 months.

Every participant found the activities easy to do. The participants had varying reasons for finding them easy. These included the fact that they were easy to understand, that they were bonding with their infants and the infant was enjoying it. The participants agreed that they had the resources needed for making the sensory square or rice shaker. A couple of participants reported that it was easy because they did not need to buy any toys, which is not something they knew beforehand.

"I found them easy, they were not as hard as I thought they would be because we only think that playing with the baby requires toys."

- participant with baby aged 1 month.

"I can sew, so when I was making the toys I was also enjoying it. She enjoyed all of those and they were easy to do because most of the time these are the games that we play with the baby, it's just that we did not know that this is what we must do with our children."

- participant with baby aged 1 month.

"They were easy because it was just playing with the baby."

- participant with baby aged 2 months.

Every participant reported that they understood how to play the games with their infants, however one participant reported that the instructions were not clear. When asked what could be done to make the instructions clearer, the participant responded,

"Yeah actually I think there should be a person with training to [show us how to] play the games sometimes because we forget. So it's easy if we do a practical because other people are slow so it's easy to do a practical for everyone to remember."

- participant with baby aged 5 months

The majority of the participants (over eighty percent) stated that they had time to complete the activities. The remaining two participants were not able to complete the activities due to illness and not knowing that they were required to complete the activities again, respectively. When asked what would help them to make time in future, these two participants stated that they would like to be sent the videos again and reminders through SMS.

All of the participants felt confident that they knew how to do the activities and were doing them correctly. When asked if there was anything that would make them feel even more confident, most of the respondents suggested sending more activities to do, along with instructions on how to do the new activities. Only one participant did not find the toys easy to make.

Of the fourteen participants, just over half (eight) of the participants found it very easy to find the resources to make the toys at home, five participants found it easy to find the resources and one participant found it difficult. While most of the participants had the resources at home, one participant needed to buy a packet of chips to add the packet to the sensory square, and another participant needed to buy a needle, which they could both afford.

When it came to how and when the activities were presented, most (ninety seven percent) of the participants preferred being shown a video instead of it being presented in person, so that they could watch in their own time, slow down and pause the video, and could refer back to it as needed. When asked about how often the participants would like to receive more activities, there were varying responses. Five of the participants wanted to receive content once a week, while three participants wanted to receive the content monthly, every two weeks and every day, respectively.

4. Discussion

Understanding the complexity of the mothers' lived experience

This study aimed to determine the acceptability of a set of activities which would be included in a study intervention for mothers in Soweto. The findings suggest that while many of the participants did enjoy playing with their infants and seeing the impact of play on their child's development, the mothers were also dealing with a range of complex factors, all at the same time, which hindered their participation in play. Some of these factors discussed included lack of time or motivation, environmental constraints as well as limited availability of information from health workers and/or limited use of the information available, for example, in the Road to Health booklet.

When it came to the mothers' understanding of play and development, many of the mothers were only aware of the gross motor developmental milestones and perceived their infant reaching these milestones to be a good sign of growth. Another study with a similar population group in Soweto, similarly found that mothers were aware of the different developmental milestones and would use them as a tool for tracking development and progress [8]. While the participants understood the value of play in the younger months, it seemed that the participants were not aware of the importance of play in every aspect of development (e.g. not just physical/motor development), or of the importance of their own role in promoting play with their infants in the early months. Likewise, a Bangladeshi study found that rural mothers had basic knowledge about the benefits of play but lacked insight into the importance of it in every aspect of development, particularly the positive impact on cognitive development [15].

Round 1's discussions highlighted a significant lack of self-efficacy in the mothers, because of their difficult and complex lived experiences. Some of this was due to lack of knowledge and experience but some was linked to difficult circumstances and the environment around them, such as lack of resources and space. This was largely noticeable when many participants showed a sense of excitement and pride in knowing that they could use toys that they had

made themselves for their infant's enjoyment and development, despite their financial constraints. Supporting mothers with education and increased sense of capability, has been shown to have a positive impact on children's development, seen in a study conducted in India, which found that maternal education and mental health were one of the primary indicators for a positive home environment at 6 and 24 months of age [16].

The participants expressed a strong distrust of the health workers at the clinic (who, in South Africa, are predominantly nurse-led). This distrust is largely as a result of the lack of confidentiality and mistreatment by certain health workers, resulting in a distrust in the information provided to mothers in the clinics. Unfortunately, this is something that is widely reported throughout South Africa [17]. Studies conducted in similar settings have reported women feeling insulted by healthcare workers during birth and ante/postnatal care, with health workers being apathetic to their pain or current needs. This resulted in women feeling disempowered to ask for information or not receiving information when asked [18, 19]. As some participants expressed a distrust in information provided by health workers, and others did not trust information given by family or friends, it's clear that there needs to be alternative sources of accurate information that can be relied on. Furthermore, better health literacy in the communities would allow mothers to know where to seek factual, evidence-based information, to know which sources of information to trust, and to know how to apply the information to their own context. These findings guided the researchers to provide intervention content on reliable online play and development resources, as well as how to prepare for clinic visits and meetings with Health Care Professionals.

One of the dominant themes that was repeatedly mentioned, was the impact of the home environment (both inside and outside) on the participants' movement behaviours and activities for both them and their children. Regarding the outside environment, the main concern around physical safety for the child is valid given the surroundings in which the participants live. Soweto is an informal settlement or "township" situated on the southwest of Johannesburg, where the number of child kidnappings, and pedestrian road traffic injuries are high [20, 21]. Similar concerns have been voiced by other mothers in the same Sowetan community. Prioreschi et al. [8] found that mothers expressed concerns around their children being hit by cars, being abducted, kidnapped or raped, as well as other concerns which weren't mentioned in this study but would also be applicable, such as the child hurting themselves or falling into communal toilets. The literature is clear in showing the impact of limited opportunities for movement in home environments (either due to lack of space, overcrowding, etc.) on active play and therefore, motor and cognitive development in infants [22–24]. Most of the participants reported to having limited space indoors and their environment outside being unsafe. This had major implications in the mother's ability to encourage active play, both inside and outside. In view of these circumstances, it was imperative that for any intervention involving active play to be feasible in this community, limited indoor and outdoor space needed to be considered. This resulted in the researchers focusing on increasing health literacy around the value and benefits of play, and specifically how to adapt the home environment, to encourage safe and active infant play.

Prototype development and engagement

The development and testing of the prototype provided some important insight into how the participants wanted content to be presented. Overall, the participants were happy to try out the activities at home. However, when presenting the activities as part of the prototype, many of the videos or activities did not have a diverse range of ethnicities or socioeconomic groups represented, which the participants indicated would not be their preference. This led to the

intervention only including people, environments and resources that were representative of the Soweto community.

With regards to "tummy time" and sleep related content, many of the participants felt that babies slept better in prone position and were not aware of the associated dangers compared to supine sleeping. This finding is similar to a South African study which found that only 3% of 6-week old babies were sleeping exclusively in a supine position [25] further highlighting the need for greater levels of health literacy within the community, and encouraging the researchers to include tummy time information and associated safety precautions in the intervention activities [1,2].

Acceptability of the intervention

Despite the small sample size, the results of the study provided important guidance when creating an acceptable intervention. Firstly, the intervention needed to include simple activities that encouraged age-appropriate play, using very limited resources which were available in the home. Secondly, the activities needed to be culturally appropriate for this specific group, and thirdly, due to crowded living spaces and limited outside play areas, the activities needed to encourage active play within the constraints of small spaces. Lastly, due to the lack of reliable information (and support) available to the mothers, the intervention needed to work alongside the current health system, by providing additional information on play and development that corresponded with information provided by the health care providers. For the activities to be feasible in a real-world setting, activities needed to be simple and achievable, to develop a sense of self-efficacy in the mothers. Content also needed to be accessible given that access to WiFi and data are significant barriers for mothers in accessing information digitally [26].

This study has certain limitations, which the researchers tried to mitigate wherever possible. We did not collect data on how actively mothers truly engaged with the intervention material, and only assessed their perception of a small sample of content. As this study had a small sample size, the findings may not be generalisable, and cannot be extrapolated to higher income settings. However, the sample could still be considered representative of other women in Soweto as certain demographic data, such as parity, education and marital status were similar to demographic data found in other studies completed in the same age group in this area [27, 28]. A common risk when using focus group discussions, is the discussion being led based on the researchers' agenda, or the agenda of specific participants in the group. This risk was minimised by having a trained facilitator who was external to the project and an expert in dealing with group dynamics to allow for equal contribution from each participant. As the author is an outsider to the study population community, with their own ideas and presuppositions, as well as this study being completed as part of a doctoral degree, it is expected that some interpreter bias was present. However, where possible, interpreter bias was minimised by having three researchers code and re-code the data as described in the methods section. Despite these limitations, this study has a number of strengths. Including the participants (end users) from the point of intervention development allowed them to shape and create the health interventions that were appropriate, acceptable and feasible in their own context. This is essential for seeing real success in changing health behaviours in real world settings [29]. Implementing this intervention has the potential to increase mothers' self-efficacy and health literacy around their and the environment's role in their child's play and development. With the right information and tools, each participant has the potential to positively impact their child's development, which if expanded to the larger community, could see large scale positive growth and developmental outcomes throughout the life course. Given the lack of trust in the healthcare system, policy

makers should focus on providing evidence-based knowledge to new mothers through other means such as data free digital products. A focus on providing safe, security patrolled open spaces and playgrounds needs to be prioritized to encourage access to active play for children and adults.

5. Conclusion

In conclusion, this study has provided insight into the acceptability of an intervention designed to improve health literacy around developmentally appropriate play during infancy, with a community advisory group of mothers in the Soweto community. The findings presented in this study will guide the development of an intervention in the form of an interactive mobile app and provide further insight and guidance for developing future interventions in low-income settings. Future health and social policies need to account for the complexity of factors and experiences which impact mothers' decisions related to their children's play and development. Further research should focus on the impact and feasibility of using digital technologies to create behaviour change in low-income settings.

Supporting information

S1 Appendix. Participant breakdown for each round of data collection.
(PDF)

S2 Appendix. Round 1 photos.
(PDF)

S3 Appendix. Acceptability questionnaire.
(PDF)

S1 Fig. Sensory square.
(JPEG)

S1 Data. Participant demographics.
(XLSX)

S2 Data. Acceptability questionnaire data.
(XLSX)

S1 Checklist. Strobe checklist.
(DOCX)

Acknowledgments

The researchers would like to acknowledge the PLAY study research team for their assistance in collecting the questionnaire data and providing administrative support in the Focus Group Discussions. We would also like to acknowledge Lebo Motlhatlhedhi for conducting the Focus Group Discussions.

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Writing – original draft: Fiona Bennin, Alessandra Prioreschi.

Writing – review & editing: Fiona Bennin, Helene Theunissen, Shane A. Norris, Alessandra Prioreschi.

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Appendix S: Supervisor Turnitin report support letter

Re: Fiona Bennin

20 March 2025

Phd Candidate
Department of Paediatrics
University of Witwatersrand

To:

The Examiners
Faculty of Health Sciences
University of the Witwatersrand

Subject: Explanation of Turnitin Report for PhD Candidate Fiona Bennin

Dear Examiners,

I am writing to provide clarification regarding the Turnitin similarity report for Fiona Bennin, a PhD candidate under my supervision. Fiona has successfully completed her Turnitin check, which returned a 29% similarity score. However, this result is primarily due to the inclusion of one of her PhD chapters, accounting for 20% of the score (15% and 5%), which has already been published in a peer-reviewed journal.

The Turnitin system has flagged sections of her thesis as 'plagiarism' because it detects content from her own previously published work. This is not an instance of academic misconduct but rather a common occurrence when candidates incorporate their published research into their dissertation. The relevant chapter has been correctly referenced and attributed within her thesis, with the accompanying published article attached as an appendix, ensuring that all academic integrity standards are upheld.

I kindly request that the examiners take this into account when reviewing the Turnitin report. If further clarification is needed, please do not hesitate to contact me.

Thank you for your time and consideration.

Yours sincerely,



Dr Alessandra Pioreschi
University of Witwatersrand