A randomized controlled, trial on effects of mobile phone text messaging in combination with motivational interviewing versus standard infant feeding counselling on breastfeeding and child health outcomes, among women living with HIV

Introduction

Lack of breastfeeding, at a minimum, doubles the risk of infant death in the first six months of life. Many infants in low-resourced settings at high risk of infectious disease morbidity and death are deprived of the immunological and nutritional benefits of breast milk, through an attenuated duration of breast milk exposure. South Africa has one of the lowest exclusive breastfeeding rates in Africa, 8% in infants under 6 months of age. Mobile phone text messaging as a simple, low-cost intervention improves medication adherence among patients with HIV, diabetes, and tuberculosis. Motivational interviewing is a patient-centred non-coercive approach that explores the patient's readiness to change behaviour and supports the person's commitment to do so in the preferred direction. Motivational interviewing has been beneficial across many health problems, including HIV viral load suppression, body weight loss, and alcohol and tobacco use. Improving breastfeeding practices in low-resource settings is key to achieving the Sustainable Development targets for under-five child survival. The need for effective intervention to support breastfeeding in resource-limited settings is increasingly pertinent in view of the increased disease burden on an already stressed public healthcare system. Combining several intervention approaches is more likely to influence behaviour change than an individual approach.

Methods

We conducted a group sequential clinical trial to determine whether text messaging combined with motivational interviewing compared to standard infant feeding counselling prolongs breastfeeding and improves infant health outcomes. Study recruitment started on the 22nd of July 2022. We screened 1145 and enrolled 276 women living with HIV and their infants at birth and randomly assigned study interventions for 6 months. We completed the study follow-up on the 15th of May 2024. A study intervention facilitator who was not involved in administering the study questionnaires at follow up visits administered the study interventions. Research assistants administered a baseline questionnaire and follow up study questionnaires.

Results

Study recruitment started on 22 July 2022. We screened 1145 mother-infant pairs and recruited 276 mother-infant pairs by 27 November 2023. We randomly assigned 138 mother-infant pairs to each study group. We completed study follow up by 15 May 2024. Figure 1 shows participant flow. One hundred five and 101 participants in the intervention group and standard care group, respectively, had outcome data evaluation across all four study visits.

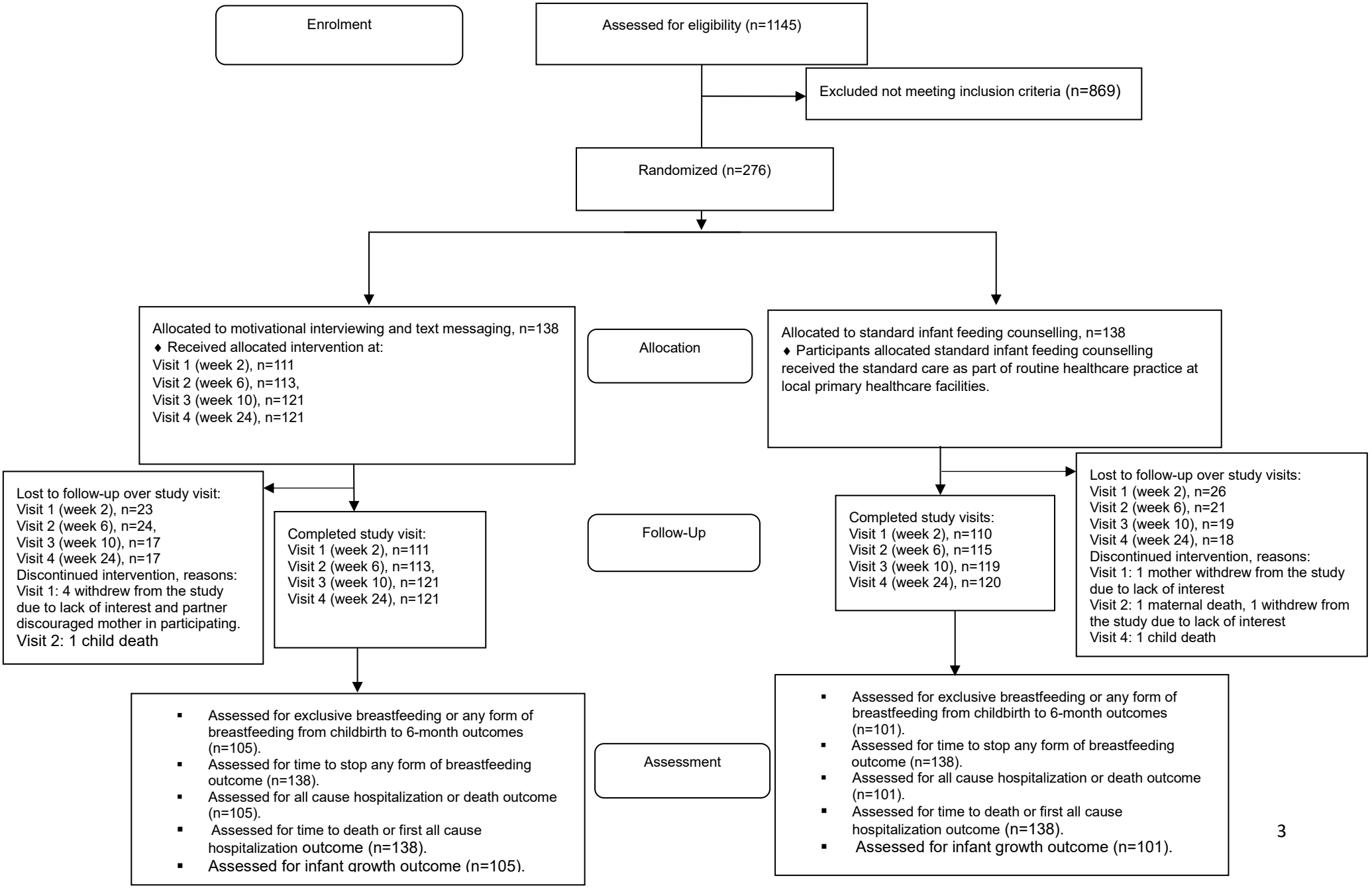
Enrolment
Assessed for eligibility (n=1145)
Excluded not meeting inclusion criteria (n=869)
Randomized (n=276)
Allocated to motivational interviewing and text messaging, n=138
♦ Received allocated intervention at:
Visit 1 (week 2), n=111
Visit 2 (week 6), n=113,
Visit 3 (week 10), n=121
Visit 4 (week 24), n=121
Allocation
Allocated to standard infant feeding counselling, n=138
♦ Participants allocated standard infant feeding counselling received the standard care as part of routine healthcare practice at local primary healthcare facilities.
Lost to follow-up over study visit:
Visit 1 (week 2), n=23
Visit 2 (week 6), n=24,
Visit 3 (week 10), n=17
Visit 4 (week 24), n=17
Discontinued intervention, reasons:
Visit 1: 4 withdrew from the study due to lack of interest and partner discouraged mother in participating.
Visit 2: 1 child death
Completed study visit:
Visit 1 (week 2), n=111
Visit 2 (week 6), n=113,
Visit 3 (week 10), n=121
Visit 4 (week 24), n=121
Follow-Up
Completed study visits:
Visit 1 (week 2), n=110
Visit 2 (week 6), n=115
Visit 3 (week 10), n=119
Visit 4 (week 24), n=120
Lost to follow-up over study visits:
Visit 1 (week 2), n=26
Visit 2 (week 6), n=21
Visit 3 (week 10), n=19
Visit 4 (week 24), n=18
Discontinued intervention, reasons:
Visit 1: 1 mother withdrew from the study due to lack of interest
Visit 2: 1 maternal death, 1 withdrew from the study due to lack of interest
Visit 4: 1 child death
Assessed for exclusive breastfeeding or any form of breastfeeding from childbirth to 6-month outcomes (n=105).
Assessed for time to stop any form of breastfeeding outcome (n=138).
Assessed for all cause hospitalization or death outcome (n=105).
Assessed for time to death or first all cause hospitalization outcome (n=138).
Assessed for infant growth outcome (n=105).
Assessment
Assessed for exclusive breastfeeding or any form of breastfeeding from childbirth to 6-month outcomes (n=101).
Assessed for time to stop any form of breastfeeding outcome (n=138).
Assessed for all cause hospitalization or death outcome (n=101).
Assessed for time to death or first all cause hospitalization outcome (n=138).
Assessed for infant growth outcome (n=101).

Figure 1. Flow of participants

Most mothers were unemployed, had high school education, were single or never married. Disclosure of HIV status to significant others was high, at 95%. Most (87%) mothers had HIV diagnosis before the index pregnancy (table 1).

Table 1 Baseline demographic and clinical characteristics of study participants, *n* = 276

Characteristic	Intervention group, n=138	Standard of care group, n=138
Mother age, mean ±SD	32 ±6 years	31 ±6 years
Gestational age at booking, mean ±SD	16 ±8 weeks	16 ±8 weeks
Gestational age at delivery in weeks, mean ±SD	39± 1	40± 1
Mother most recent CD4 count, median (IQR)	481 (318 to 627) cells/µl	471 (302 to 702) cells/µl
Mother most recent viral load, median (IQR)	20 (20 to 44) copies/ml	20 (20 to 26) copies/ml
Birthweight, mean ±SD	3218± 416 grams	3207± 383 grams
Baby length, mean ±SD	50 ±5 cm	50± 5 cm
Occupation, n (%)		
Unemployed	87 (63%)	91 (66%)
Employed	48 (35%)	41 (30%)
Student	2 (1%)	4 (3%)
Other	1 (1%)	2 (1%)
Highest level of schooling, n(%) completed		
None completed	0 (0%)	2 (2%)
Primary school	2 (1%)	3 (2%)
High school	131 (95%)	126 (91%)
Tertiary	5 (4%)	7 (5%)
Marital status, n (%)		
Single	79 (57%)	82 (59%)
Married/living with partner	57 (41%)	56 (41%)
Divorced/Widowed	2 (2%)	0 (0%)
Baby gender Girl, n (%)	69 (50%)	62 (45%)
Number of complete or incomplete pregnancies, n (%)		
1	23 (17%)	39 (28%)
2	113 (82%)	97 (70%)
3	2 (1%)	2 (2%)
Mode of delivery, n (%)		
Normal delivery	137 (99%)	136 (99%)
Assisted normal delivery	1 (1%)	2 (1%)
Time of HIV diagnosis		
Before pregnancy	121 (88%)	120 (87%)
During pregnancy	16 (11%)	18 (13%)
At delivery	1 (1%)	0 (0%)
Time cART initiation, n (%)		
Before pregnancy	123 (89%)	118 (85%)
During pregnancy	14 (10%)	20 (15%)
At delivery	1 (1%)	0 (0%)
Disclosure of HIV status to significant others, n (%)		
No	10 (7%)	4 (3%)
Yes	128 (93%)	134 (97%)
Baby on antiretroviral prevention, n (%)		
No	130 (94%)	131 (95%)
Yes	4 (3%)	0 (0%)
Don’t know	4 (3%)	7 (5%)

Infant feeding practices

Exclusive breastfeeding practices were modest in both study groups through week 10 and dramatically dropped at week 24 (table 2). We found no significant effect of the intervention on exclusive breastfeeding rates at week 24, (6% versus 7%), rate difference -1% (95% CI -6% to 4%). After inputting missing outcome data, we found rate difference of -1% (95% CI -8% to 5%) (table 3). The z-statistic of -0.36 did not exceed the predefined O'Brien-Fleming stopping boundary value of ±1.9776.

Table 2 Estimate of breastfeeding rates at each study visit by study group.

	Intervention group: n =138		**Standard care group**: n=138	
	n	Number of endpoints (%)	n	Number of endpoints (%)
Exclusive breastfeeding				
Visit 1 (week 2)	111	65 (59%)	110	73 (66%)
Visit 2 (week 6)	113	67 (59%)	115	59 (51%)
Visit 3 (week 10)	121	56 (46%)	119	41 (34%)
Visit 4 (week 24)	121	13 (11%)	120	10 (8%)
Any form of breastfeeding				
Visit 1 (week 2)	111	107 (96%)	110	108 (98%)
Visit 2 (week 6)	113	105 (93%)	115	110 (96%)
Visit 3 (week 10)	121	110 (91%)	119	107 (90%)
Visit 4 (week 24)	121	87 (72%)	120	92 (77%)

Table 3 Estimate of breastfeeding rates, complete case analysis

	Intervention group: n = 138		Standard care group: n=138			
	n	Number of endpoints (%)	n	Number of endpoints (%)	p-value	Rate difference (95% CI)
Co-primary outcomes						
Exclusive breastfeeding from childbirth to 24 weeks	**105**	**6 (6%)**	**101**	**7 (7%)**	**0.72**	**-0.01(-0.06 to 0.04)**
Any form from breastfeeding from childbirth to 24 weeks	**105**	**79 (75%)**	**101**	**79 (78%)**	**0.61**	**-0.03 (-0.15 to 0.09)**
Secondary outcomes						
Exclusive breastfeeding from childbirth to 6 weeks	105	47 (45%)	105	43 (41%)	0.58	0.04 (-0.10 to 0.17)
Any form of breastfeeding from childbirth to 6 weeks	105	98 (93%)	105	96 (91%)	0.60	0.02 (-0.05 to 0.09)
Exclusive breastfeeding from childbirth to 10 weeks	105	29 (28%)	102	24 (24%)	0.50	0.04 (-0.08 to 0.16)
Any form of breastfeeding from childbirth to 10 weeks	105	97 (92%)	102	91 (89%)	0.43	0.03 (-0.05 to 0.11)
All-cause child hospitalization or death	105	4 (2.9%)		9 (6.5%)	0.16	

The odds of exclusive breastfeeding at week 24 were 19% non-significantly lower in the intervention group compared to the standard care group, OR 0.81 (95% CI 0.26 to 2.51), $p = 0.72$.

Most mothers continued breastfeeding while adding other foods through week 24 (table 2 and 3). The intervention had no effect on any form of breastfeeding rates (75% versus 78%), rate difference -3% (95% CI -15% to 9%) in complete case analysis and after inputting missing outcome data, -3% (95% CI -15% to 9%) (table 3). The odds of any form of breastfeeding to week 24 were 15% non- significantly lower in the intervention group compared to the standard care group, OR 0.85 (95% CI 0.44 to 1.62), $p = 0.61$.

Sixty-two of 276 (22%) (34 (25%) in the intervention group and 28 (20%) standard care group) mother-child pairs completely stopped breastfeeding before week 24. The median (IQR) age at time of stopping breastfeeding was 16 (6 to 20) weeks. Time to stopping breastfeeding was similar in the study groups, $p = 0.37$, Figure 2. The most common reasons reported by mothers for stopping breastfeeding were the mother needing to return to work or look for work, 66% (n=41) and insufficient breastmilk or child refused breastmilk, 19% (n=12).

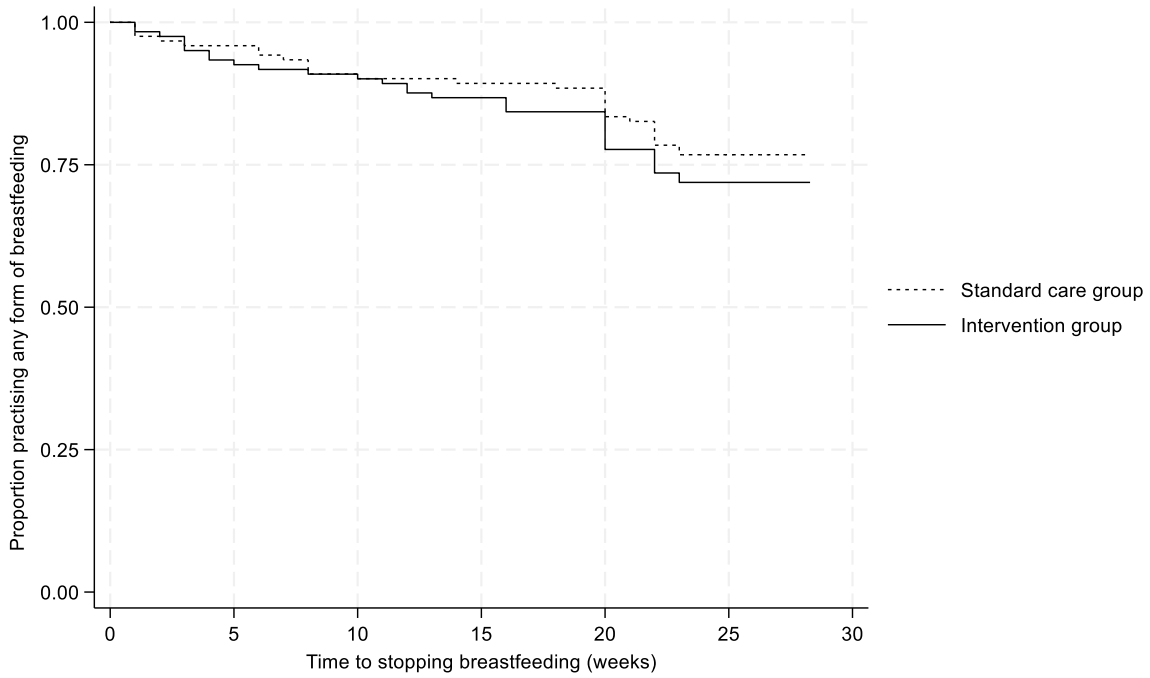

Figure 2. Time to stopping any form of breastfeeding, by study group

All-cause child hospitalization or death

Thirteen children experienced 14 hospital admissions. Twelve children were hospitalized once, and one child in the intervention group was hospitalized twice. Two hospitalized children died, one from each study group. The number of children hospitalized was not different between the intervention group and standard care group, 4 (2.9%) versus 9 (6.5%), p = 0.16. The intervention reduced the odds of hospitalization or death by 61%, OR 0.39 (95% CI 0.10 to 1.57), p = 0.19. Time to child death or first hospitalization was similar in the groups (Figure 3), p = 0.18. Early breastfeeding cessation increased risk of child hospitalization or death compared to breastfeeding to 6 months, among children who completed all visits, 10% (5/48) versus 3% (5/158), p=0.055. Early breastfeeding cessation more than tripled the odds of child hospitalization or death, OR 3.56 (95% CI 0.98 to 12.86).

Most children had diarrhea. Incidence of diarrhea decreased over time, rates were 91% at week 2, 86% at week 6, 63% at week 10 and 16% at week 24. Non-routine medically attended visits were similar; 29 in the intervention group and 30 for standard care.

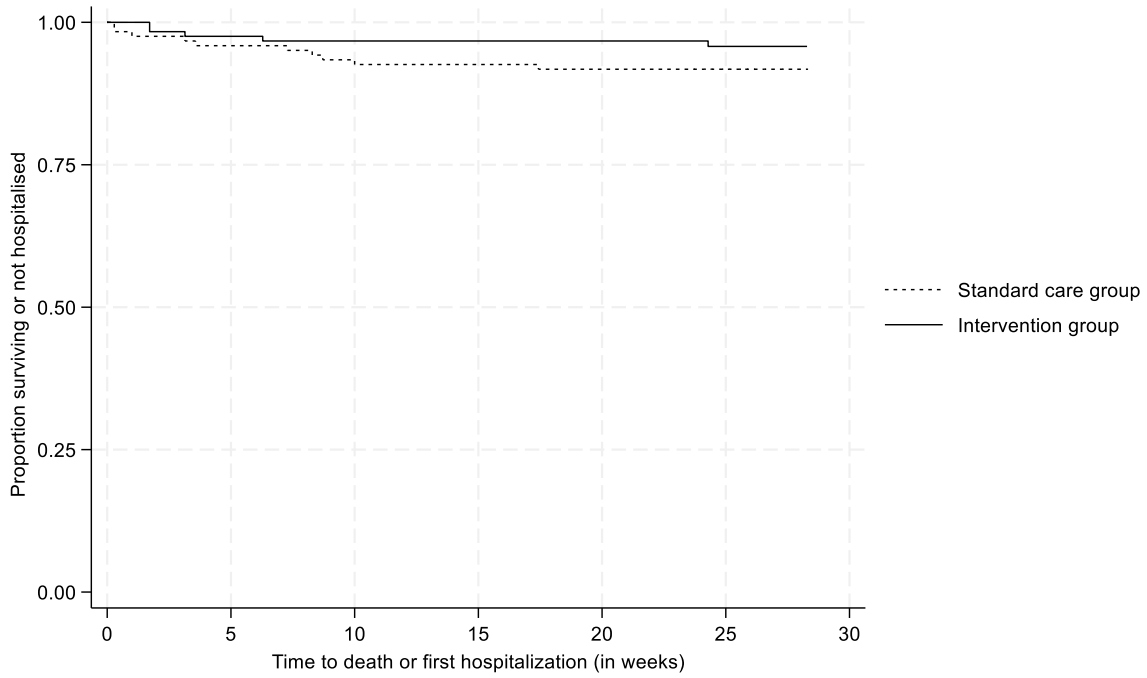

Figure 3. Time to death or first hospitalization, by study group

Most children had diarrhea. Incidence of diarrhea decreased over time, rates were 91% at week 2, 86% at week 6, 63% at week 10 and 16% at week 24. Non-routine medically attended visits were similar; 29 in the intervention group and 30 for standard care.

Infant growth

Infant growth was similar between study groups, (Figures 4 and table 4). Mean weight for age z-scores increased over time in both groups (Figure 4), with no significant difference between groups, $p = 0.87$. We found no significant difference in mean length for age z-scores, $p = 0.21$ and mean weight for length z-scores, $p = 0.88$.

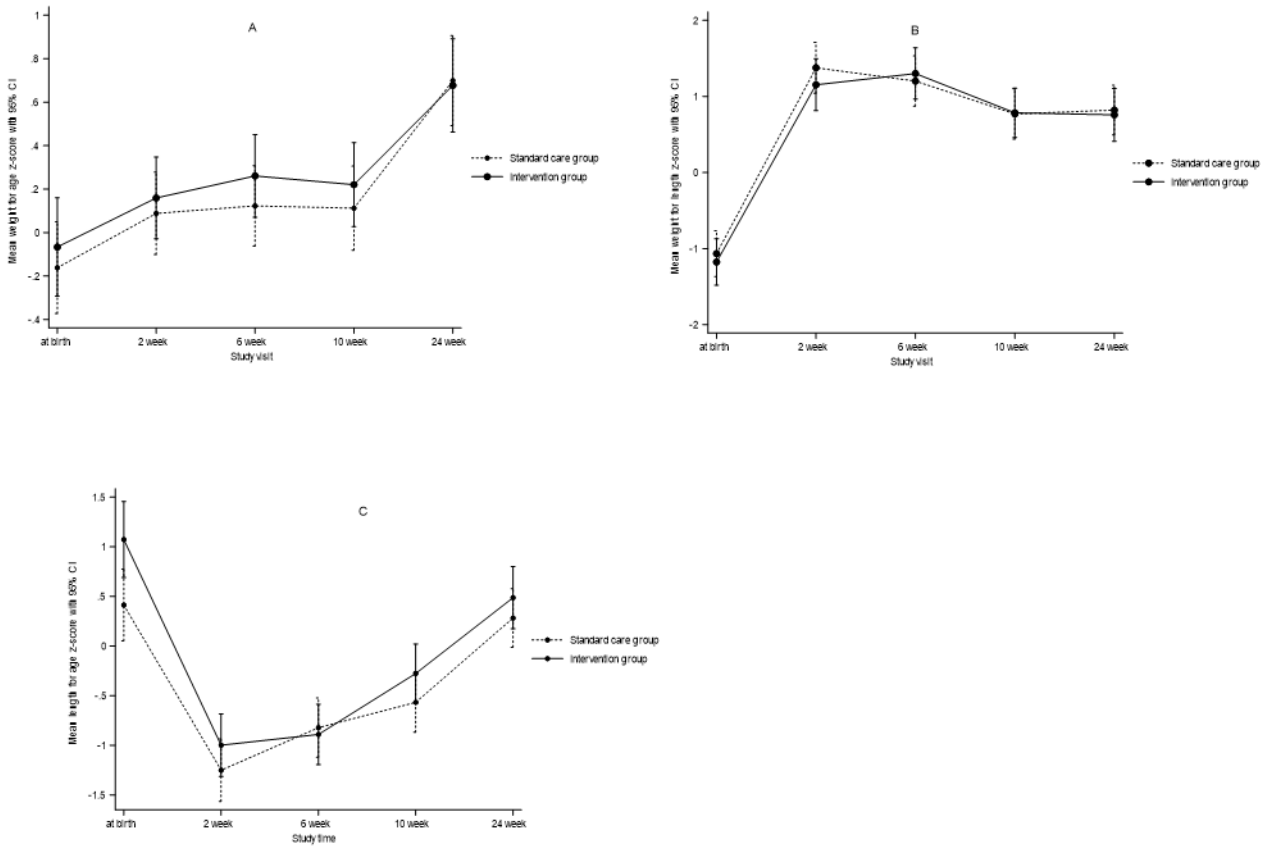

Figure 4. Mean weight for age z-score, weight for length z-score, length for age z-score, by study group

Table 4 Infant growth outcomes, mean z-scores by study group

Study visit	Intervention	Standard care	Mean difference (95% CI)
Mean weight for age z-score			
Visit 2 (6 week)	0.26	0.12	0.14 (-0.13 to 0.40)
Visit 3 (10 week)	0.22	0.11	0.11 (-0.16 to 0.38)
Visit 4 (24 week)	0.68	0.70	-0.02 (-0.32 to 0.28)
Mean length for age z-score			
Visit 2 (6 week)	-0.89	-0.82	-0.07(-0.49 to 0.36)
Visit 3 (10 week)	-0.28	-0.57	0.29 (-0.13 to 0.71)
Visit 4 (24 week)	0.49	0.28	0.21 (-0.22 to 0.63)
Mean weight for length z-score			
Visit 2 (6 week)	1.30	1.20	0.10 (-0.37 to 0.57)
Visit 3 (10 week)	0.78	0.77	0.01 (-0.45 to 0.48)
Visit 4 (24 week)	0.76	0.82	-0.06 (-0.54 to 0.41)

Safety outcomes

Most mothers reported cART adherence in the month prior to each visit as very good or excellent across all visits, rates of very good or excellent adherence ranged between 90% and 97%. Study participation led to no involuntary disclosure of HIV status. No mother reported relationship conflicts with their partners due to study participation. Child immunization profiles were similar across study groups, all infants received BCG at birth, 99% received the week 6, 10 and 14 immunizations and only 19% had received the six-month immunizations.

Conclusion

Socio-economic pressures influenced mothers' decision to stop breastfeeding. Introduction of other foods before six months while breastfeeding remains common. Early cessation of breastfeeding is a public health threat. Finding interventions to enhance exclusive breastfeeding and the provision of high-quality HIV services remains critical. Innovative interventions responsive to socio-economic challenges faced by mothers may be more effective in improving exclusive breastfeeding rates.