The Feasibility of a Randomized Controlled Trial to evaluate interactive weekly mobile phone text messaging plus motivational interviewing to promote breastfeeding among women living with HIV

Moleen Zunza (✉ moleenz@sun.ac.za)  
Stellenbosch University

Taryn Young  
Stellenbosch University

Mark F. Cotton  
Stellenbosch University

Amy Slogrove  
Stellenbosch University

Lawrence Mbuagbaw  
McMaster University

Louise Kuhn  
Vagelos College of Physicians and Surgeons, Columbia University Irving Medical Center

Lehana Thabane  
McMaster University

Research Article

Keywords: Vertical transmission of HIV, breastfeeding, motivational interviewing, text messaging, feasibility trial

Posted Date: November 4th, 2022

DOI: https://doi.org/10.21203/rs.3.rs-2147255/v1

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Abstract

Background

In 2011, South Africa changed infant feeding guidelines for women with HIV from government-supplied formula feeding to exclusive breastfeeding for six months and continued breastfeeding for two years or longer. With only 8% of infants under 6 months of age being breastfed, interventions are required to improve breastfeeding rates. We assessed whether an appropriately powered randomized trial was feasible regarding i) recruitment and retention, and ii) protocol adherence. We explored the potential effects of the intervention on sustaining exclusive breastfeeding at 24 weeks postpartum.

Methods

We conducted a randomized parallel, two arm feasibility trial. Women were included if they initiated breastfeeding within 24 hours of giving birth at the Worcester midwife obstetric unit, on antiretroviral treatment, and aged ≥ 18 years. We randomly assigned mother-infant pairs to receive weekly text messaging encouraging exclusive breastfeeding plus in-person individual motivational interviews postpartum at weeks 2, 6, and 10 at Family Clinical Research with Ubuntu or standard infant feeding counselling during routine postnatal clinic visits.

Results

Of 123 mothers consented for screening, 52 eligible participants consented for study participation. We recruited an average of five participants per month over 11 months. Most participants were unemployed (75%), had some high school education (84%), and disclosed their HIV status to someone close (88%). About 65% participants completed outcome evaluation at week 10, decreasing to 35% at week 24. Twenty participants had the week 24 visit planned between 20 March and August 2020, during COVID-19 lockdown. Of these, four completed the visit telephonically, 16 were lost to follow up. Exclusive breastfeeding rate remained relatively high across both groups through week 24. Although the intervention group had higher rates of exclusive breastfeeding at week 24 than the control group this difference was minimal; rate difference 22.2% [95% confidence interval (CI) -20.1% to 64.5%].

Conclusions

With a large enough eligible target population recruitment targets could be achieved for the large randomized trial. Strategies to retain participants, such as remote monitoring in addition to in-person follow-up visits, will be essential.

Trial registration: The trial was registered on ClinicalTrials.gov on 31/10/2016; NCT02949713 and on Pan African Clinical Trial Registry on 08/11/2016; PACTR201611001855404.

Key Messages Regarding Feasibility
We were uncertain on the feasibility of a larger randomized trial with regards to recruitment and retention, and protocol adherence.

We recruited from a rural healthcare facility, serving a small number of our target population which prolonged our recruitment period.

Retention was sub-optimal.

With a large enough eligible target population, recruitment targets could be achieved as willingness to participate in the trial was high.

Strategies to retain participants, such as remote monitoring in addition to in-person follow-up visits, will be essential.

**Background**

Breastfeeding protects against death from diarrhea and respiratory tract infections which are among the leading causes of child death in low resource settings (1). The 2016 World Health Organization (WHO) infant feeding guideline recommends, irrespective of HIV status, exclusive breastfeeding for the first 6 months of life, followed by introduction of complementary foods and continued breastfeeding for two years or longer (2). With the adoption of the “Option B+” strategy into policy, women living with HIV now commence lifelong combination antiretroviral treatment (cART) as early as in pregnancy if not yet on cART. HIV transmission through breastfeeding has now declined to 3% or less (3)(4). In South Africa, government-supplied formula feeding was supported between 2002 and 2011. Thereafter, the policy changed to support exclusive breastfeeding for 6 months and continued breastfeeding for two years or longer, regardless of HIV status (2)(5).

The benefits of exclusive breastfeeding against infectious diseases and nutritional risks in resource-poor settings are well established (6). Also, mixed feeding is associated with an increased risk of HIV transmission through breastfeeding. Exclusive breastfeeding is not well accepted in South Africa (7)(8)(9) having one of the lowest exclusive breastfeeding rates in Africa, with only 8% in infants under 6 months of age reported to be exclusively breastfed(10).

Interventions such as antenatal education, lactation counselling, peer counsellor support, telephonic support, and group counselling improve breastfeeding practices (11). Counselling and education have a higher impact on sustaining breastfeeding when delivered concurrently rather than at different times (11). Interactive mobile text messaging and motivational interviewing are beneficial across many health problems, including viral load suppression for HIV and medication adherence for both HIV and tuberculosis (12)(13). Motivational interviewing is a non-coercive patient-centered approach that explores the patient's readiness to change behavior in the preferred direction and has been shown to be beneficial across many health problems (14)(15).

Current research suggests that combining a number of approaches is more likely to change behavior than a single approach (16). Women struggling with breastfeeding may benefit from telephonic support and motivational interviewing. Assuming widespread implementation of telephonic support and motivational
interviewing, the combined intervention should be cost-effective, simple to implement and easily integrated within the established infant feeding counselling processes. To the best of our knowledge there are no randomized controlled trials (RCTs) assessing the effect of motivational interviewing plus mobile phone text messaging on infant feeding practices among women living with HIV. To undertake a RCT on infant feeding raises practical concerns. These include ascertaining interest in the study, protocol adherence and choice of staff to implement the intervention. We conducted a feasibility study to assess whether a future appropriately powered RCT on the efficacy of motivational interviewing plus mobile phone text messaging on infant feeding practices in individual participants was feasible with regards to i) recruitment and retention, and ii) protocol adherence. In addition, we explored the potential effect of the intervention on sustaining exclusive breastfeeding.

Methods

We followed the Consolidated Standards of Reporting Trials: extension for reporting randomised pilot and feasibility trials (17). The Stellenbosch University Health Research Ethics Committee (reference number N16/09/11) approved the study. The trial was registered on ClinicalTrials.gov on 31/10/2016; NCT02949713 and on Pan African Clinical Trial Registry on 08/11/2016; PACTR201611001855404.

Study Design

We conducted a randomized parallel, two arm standard of care-controlled feasibility trial as previously outlined (18). Briefly, we randomly assigned mother-infant pairs to receive weekly mobile phone text messaging plus in-person motivational interview or standard infant feeding counseling. The principal investigator generated the random allocation sequence using a random number generating R program, with 1:1 allocation ratio and a block size of two. The sequentially numbered random allocation sequence was saved in an Excel spreadsheet on the research nurse’s password-protected laptop. After study counsellors enrolled women meeting inclusion criteria, the research nurse immediately assigned a study group in sequential order. Neither study participants nor the research team were blinded to assignment. We removed viral load of < 400 copies/ml as an inclusion criterion as viral loads were unavailable in some potential participants.

Setting And Study Population

The Worcester midwife obstetric unit provides primary level antenatal care, serving the Breede Valley rural community, 120 km from Cape Town. Antenatal care is provided to about 3 600 women annually, with an antenatal HIV prevalence of 16%. Most patients have neither private medical insurance nor high school education and are unemployed. Women were invited to participate within 24 hours of giving birth at the primary healthcare Worcester midwife obstetric unit. Women verbally consented for screening, the research counsellor completed the eligibility criteria checklist and mothers meeting the inclusion criteria provided written informed consent for a baseline maternal interview and study follow up. Participants
received R250 (~ US$18) at each study visit for their participation time, lunch on study visits and inconvenience.

**Eligibility Criteria**

Women living with HIV were included if they initiated breastfeeding within 24 hours of giving birth, on cART, 18 years of age or older, owned a mobile phone and their infants were considered healthy (discharged within 6 hours of delivery). We excluded women who initiated formula feeding immediately after giving birth, gave birth to more than one infant, had an infant with a birth weight < 2500 grams or gestational age < 36 weeks.

**Study Interventions**

All mothers and their infants, irrespective of study assignment, received standard infant feeding counselling according to the provincial guidelines applicable in the public healthcare sector during the study period.

**Mobile Phone Text Messaging**

The research counselor sent weekly text messages encouraging mothers to exclusively breastfeed and inquired if mothers had any breastfeeding problems. The research counselor contacted mothers by phone if they did not respond to the text messages within 48 hours of receiving it. The research counselor and nurse counseled women who experienced problems with breastfeeding during the telephone calls.

**Motivational Interviewing**

In addition to text messaging, women had in-person individual motivational interviews postpartum at weeks 2, 6, and 10, at Family Clinical Research with Ubuntu (FAMCRU) in Worcester. A research counselor and research nurse trained in motivational interviewing by the principal investigator interviewed the participants. We had 10 training sessions over 10 weeks, each session was an hour long. The principal investigator had periodic in-person joint motivational interviewing sessions with the research counsellor and the research nurse, moderating some of the interviews to identify any additional motivational interviewing training needs.

**Standard Infant Feeding Counselling**

Mothers assigned to the standard infant feeding counselling group were counselled to exclusively breastfeed for the first six months by nurses and trained lay counsellors during routine postnatal clinic
visits at their local primary healthcare clinics. Mothers who reported adherence concerns during study visits were referred for counselling at their local primary healthcare clinics.

Sample Size

We assumed a study size of 60 mother-infant pairs was large enough to determine feasibility of the larger trial with regards to recruitment and retention, and protocol adherence (18). We enrolled and assigned study interventions to 52 of the planned 60 mother-infant pairs between 02 May 2019 and 17 March 2020. Enrollment stopped at the end of March 2020 due to lockdown measures for reducing COVID-19 infection transmission risk.

Study Measurements And Procedures

Two research counselors fluent in the participants’ language completed baseline questionnaires and follow up questionnaires at weeks 2, 6, 10 and 24. To avoid bias, a research counselor not trained in motivational interviewing completed the follow up questionnaires for mothers assigned to standard of care. The counselor trained in motivational interviewing completed the follow up questionnaires for mothers in the intervention group. Participants had in-person follow-up visits until 27 March 2020, because of the COVID-lockdown measures which were implemented in South Africa. Thereafter, we conducted the follow up interviews and collected data by phone until August 2020.

Study Endpoints

Primary feasibility endpoints

The feasibility endpoints included the number of participants invited to the study who consented to participate and the number with complete evaluation of infant feeding practices at all study visits. Pre-specified criteria used to judge whether or how to proceed with a future definitive RCT included:

- Five participants recruited per week (i.e., 60 participants over 12 weeks).
- About 75% of all eligible participants consent to participate.
- Complete evaluation of outcomes in at least 70% of all recruited participants.

Secondary Exploratory Endpoint

- The number of participants who exclusively breastfed at 24 weeks postpartum (exit visit).

We assessed infant feeding practices using mothers’ self-report of food items given to the baby in the last 24 hours and one-week preceding inquiry. We defined infant receiving breastmilk and no other foods
from birth up to a specific study visit as exclusively breastfeeding and mixed feeding if the mother reported breastfeeding in addition to giving other foods.

**Statistical Methods**

We summarized measured variables as mean (standard deviation), median (interquartile range) and categorical variables as count (percent). We reported difference in exclusive breastfeeding rates with corresponding 95% confidence interval. We used Stata 17 (StataCorp, College Station, TX, USA) for analysis.

**Results**

We randomly assigned 27 and 25 mother-infant pairs to the intervention and control groups respectively (Fig. 1 Participant flow). One mother and her infant assigned to the control group were incorrectly captured in the study database as being in the intervention group. After discovering that the pair had received the intervention at first follow up visit, we retained them in the intervention group. Baseline characteristics were similar across the groups (Table 1). Most participants were unemployed, had some high school education, were never married and had disclosed their HIV status to someone close.

One hundred and twenty-three mothers consented for screening, and we excluded 71 (58%) non-eligible participants. All eligible participants consented for study participation. We recruited an average of five participants per month over 11 months.
Table 1
Baseline characteristics of study participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention group: n = 27</th>
<th>Control group: n = 25</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black Africa</td>
<td>16 (59.3)</td>
<td>15 (60.0)</td>
</tr>
<tr>
<td>Mixed race</td>
<td>10 (37.0)</td>
<td>9 (36.0)</td>
</tr>
<tr>
<td>Indian or Asian</td>
<td>1 (3.7)</td>
<td>1 (4.0)</td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>18 (66.7)</td>
<td>21 (84.0)</td>
</tr>
<tr>
<td>Employed</td>
<td>9 (33.3)</td>
<td>4 (16.0)</td>
</tr>
<tr>
<td>Highest level of schooling completed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None completed</td>
<td>1 (3.9)</td>
<td>1 (4.0)</td>
</tr>
<tr>
<td>Primary school (grade 1–7)</td>
<td>3 (11.5)</td>
<td>3 (12.0)</td>
</tr>
<tr>
<td>High school (grade 8–12)</td>
<td>22 (84.6)</td>
<td>21 (84.0)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single/ never married</td>
<td>16 (66.7)</td>
<td>16 (66.7)</td>
</tr>
<tr>
<td>Married or living with partner</td>
<td>8 (33.3)</td>
<td>8 (33.3)</td>
</tr>
<tr>
<td>Mother’s mean (SD)* age in years</td>
<td>29.16 (5.38)</td>
<td>26.21 (9.46)</td>
</tr>
<tr>
<td>Gestational age at delivery mean (SD)</td>
<td>38.42 (1.75)</td>
<td>38 (2.25)</td>
</tr>
<tr>
<td>Timing of HIV diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before pregnancy of the baby in the study</td>
<td>20 (74.1)</td>
<td>19 (79.2)</td>
</tr>
<tr>
<td>During pregnancy of the baby in the study</td>
<td>7 (25.9)</td>
<td>5 (20.8)</td>
</tr>
<tr>
<td>Disclosed HIV status (yes)</td>
<td>23 (85.2)</td>
<td>22 (88.0)</td>
</tr>
<tr>
<td>CD4 count median (IQR)*</td>
<td>440 (321 to 605)</td>
<td>516 (257 to 645)</td>
</tr>
<tr>
<td>Baby gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Girls</td>
<td>11 (47.8)</td>
<td>11 (47.8)</td>
</tr>
<tr>
<td>Boys</td>
<td>12 (52.2)</td>
<td>12 (52.2)</td>
</tr>
<tr>
<td>Birthweight, mean (SD) in weeks</td>
<td>2910.80 (335.14)</td>
<td>3111.74 (377.85)</td>
</tr>
</tbody>
</table>

*SD = standard deviation, IQR = interquartile range
Figure 1 shows mother-infant pairs completing each study visit, the remainder were lost to follow up. About 65% of the participants had complete outcome evaluation at the week 10 visit, decreasing to 35% at week 24. Nineteen mother-infant pairs were followed up until breastfeeding was completely stopped \((n = 1)\) and until end of study \((n = 18)\). A mother in the control group completely stopped breastfeeding at week one due to painful breasts.

Table 2 shows feasibility results. About 44% \((14 \text{ of } 32)\) of the participants who had study exit visit \((\text{week } 24)\) scheduled before 20 March 2020, completed the visit. Of the participants who had study exit visit scheduled between 20 March and August 2020, the COVID-19 lockdown period, 25% \((5 \text{ of } 20)\) completed the visit telephonically.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Target, %</th>
<th>Observed, %</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment, (n)</td>
<td>60</td>
<td>52</td>
<td>• Low number of target population in the study setting; took several months to recruit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• We stopped recruitment because of the COVID-19 lockdown restriction measures</td>
</tr>
<tr>
<td>Consented for study participation</td>
<td>75</td>
<td>100</td>
<td>• Acceptance rate was high; all eligible participants consented for study participation</td>
</tr>
<tr>
<td>Complete evaluation of outcomes</td>
<td>70</td>
<td>35</td>
<td>• 33% intervention group</td>
</tr>
<tr>
<td>Protocol adherence</td>
<td>100</td>
<td>100</td>
<td>• All participants remained in the study group they were assigned until end of study or lost to follow up</td>
</tr>
</tbody>
</table>

Exclusive breastfeeding rates remained relatively high across both groups through week 24. Although the intervention group had higher rates of exclusive breastfeeding at week 24 than the control group \((77.8\% \text{ versus } 55.6\%)\) this difference was not significant; rate difference 22.2\% \([95\% \text{ CI -20.1–64.5\%}]\) (Table 3). Women who completed study follow up were either exclusively breastfeeding or breastfeeding in addition to giving other liquid or solid food.
Table 3
Estimates of exclusive breastfeeding rates by study group

<table>
<thead>
<tr>
<th></th>
<th>Intervention group: n = 27</th>
<th>Control group: n = 25</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exclusive breastfeeding</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visit 1 (week 2)</td>
<td>20</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>17 (85.0)</td>
<td>16 (88.9)</td>
</tr>
<tr>
<td>Visit 2 (week 6)</td>
<td>19</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>16 (84.2)</td>
<td>14 (87.5)</td>
</tr>
<tr>
<td>Visit 3 (week 10)</td>
<td>16</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>12 (75.0)</td>
<td>15 (83.3)</td>
</tr>
<tr>
<td>Visit 4 (week 24)</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>7 (77.8)</td>
<td>5 (55.6)</td>
</tr>
</tbody>
</table>

Estimates are calculated from time of randomization until the specific study visit.

During observations of some of the motivational interviewing sessions, we found that for mothers who were mixed feeding, the research counselor tended to give advice instead of exploring the mother’s readiness to change feeding practice and support the mother’s commitment to do so.

**Discussion**

Study recruitment took 11 months; eight months longer than planned, 35% had complete outcome evaluation at the end of the study, much below the expected 75%. Despite these findings, we recommend proceeding with a definitive trial addressing the challenges to recruitment and retention.

In terms of recruitment, we initially planned to conduct the study at a primary healthcare facility attended by many eligible women living with HIV intending to breastfeed. However, we were only granted access to recruit from a rural healthcare facility, serving a small number of our target population which prolonged our recruitment period. Study investigators should thoroughly assess the size of the target population in a selected study setting to determine a realistic recruitment timeline because of the implications on study duration and costs. With a large enough eligible target population, recruitment targets could be achieved as willingness to participate in the trial was high. Our proposed suggestions based on our experiences may guide planning for large trials in similar settings.

In terms of retention, study participation was relatively high until the third study visit at week 10 but dropped to 35% by week 24, the last study visit. The last study visit coincided with COVID-19 lockdown measures, an unforeseen event. Lockdown restriction measures may have contributed to low study participation at the exit visit, this is corroborated by low participation of participants who had exit visit scheduled after 20 March 2020 compared with participants whose exit visit was scheduled before 20 March 2020 (25% versus 44%). While we may attribute the poor study participation at the exit visit to the COVID-19 lockdown restriction measures, we do not exclude other external contributory factors. Retention was sub-optimal prior to the pandemic. To reduce early withdrawal or loss to follow up, and overcome logistical challenges, providing an option to participate remotely in addition to in-person follow-up visits.
may increase study participation at later follow up. Other strategies to support retention also need to be implemented.

We trained a research counselor and nurse on motivational interviewing to allow variation of choice of health care staff to implement the intervention and enhance generalizability of the technique. Because of the complexity of the motivational interviewing technique, we found that the research counselor tended to give advice instead of exploring the mother’s readiness to change behavior and support the mother’s commitment to do so, especially mothers who struggled with breastfeeding. We allowed the research counselor to lead the interviews, with the research nurse and principal investigator moderating some of the interviews. We cannot rule out a dilution of the intervention effect. In future definitive RCTs, investigators will need qualified research nurses to implement the motivational interview to avoid performance bias that might affect the intervention effect estimates. Although we suggest using research nurses in implementing the intervention, over-stringent selection criteria of staff offering motivational interviewing may increase perceived intervention effect yet limit the intervention’s usefulness in settings where trained lay counsellors predominantly offer infant feeding counselling. In such settings, we recommend adequate training sessions for the counselors, followed by supervised application of the intervention, allowing the counselors to implement the intervention independently at a later stage.

Since there were only a few participants in each group, the study was not powered to identify the number of participants making meaningful changes in exclusive breastfeeding rates between groups at week 24, however, we found that rates of exclusive breastfeeding were slightly higher at 24 weeks in the intervention group although this did not attain clinical significance. Breastfeeding rates were higher than anticipated in both groups which may suggest that the counseling and support provided in the context of the study had some beneficial effect. This poses challenges for inference about the benefits of an intervention as these may be diluted by the upgrade in “standard of care” provided by the study.

We made an attempt to collect data on breastfeeding practices independently of the intervention by having the counselors switch around. However, this may have further contributed to diluting of the effect of the intervention. We cannot rule out retention bias. Mothers who completed the study were possibly more likely to be breastfeeding, and those who were lost to follow up had possibly stopped breastfeeding. However, we do not expect infant feeding practices of those who were lost to follow up to be different between the study groups, thus associations if any are expected to have been biased towards rather away from the null.
Key lessons

- Study investigators should thoroughly assess the size of the target population in a selected study setting to determine a realistic recruitment timeline.
- With a large enough eligible target population, recruitment targets could be achieved as willingness to participate in the trial was high.
- Unexpected external factors may affect study retention, requiring rapid change in study design to mitigate study attrition.
- Strategies to retain participants, such as remote monitoring in addition to in-person follow-up visits, may increase study participation at later follow up.
- Training of the motivational interviewing technique should be tailored to the staff’s qualifications and background training.

Conclusion

Although all predetermined feasibility criteria were not fully met, we plan to implement a larger randomized controlled trial with several changes. Study investigators should thoroughly assess the size of the target population in a selected study setting to determine a realistic recruitment timeline. With a large enough eligible target population recruitment targets could be achieved. Strategies to retain participants, such as remote monitoring in addition to in-person follow-up visits, will be essential.

Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>cART</td>
<td>Combination antiretroviral treatment</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence interval</td>
</tr>
<tr>
<td>COVID-19</td>
<td>Coronavirus disease 2019</td>
</tr>
<tr>
<td>FAMCRU</td>
<td>Family Clinical Research with Ubuntu</td>
</tr>
<tr>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
</tr>
<tr>
<td>IQR</td>
<td>Interquartile range</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>SD</td>
<td>Standard deviation</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>

Declarations

Ethics approval and consent to participate

Participants provided written informed consent. The Stellenbosch University Human Research Ethics Committee approved the study protocol (Ref number: N16/09/110). The study was conducted according
to the ethical guidelines and principles of the International Declaration of Helsinki, South African Guidelines for Good Clinical Practice, and the Medical Research Council Ethical Guidelines for Research.

Consent for publication

Not applicable. Study results are presented in aggregate format in technical reports and journal publications.

Availability of data and materials

The individual participant data is available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

Janssen/CTN Postdoctoral International Fellowship Award of the CIHR Canadian HIV Trials Network and Stellenbosch University (reference no. SU-PT-16/09-000054). The funding body had no role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript or decision to submit the manuscript for publication.

Authors' contributions

MZ conceived the study, study design, data analysis and interpretation and drafted the manuscript. TY participated in study design, revised the manuscript critically for important intellectual content. MFC participated in study design and revised the manuscript critically for important intellectual content. AS assisted with data acquisition, data interpretation and revised the manuscript critically for important intellectual content. LM participated in study design, data interpretation and revised the manuscript critically for important intellectual content. LK assisted with data interpretation and revised the manuscript critically for important intellectual content. LT conceived the study, participated in its design, data interpretation and revised the manuscript critically for important intellectual content. All authors read and approved the final manuscript.

Acknowledgements

This work was supported by Janssen/CTN Postdoctoral International Fellowship Award of the CIHR Canadian HIV Trials Network and Stellenbosch University. We thank the mothers and infants who generously donated their time to the study and without whose participation the study would not have been possible. We gratefully acknowledge the expert assistance provided by the staff at Family Clinical Research with Ubuntu, Tygerberg Academic Hospital, Stellenbosch University, Cape Town, South Africa.

References


Figures
Figure 1

Participant flow