The Amagugu intervention for disclosure of maternal HIV to uninfected primary school-aged children in South Africa: a randomised controlled trial

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Summary

Background **Increasing populations of children who are HIV-exposed but uninfected will face the challenge of disclosure of parental HIV infection status. We aimed to test the efficacy of an intervention to increase maternal HIV-disclosure to primary school-aged HIV-uninfected children.**

Methods **This randomised controlled trial was done at the Africa Health Research Institute in KwaZulu-Natal, South Africa. Women who had tested HIV positive at least 6 months prior, had initiated HIV treatment or been enrolled in pretreatment HIV care, and had an HIV-uninfected child (aged 6–10 years) were randomly allocated to either the Amagugu intervention or enhanced standard of care, using a computerised algorithm based on simple randomisation and equal probabilities of being assigned to each group. Lay counsellors delivered the Amagugu intervention, which included six home-based counselling sessions of 1–2 h and materials and activities to support HIV disclosure and parent-led health promotion. The enhanced standard of care included one clinic-based counselling session. Outcome measures at 3 months, 6 months, and 9 months post baseline were done by follow-up assessors who were masked to participants' group and counsellor allocation. The primary outcome was maternal HIV disclosure (full [using the word HIV], partial [using the word virus], or none) at 9 months post baseline. We did the analysis in the intention-to-treat population. This study is registered with ClinicalTrials.gov (NCT01922882).**

Findings **Between July 1, 2013, and Dec 31, 2014, we randomly assigned 464 participants to the Amagugu intervention (n=235) or enhanced standard of care (n=229). 428 (92%) participants completed the 9 month assessment by Sept 3, 2015. Disclosure at any level was more common in the Amagugu intervention group (n=204 [87%]) than in the enhanced standard-of-care group (n=128 [56%]; adjusted odds ratio 9·88, 95% CI 5·55–17·57; p<0·0001). Full disclosure was also more common in the Amagugu intervention group (n=150 [64%]) than in the enhanced standard-of-care group (n=98 [43%]; 4·13, 2·80–6·11; p<0·0001). Treatment-unrelated adverse effects were reported for 17 participants in the Amagugu intervention group versus six in the enhanced standard-of-care group; adverse effects included domestic violence (five [2%] in the Amagugu intervention group *vs* one [<1%] in the enhanced standard-of-care group), sexual assault (four [2%] *vs* one [<1%]), participant illness or death (four [2%] *vs* four [2%]), and family member illness or death (four [2%] *vs* none). No treatment-related deaths occurred.**

Interpretation **The lay-counsellor-driven Amagugu intervention to aid parental disclosure has potential for wide-scale implementation after further effectiveness research and could be adapted to other target populations and other diseases. Further follow-up and effectiveness research is required.**

Funding **National Institutes of Health.**

Introduction

Successful prevention of mother-to-child transmission programmes and HIV treatment access have reduced the number of infected children, but increased the number of children living with HIV-infected parents[1] on antiretroviral treatment (ART).[2] In the scientific literature about parental HIV, uninfected children are grouped as those who are HIV exposed because their mothers were infected during pregnancy, resulting in biological exposure and effects through contextual or caregiving pathways, or as those who are HIV affected because their mother, father, or primary caregiver has become infected after birth, so although biologically unexposed, the child might still be affected through contextual or caregiving pathways. These children have developmental,[3] health,[4] and psychological challenges,[5] particularly where stigma is high.[6] Risks are increased when mothers become ill or die,[7] or when care is unstable.[8] Parental HIV might have negative effects on children's later sexual health, particularly when children have multiple cumulative risks,[9] potentially increasing their risk of becoming HIV infected when they reach adolescence.[10] The success of HIV programmes needs to be followed up with public health strategies to improve children's life chances, for example by safeguarding their health, ensuring ongoing care if their parents become ill, and minimising risks of HIV acquisition. This is important because adolescents are the only population in whom HIV incidence is not decreasing globally.[11]

Parental HIV disclosure to children is a good starting point in improving the outcomes for HIV-exposed,

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Research in context

Evidence before this study

WHO guidelines recommend HIV disclosure to exposed or affected children younger than 12 years. We searched PubMed for articles in English published up to April 29, 2017, with the terms "children" AND "parental HIV disclosure" AND "interventions". In most of the 47 articles that were returned in the search, the focus was on interventions for adolescents or HIV-infected children in high-income countries. Outcomes of HIV-infected, HIV-exposed, and affected children and the associations between parental HIV, illness or death, and children's physical, cognitive, educational, and socioemotional outcomes have been reported in systematic reviews. Benefits of disclosure are consistently reported in observational research from high-income countries, with non-disclosure leading to negative effects. Nevertheless, disclosure rates are low (range 5–67%; median 41%). Disclosure occurs most often in adolescent children, and little research is focused on younger primary school-aged children. In a systematic review of interventions in low-income and middle-income countries, 13 studies were identified and the Amagugu intervention was the only intervention for primary school-aged children. Parental HIV disclosure interventions targeting adolescent and preadolescent children have been tested in a high-income country (USA); in the pilot trial of the TRACK intervention targeting children aged 6–12 years (n=80 families), disclosure occurred in 33% of participants in the intervention group versus 7% in the control group.

Added value of this study

The Amagugu intervention is an established, locally developed conceptual model of a complex intervention, to increase maternal HIV disclosure to primary school-aged children who are HIV exposed but uninfected. For the first time in Africa and low-income and middle-income countries, we show that the Amagugu intervention increases the likelihood of disclosure, improves parent–child communication about HIV and health, and promotes custody planning, with no negative effects on maternal or child mental health.

Implications of all the available evidence

This parent-centred behavioural intervention delivered by lay counsellors rather than nurses, in a task-shifting model suited to low-resource settings, changed the behaviour of HIV-infected parents towards disclosure. Given support, and specific educational guidance, mothers engaged in HIV disclosure at much higher rates than previously reported. The Amagugu intervention is culturally acceptable, effective, and transferable, it has potential for wide-scale implementation after further effectiveness research, and it could be adapted for use with HIV-infected children and to other target populations and diseases.

uninfected children. WHO recommends disclosure to children younger than 12 years,[8] but little guidance exists on how to approach disclosure with children. Maternal HIV disclosure to children benefits mothers[4,6] by improving HIV treatment adherence and compliance, parent–child and family relationships, and mental health, and by reducing stigma. For children, evidence suggests that maternal HIV disclosure improves custody, care plans, and, in high-income countries, mental health. Some qualitative studies report negative effects of unintended or unplanned disclosures.[12] Non-disclosure has negative mental health effects on children and is associated with non-adherence to treatment by mothers.[6] Despite the reported benefits of maternal HIV disclosure,[12] parental disclosure remains low globally,[8] with few interventions developed in and appropriate to low-resource settings.[13]

See Online for appendix

Parental HIV disclosure interventions have been tested in two clinical trials in high-income settings; one with adolescents[6] and the other with children aged 6–12 years.[14] In the TRACK trial,[14] 80 families in the USA were randomly assigned to an intervention that involved three home visits, telephone support, and educational material or standard of care. Mothers in the intervention group were almost five times more likely to disclose their HIV status than mothers in the control group (33% *vs* 7%). Interventions for primary school-aged children are particularly important in settings where HIV is prevalent because household HIV burden is high.[12] In a systematic review[13] of 13 disclosure interventions in low-income and middle-income countries, 12 interventions were focused on adult disclosure to other adults, whereas only one intervention, the Amagugu intervention, focused on parental HIV disclosure to primary school-aged children.

Amagugu means treasures in IsiZulu and is a reference to the importance of children and families in society. The conceptual framework behind the Amagugu intervention (appendix)[15] draws on well established evidence that maternal avoidant coping, non-disclosure and the absence of communication by parents living with a life-threating illness can lead to psychological distress in children and increased pressure on the parenting role. The intervention is designed to shift maternal parenting behaviours to an active coping style and emphasise behavioural change towards parenting practices that address important issues linked to the children's wellbeing, including health education and custody planning. Before this randomised controlled trial, we completed a pilot study[16] and a large-scale uncontrolled assessment of 281 families.[17,18]

The primary aim of this study was to compare the efficacy of the Amagugu intervention with that of enhanced standard of care, a single counselling session at a primary health-care facility. We hypothesised that the Amagugu intervention would increase rates of maternal HIV disclosure to HIV-uninfected children aged 6–10 years,

leading to secondary benefits such as improvements in health-care engagement, custody planning, and the parent–child relationship.

Methods

Study design and participants

This randomised controlled trial took place at the Africa Health Research Institute (AHRI), previously known as the Africa Centre for Population Health, in a rural, HIV-endemic region of KwaZulu-Natal, South Africa, where HIV treatment coverage is good.[19] The study community included one periurban township, one district level hospital, and 18 primary health-care facilities. We recruited participants from primary health-care facilities with well established HIV treatment programmes. To be eligible for enrolment, participants had to have tested HIV positive at least 6 months prior, have initiated HIV treatment or be enrolled in pretreatment HIV care, be the mother of an HIV-uninfected child (aged 6–9 years) residing in her household, and have mental capacity to consent. We excluded women who had already disclosed to any children in the household younger than 10 years or who had participated in the previous Amagugu pilot or evaluation studies. In response to a slow recruitment rate in the first 6 months, we increased the age range of children to 6–10 years, and we expanded the number of recruitment sites from one to four primary health-care facilities. We completed screening, enrolment, randomisation, and data collection (appendix p 2) with the Mobenzi Mobile Researcher Platform (MRP), previously validated and used in South Africa.[20]

Ethical approval was granted by the University of KwaZulu-Natal Biomedical Research Ethics Committee (BREC; BFC273/12) and the Department of Health Provincial Research Ethics Committee (HRKM078/13). This trial is registered with ClinicalTrials.gov (NCT01922882), and the full study protocol is available on the AHRI data repository.

Randomisation and masking

Participants were randomly allocated to either the Amagugu intervention or enhanced standard of care, using a computerised algorithm based on simple randomisation and equal probabilities of being assigned to each group. Randomisation was completed in the MRP with guidance from the trial's statistician. We used a computer-generated random-numbers algorithm (Microsoft C#) to create a prerandomised list of participant identification numbers linked to each of the four primary health-care facilities. We estimated the number of participants to be randomised on the basis of estimated maximum recruitment. The baseline assessor informed the participant of their allocation, and participants were allocated counsellors electronically (ensuring even distribution). Counsellors were notified of their participant's contact details via SMS. We collected outcome measures with surveys that were completed by independent follow-up assessors who were masked to participants' randomisation and counsellor allocation. A Mobenzi mobile phone app allocated surveys to follow-up assessors electronically, and supervision strategies were implemented to ensure that the follow-up assessor worked independently of other trial staff. Follow-up surveys were carefully designed to ensure questions were standardised between groups and did not reveal randomisation. The success of masking was not assessed.

Procedures

Assessments were done with the Mobenzi app and uploaded to the MRP via secure SMS data transfer. The MRP automated system delivered surveys and contact details of participants to the follow-up assessors' mobile phones 1 week before the assessment date. Follow-up assessment at 9 months was based on 9 months post baseline. Our data collection protocol allowed the 9 month assessment to be completed for up to 60 days after its due date. Most assessments were completed within 20 days of being due, and we declared participants lost to follow-up if they could not be traced.

The Amagugu intervention included six 1–2 h sessions delivered to mothers in their homes over an 8–12 week period. Printed materials and activities were provided to support age-appropriate disclosure and to prepare mothers for their children's emotional reactions and questions after disclosure.[16–18] A detailed description of the intervention and the content of each of the sessions are included in the appendix (p 5). Although structured, the intervention allowed mothers to adjust the content to suit their circumstances and their child's developmental needs. Mothers selected the level of disclosure they were comfortable with: partial disclosure (using the word virus), full disclosure (using the word HIV), or no disclosure. Female lay-counsellors, all high school graduates with several years' counselling experience, did not intervene directly with children but supported mothers to communicate with their children independently, thus enabling skills transference. Counsellors completed a 2 week training programme with the Amagugu training materials, including practical exercises and competency testing. We saw the intervention counsellors fortnightly for supervision, and each counsellor managed 15–25 families concurrently.

The South African Department of Health has no defined standard of care with respect to parental HIV disclosure to HIV-uninfected children, other than a recommendation to counsel-to-disclose. We offered participants allocated to enhanced standard of care a 1 h counselling session focused on disclosure, delivered at the primary health-care facility as part of routine HIV services, either immediately or at a convenient time. We approached participants again if they deferred counselling to remind them about the offer of counselling, both by telephone and at their regular clinic visits, but we did not do any counselling outside the facility. During the session, participants were provided

For the **Mobenzi service** see www.mobenzi.com

For the **Africa Health Research Institute data repository** see http://www.africacentre.ac.za

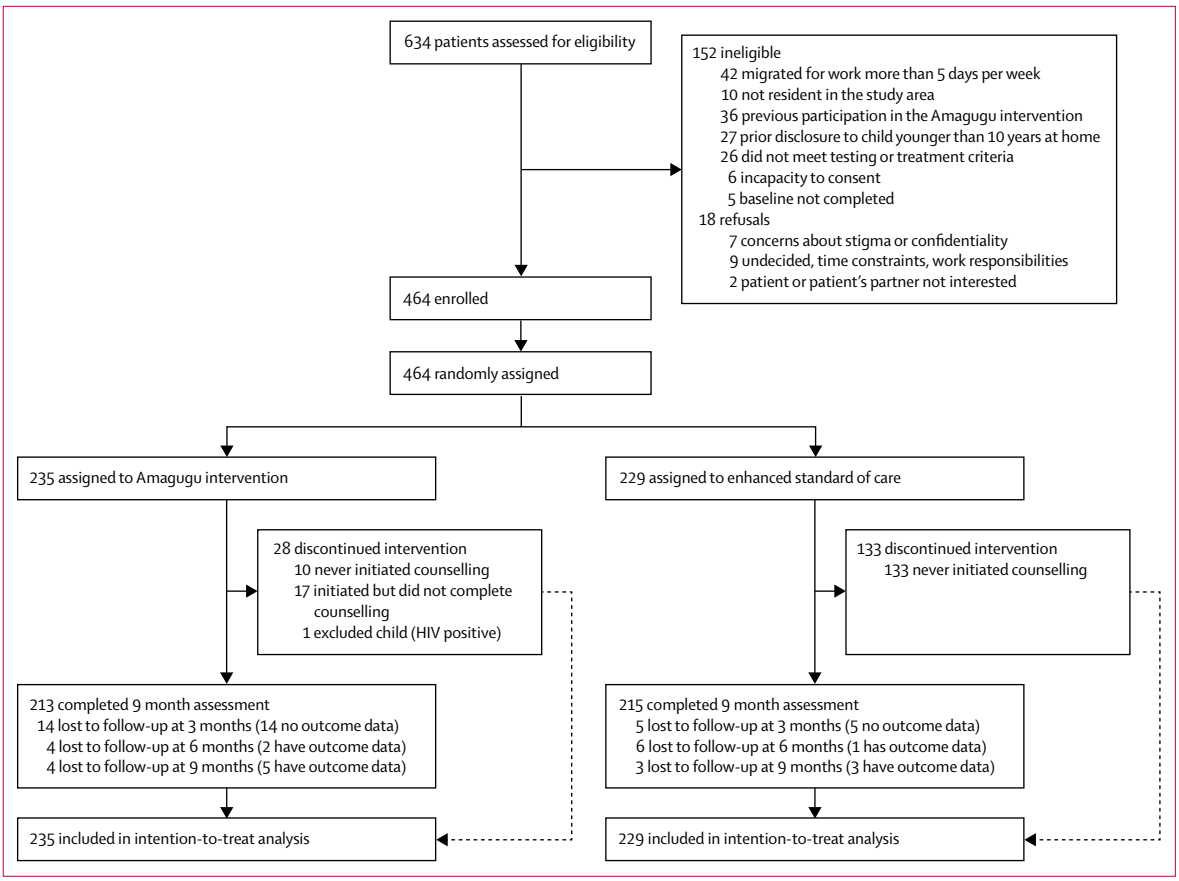

Figure 1: **Trial profile**

information on the benefits of disclosure and disclosure guidance using a short vignette, and we encouraged mothers to bring their children to a clinic visit and undertake custody planning. Counselling took place in a private, furnished room; however, unlike in the Amagugu intervention, we did not provide intervention materials. Counsellors delivering the enhanced standard of care had equivalent qualifications and experience to those in the intervention group and participated in a 1 day training workshop with a training manual, role plays, and competency testing. We saw the enhanced standard-of-care counsellors every 2 months for supervision.

All health-care staff, including HIV-treatment nurses and counsellors, participated in a half-day workshop about the benefits of HIV disclosure, health-care engagement, and custody planning for HIV-exposed children.

We completed case reviews and study-specific fidelity checklists (developed and tested during the evaluation study[17,18]) with counsellors in both the Amagugu intervention and the enhanced standard-of-care groups. An experienced trainer (a Zulu-speaking PhD student) completed fidelity observations (using study-specific scoring sheets) with 10% of participants in both the Amagugu intervention and enhanced standard-of-care groups, including all counsellors across all intervention sessions. Average fidelity scores were more than 90% during the trial. The counselling teams operated completely independently of each other. Counsellors were line-managed by different individuals, used separate transport services, were supervised separately, had differing scopes of work, and were based at different geographical locations. We operationalised case reviews, supervision, and all aspects of the two groups separately, and we took steps to ensure contact between staff members in each group was minimised.

Outcomes

The primary outcome was disclosure over 9 months post baseline. If participants reported partial disclosure at an earlier timepoint, we repeated the survey at all further assessments or until full disclosure was reported. The secondary outcomes were health-care engagement, care, and custody planning, using previously developed and tested study-specific surveys[17,18] at 3 months, 6 months, and 9 months post baseline. Other secondary outcomes were measured using psychometric scales in interview format, translated into IsiZulu and all used previously, either in the study population or in other research with similar South African populations. We used the Patient Health Questionnaire Depression Scale (PHQ-9) and General

Anxiety Disorder Scale (GAD-7) to measure maternal mental health at baseline, 3 months, 6 months, and 9 months post baseline; the General Health Subscale of the Rand Health Medical Outcomes Study 36-item Short Form (MOS-36SF) to measure health-related quality of life at baseline and 9 months post baseline; the Parenting Stress Index Short Form (PSI-36SF) to measure parenting and the parent–child relationship at baseline, 3 months, 6 months, and 9 months post baseline; the Child Behaviour Checklist (CBCL) to measure child mental health at baseline, 6 months, and 9 months post baseline; and the General Functioning Subscale of the McMaster Family Assessment Device (FAD) to measure family functioning at baseline, 3 months, 6 months, and 9 months post baseline. All measures had good reliability scores in this randomised controlled trial (appendix p 6).

We established a Data Safety and Monitoring Board (DSMB) before recruitment and completed four reviews during the trial. The MRP provided an automated weekly report identifying potential harms using follow-up assessment data; these data included measures of potential suicide ideation and adverse effects of disclosure. We defined serious adverse events by a Terms of Reference approved by the DSMB and BREC, and reported adverse events to the DSMB and BREC within 3 days and 7 days, respectively. Serious adverse events included maternal or child death, illness necessitating admission to hospital for more than 5 days, or severe psychological or psychiatric illness (including psychosis, suicide ideation), trauma, violence, or stigma as a direct result of the intervention or control conditions.

Statistical analysis

We calculated that a sample size of 480 participants followed up at 9 months would achieve 90% power to detect a difference in disclosure of 30% versus 45% (probability of type-I error of 5%, two-tailed), allowing for a 20% loss to follow-up (ie, final sample of 384 women). In line with an intention-to-treat principle, no imputation procedure was implemented to deal with participants who were lost to follow-up.

We compared continuous variables using independent two-sample *t* tests and Wilcoxon-Mann-Whitney tests. We assessed normality with the Shapiro-Wilk test and homoscedasticity with the Bartlett's test. We used IQR as a measure of dispersion. We fitted logistic and ordinal (proportional odds) regression models, adjusting for covariates where necessary, to compare the main outcomes. We analysed time to disclosure using Kaplan-Meier estimates and differences in time to disclosure by group using the log-rank test. We fitted mixed-effects models with random effects in the intercept to account for the repeated measures resulting from the trial's protocol. We also fitted Cox proportional hazard models to analyse outcomes related to time to any and full disclosure. We evaluated the assumption of proportional hazards using the Therneau-Grambsch test.[21] We used R (version 3.2.1) for analyses. Statistical analysis was done by an independent trial statistican.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between July 1, 2013, and Dec 1, 2014, we approached 634 women attending HIV facilities. 482 women met eligibility criteria, and 18 (4%) women declined participation. 464 women were enrolled and randomly assigned, 235 to Amagugu intervention and 229 to enhanced standard of care (figure 1). 428 (92%) participants completed the 9-month endpoint assessment (on Sept 3, 2015). At baseline, participants in the Amagugu intervention group had a higher proportion of sons (p=0·009) and higher levels of maternal employment (p=0·022) than did those in the enhanced standard-of-care group (table 1); we also detected significant differences in child age between the two groups (p=0·022), but the actual difference was small.

22 women (9%) in the Amagugu intervention group and 14 women (6%) allocated to receive enhanced standard of care did not complete the 9-month assessment (χ^2 p=0·2568). 96 participants in the enhanced standard-of-care group received counselling and 133 did not. Nine of the women who received counselling and five of the women who did not receive counselling were not followed up at 9 months. We detected no difference in the distribution of

	Total (n=464)	Amagugu intervention (n=235)	Enhanced standard of care (n=229)
Maternal age (years)	33 (29–39)	32 (29–39)	34 (29–39)
Maternal duration of antiretroviral therapy (years)	2·58 (1·29–4·66)	2·60 (1·29–5·02)	2·50 (1·29–4·33)
Maternal education			
None	25 (5%)	18 (8%)	7 (3%)
Some primary	74 (16%)	31 (13%)	43 (19%)
Grade 5 (primary school complete)	102 (22%)	47 (20%)	55 (24%)
Some secondary	143 (31%)	78 (33%)	65 (28%)
Grade 12 (secondary complete)	115 (25%)	57 (24%)	58 (25%)
Tertiary	5 (1%)	4 (2%)	1 (<1%)
Maternal employment			
Yes	111 (24%)	67 (29%)	44 (19%)
No	353 (76%)	168 (71%)	185 (80%)
Maternal HIV treatment			
Yes	416 (90%)	207 (88%)	209 (91%)
No	49 (10%)	28 (12%)	21 (9%)

(Table 1 continues on next page)

	Total (n=464)	Amagugu intervention (n=235)	Enhanced standard of care (n=229)
(Continued from previous page)			
Maternal health perceptions (Medical Outcomes Study General Health Subscale, item 1)			
Excellent	87 (19%)	47 (20%)	40 (17%)
Very good	150 (32%)	75 (32%)	75 (33%)
Good	134 (29%)	63 (27%)	71 (31%)
Fair	74 (16%)	41 (17%)	33 (14%)
Poor	20 (4%)	9 (4%)	11 (5%)
Maternal relationship status			
Not in a relationship	63 (13%)	34 (14%)	29 (13%)
In a relationship with child's father	185 (40%)	89 (38%)	97 (42%)
In relationship with new partner	216 (47%)	112 (48%)	104 (45%)
Mother living with partner			
Yes	132 (28%)	63 (27%)	69 (30%)
No	270 (58%)	138 (59%)	132 (57%)
Not in relationship	63 (14%)	34 (14%)	29 (13%)
Mother knows partner's HIV status			
Yes	151 (33%)	78 (33%)	73 (32%)
No	119 (26%)	60 (26%)	59 (26%)
Not applicable	195 (42%)	97 (41%)	98 (42%)
HIV status of mother's partner			
Positive	117 (25%)	64 (27%)	53 (23%)
Negative	31 (7%)	13 (6%)	18 (8%)
Indeterminate	2 (<1%)	1 (<1%)	1 (<1%)
Declined to answer	1 (<1%)	0	1 (<1%)
Not applicable	314 (68%)	157 (67%)	157 (68%)
Mother disclosed HIV status to partner			
Yes	210 (45%)	107 (46%)	103 (45%)
No	60 (13%)	31 (13%)	29 (12%)
Not applicable	195 (42%)	97 (41%)	98 (43%)
Level of disclosure to partner			
Full (using the word HIV)	204 (44%)	102 (43%)	102 (44%)
Partial (using the word virus)	6 (1%)	5 (2%)	1 (<1%)
No disclosure or not applicable	255 (55%)	128 (55%)	127 (55%)
Child's father alive			
Yes	363 (78%)	177 (75%)	186 (81%)
No	94 (20%)	52 (22%)	42 (18%)
Don't know	8 (2%)	6 (3%)	2 (1%)
Child's age (years)	7·90 (6·98–8·92)	7·78 (6·86–8·76)	7·97 (7·19–9·05)
Child's sex			
Male	232 (50%)	131 (56%)	101 (44%)
Female	233 (50%)	104 (44%)	129 (56%)

Data are median (IQR) or n (%).

***Table 1*: Baseline characteristics**

participants who were lost to follow-up in the three groups (intervention, standard-of-care treatment compliant, and standard-of-care treatment non-compliant; χ^2 p=0·2218).

Any level of disclosure (partial or full) was achieved by more participants in the Amagugu intervention (204 [92%] of 221 participants) than in the standard-of-care group (128 [57%] of 224 participants). A larger proportion of participants achieved full disclosure with the Amagugu intervention (150 [68%] of 221 participants) than with standard of care (98 [44%] of 224 participants). When adjusted for child's sex, maternal employment level, and child's age, the odds of any disclosure to children (including partial or full disclosure) was nine times higher (adjusted odds ratio [aOR] 9·88, 95% CI 5·55–17·57; p<0·0001) and the odds of full disclosure four times higher (4·13, 2·80–6·11; p<0·0001) in the Amagugu intervention group than in the enhanced standard-of-care group (table 2). These findings did not differ substantively from the unadjusted analysis.

Unadjusted time to any disclosure was shorter in the Amagugu intervention group than in the enhanced standard-of-care group (median 2·14 months *vs* 7·46 months, log-rank test p<0·0001), as was time to full disclosure (median 2·83 months *vs* 9·10 months, log-rank test p<0·0001; appendix p 7). To account for the three covariates associated with trial group, we fitted multivariable Cox proportional hazard models to both times to disclosure. In both models, the assumption of proportional hazards was not rejected. For time to any disclosure, the adjusted hazard ratio (aHR) was 0·29 (95% CI 0·23–0·36; p<0·0001), indicating that participants in the enhanced standard-of-care group had a 29% probability of completing disclosure compared with the Amagugu intervention. Only the child's sex had a significant effect on time to disclosure (1·25, 1·00–1·56; p=0·047), such that participants in enhanced standard of care were 25% more likely to disclose if disclosure was to a daughter rather than a son. For time to full disclosure (aHR 0·39, 0·31–0·49; p<0·0001), the only covariate with a significant effect was child age (aHR 1·12, 1·01–1·23; p=0·025).

In an exploratory analysis of potential intergroup differences in maternal disclosure among the 403 mothers with more than one child, 60 (30%) of 197 mothers in the Amagugu intervention group and 44 (21%) of 206 mothers in the enhanced standard-of-care group disclosed their HIV status to at least one other child aged 6 years or older (OR 1·61, 1·00–2·60; p=0·041).

Compared with participants receiving enhanced standard of care, more participants in the Amagugu intervention group visited the clinic with their child (OR 27·17, 95% CI 15·63–47·24; p<0·0001), completed a care plan (5·01, 3·25–7·74; p<0·0001), and discussed the care plan with the child (2·90, 1·40–5·98; p<0·0001; table 2). A greater number of participants in the Amagugu intervention group appointed a guardian (2·20, 1·25–3·85) than in the enhanced standard-of-care group, and guardians were appointed earlier in the intervention group than in the enhanced standard-of-care group (0·39, 0·26–0·59).

We found no differences between the effects of the Amagugu intervention and the enhanced standard of care on a range of psychological secondary outcomes. Both groups showed improvements in maternal and

child mental health, family functioning, health-related quality of life, and overall parenting stress. However, compared with the enhanced standard of care, participants in the Amagugu intervention group had significantly lower scores on the Parent–Child Dysfunctional Relationship subscale of the PSI-36SF (table 3, figure 2).

17 adverse events were recorded in the Amagugu intervention group versus six adverse events in the enhanced standard-of-care group, none of which were related to treatment. Adverse effects included domestic violence (five [2%] in the Amagugu intervention group *vs* one [<1%] in the enhanced standard-of-care group), sexual assault (four [2%] *vs* one [<1%]), participant's illness or death (four [2%] *vs* four [2%]), and family member's illness or death (four [2%] *vs* none). No treatment-related deaths occurred.

Discussion

This low-intensity intervention, delivered by lay counsellors, led to substantially increased rates of maternal HIV disclosure in a relatively short time period, with significant improvements in measures of health-care engagement and care planning for the child and further disclosures to other children in the home. Disclosure rates, health-care engagement, and care planning were substantially lower in the enhanced standard-of-care group than in the Amagugu intervention group. We did not find differences in psychological outcomes between groups, although both groups showed marked improvements from baseline, suggesting that disclosure did not lead to obvious negative mental health effects. We found evidence of benefits to the quality of the parent–child relationship from the Amagugu intervention.

These findings are important because, notwithstanding access to lifesaving ART, HIV-infected mothers still have challenges that include maintaining lifelong treatment and negotiating possible periods of illness and hospital admissions, which affect family life and caregiving.[7] Stigma is often high,[9] leaving parents and children socially isolated and stressed.[4] Although parents often avoid disclosure about HIV in an effort to protect children,[6,17] children are likely to be aware of parental HIV by primary school age, particularly in epidemic areas.[12,15,17] Rates of disclosure in the Amagugu intervention were higher than those recorded in other research from other parts of the world (50% in Uganda; 35% in Thailand; 31% in Canada, and 11% in Europe).[6] Likewise, participants were willing to disclose to children at younger ages than has generally been reported in scientific literature from low-income and middle-income countries.[6] Developmental literature[22] about parents with other life-threating diseases suggests that the absence of communication about parental illness has negative effects on children. With millions of families affected by HIV in sub-Saharan Africa,[1] interventions that improve family communication and planning[23] in the context of HIV[4,7] could have important public health benefits.

In view of evidence that increased maternal disclosure to children is associated with improved treatment adherence and compliance with clinical appointments and improved family communication, it is plausible

	Total (n=464)	Amagugu intervention (n=235)	Enhanced standard of care (n=229)	OR (95% CI)	Adjusted OR (95%CI)
Primary outcome					
Disclosed HIV status					
Yes	332 (75%)	204 (92%)	128 (57%)	9·00 (5·14–15·77)	9·88 (5·55–17·57)
No	113 (25%)	17 (8%)	96 (43%)	..	..
Missing	19	14	5	..	..
Level of disclosure					
Full disclosure	248 (56%)	150 (68%)	98 (44%)	3·67 (2·52–5·35)	4·13 (2·80–6·11)
Partial disclosure	84 (19%)	54 (24%)	30 (13%)	..	..
No disclosure	113 (25%)	17 (8%)	96 (43%)	..	..
Missing	19	14	5	..	..
Secondary outcomes					
Took child to clinic visit					
Yes	265 (60%)	202 (91%)	63 (28%)	27·17 (15·63–47·24)	31·49 (17·51–56·61)
No	180 (40%)	19 (9%)	161 (72%)	..	..
Missing	19	14	5	..	..
Completed care plan for child					
Yes	290 (65%)	182 (82%)	108 (48%)	5·0 (3·25–7·74)	5·55 (3·53–8·71)
No	155 (35%)	39 (18%)	116 (52%)	..	..
Missing values	19	14	5	..	..
Discussed care plan with child					
Yes	255 (57%)	168 (76%)	87 (39%)	2·90 (1·40–5·98)	3·56 (1·64–7·69)
No	35 (8%)	14 (6%)	21 (9%)	..	..
No care plan completed	155 (35%)	39 (18%)	116 (52%)	..	..
Missing	19	14	5	..	..
Legal guardian appointed					
Yes	382 (86%)	200 (90%)	182 (81%)	2·20 (1·25–3·85)	2·22 (1·25–3·94)
No	63 (14%)	21 (10%)	42 (19%)	..	..
Missing values	19	14	5	..	..
Timing of guardian appointment					
3 months	223 (50%)	139 (63%)	84 (38%)	0·39 (0·26–0·59)	0·40 (0·26–0·61)
6 months	121 (27%)	47 (21%)	74 (33%)	..	..
9 months	38 (9%)	14 (6%)	24 (11%)	..	..
No guardian appointed	63 (14%)	21 (10%)	42 (19%)	..	..
Missing	19	14	5	..	..

Data are n (%) unless indicated otherwise. Adjusted OR was OR adjusted by maternal employment level, child's age, and child's sex. OR=odds ratio.

***Table 2*: Disclosure (primary outcome) and secondary outcomes of health-care engagement, care, and custody planning**

	Baseline		9-month follow-up		Unadjusted p value*	Adjusted p value†
	Intervention (n=235)	Enhanced standard of care (n=229)	Intervention (n=213)‡	Enhanced standard of care (n=215)‡		
General health subscale (MOS-36SF)§	63·3 (12·6)	64·1 (11·6)	67·3 (19·8)	66·7 (20·9)	0·36	0·51
Depression (PHQ-9)	5·6 (5·0)	6·0 (5·7)	4·9 (4·7)	5·0 (4·9)	0·53	0·52
Anxiety (GAD-7)	4·5 (4·5)	5·0 (5·0)	3·1 (4·0)	3·3 (4·0)	0·33	0·54
Parenting stress total (PSI-36SF)	86·9 (26·1)	84·9 (24·0)	75·6 (29·5)	77·7 (25·4)	0·31	0·12
Parental distress subscale	34·7 (12·8)	34·7 (12·5)	27·6 (12·9)	28·4 (11·5)	0·60	0·50
Parent–child relationship dysfunction subscale	24·7 (8·8)	22·8 (7·5)	23·1 (10·6)	23·2 (9·5)	0·025	0·044
Difficult child subscale	27·4 (8·6)	27·5 (8·6)	24·9 (9·8)	26·1 (8·8)	0·95	0·19
Child						
Child behaviour total problems (CBCL)¶	52·9 (9·1)	52·0 (8·9)	47·1 (10·5)	47·1 (9·8)	0·32	0·27
Internalising	53·7 (9·8)	53·0 (9·5)	47·0 (10·5)	47·3 (9·9)	0·38	0·32
Externalising	51·9 (10·8)	51·9 (9·9)	46·4 (11·6)	46·1 (10·8)	0·845	0·75
Family						
General functioning subscale (FAD)	2·5 (0·3)	2·5 (0·3)	2·4 (0·3)	2·4 (0·3)	0·65	0·24

Numbers are mean (SD). MOS-36SF=Rand health Medical Outcomes Study 36-item short form. PHQ-9=Patient Health Questionnaire Depression Scale. GAD-7=Patient Health Questionnaire General Anxiety Scale. PSI-36SF=Parenting Stress Index Short Form. CBCL=Child Behaviour Checklist. FAD=McMaster Family Assessment Device. *For the General Health Subscale of the MOS, a high score means improved health-related quality of life. †For the CBCL Ratings to Score, a test developer-norming software produces a standardised *t* score by disorder; the scores are based on the number of emotional or behavioural problems a mother rates her child to have; the higher the total problems score, the more problems a mother thinks her child has. ‡Analysis based on complete cases at 9 months, using all available data, excluding loss to follow-up in intervention (n=22) and enhanced standard of care (n=14) groups. §p-values result from a *t* test for difference between 9 months and baseline by groups. ¶p values are for main effects of differences between 9 months and baseline by group adjusting for maternal employment, sex, and age; the models included an interaction term between timepoint and group (interaction model).

***Table 3*: Secondary outcomes for parent–child relationships, maternal and child mental health, and family functioning**

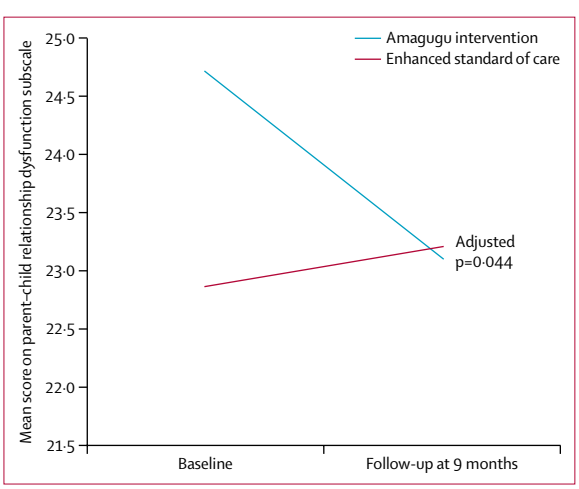

***Figure 2*: Changes in the parent–child relationship dysfunction subscale, by group**

The parent-child dysfunction interaction subscale is a subscale of the Parenting Stress Index PSI-36SF. It consists of 12 items scored 1 (strongly disagree) to 5 (strongly agree); total scores range from 12 to 60. The scale measures the extent to which parent–child interactions are satisfying, whether the child is seen as a disappointment, or whether the parent feels rejected by, or alienated from, the child. High scores indicate high parent–child relationship dysfunction.

that maternal disclosure to children holds long-term benefits for both mother and child.[6] That the Amagugu intervention achieved a high level of behavioural change in the mother, not only with respect to HIV disclosure but also in engagement with a clinic visit and custody planning, in a short time, is encouraging. Findings from another parenting intervention in South Africa[24,25] suggest that if programmes for HIV-infected parents and their children do not target HIV disclosure directly, disclosure rates remain low, and this non-disclosure is associated with increased behavioural problems in children over time. The primary and secondary outcomes of this trial suggest that without an intervention that actively encourages parents to deal with communication about HIV, health education, and care planning, the rates of these actions remain low, which is concerning since the absence of these actions confers risks.[5,15]

Mothers receiving enhanced standard-of-care were more likely to disclose their HIV status to daughters than to sons,[6,7] which is possibly linked to expectations that girls will assist with caregiving during illness. HIV-infected parents have multiple stressors, including strained family relationships, which complicate care planning for children.[26] When HIV disclosure does not occur, or if it occurs during periods of maternal illness, children are more likely to have emotional and behavioural difficulties[6] and risk of neglect.[27] Timely maternal disclosure of HIV status, with planning before illness, might mitigate some of the effects of maternal

HIV-related illness on children. Furthermore, in view of evidence of increased sexual and reproductive health risks in populations of HIV-exposed and HIV-affected adolescent children, disclosure communication in younger primary school-aged children could also provide opportunities to begin prevention early.[15]

A key aspect of the intervention was that primary school-aged children were given the opportunity to learn about HIV (or a virus), to become familiar with their local health-care clinic, and to have input into their own care plan. According to the Amagugu model (appendix),[15] providing children with age-appropriate health and disease information[22,23] could lead to preventive effects by improving children's ability to develop healthy practices, thus preventing long-term risky behaviors.[28,29] Central to the model is the improvement of parental capacity to communicate with children, thus strengthening the parent–child relationship. Participants in the Amagugu intervention group reported significant improvements in parent–child interactions. That mothers receiving the Amagugu intervention were more likely to take their child to visit a clinic is encouraging because children would seldom accompany an adult to clinic in this context because of financial and time barriers. Early engagement of children in health care has benefits both within and beyond the context of life-threatening parental illness.[22]

Another key positive outcome was the increase in custody planning by mothers in the Amagugu intervention group. HIV-infected parents often express concerns about the future care of their children in the event of their own death.[26] Custody planning can decrease the likelihood of children being moved between households, separated from siblings, or placed in foster care.[5,7] Findings from empirical studies[6,7] of the adjustment of children orphaned after HIV-related death in the family highlight the importance of providing a supportive family environment and limiting the number of household moves during illness or after a parent's death. Custody planning can therefore temper the potential detrimental effects of parental illness and possible death on the child.

Our study had several limitations. The study area had an established HIV treatment programme, so our findings might not be generalisable to other parts of sub-Saharan Africa where access to HIV treatment is poor. Furthermore, the follow-up period was relatively short, and longer follow-up might be necessary to examine long-term effects on, for example, children's mental health. Although every effort was made to ensure that counsellors and assessors did not meet or discuss participants, unmasking might have happened in a few cases. Likewise, although unlikely, mothers in the two groups might have discussed their counselling, which could have led to contamination.

Strengths of this research include its focus on children aged 6–10 years who are particularly under-researched in African contexts. The Amagugu intervention specifically targeted mothers (as opposed to fathers and other caregivers) for training, a pragmatic decision since most HIV-exposed children in Africa live with their mothers.[1] However, as we have reported elsewhere,[15] the intervention is highly adaptable, allowing for inclusion of fathers and other family members in the disclosure process. An additional strength is that the intervention might be adaptable for other target populations, such as HIV-infected children. Mothers in the intervention group were able to disclose to their children independently and to other children in the household after the intervention, suggesting that skills gained through the intervention are transferable and effective for disclosure to other children in the household aged 6 years or older. Although the Amagugu intervention is low intensity (six sessions compared with 14–24 sessions in other interventions that are being tested[30]), it is possible that some sessions could be combined to reduce intensity further, thus increasing scalability.

We show that a low-intensity, lay-counsellor-driven intervention can change maternal behaviours towards communicating about HIV, leading to increased rates of mother-led disclosure, enhanced health education, and care planning. Supporting parents to disclose their HIV status to their primary school-aged children (as recommended by WHO) was not associated with any negative effects on children, and we found evidence of improvements in parent–child relationships.

Worldwide, adolescents are at high risk of HIV, and preventative interventions for this age group to date have shown little promise. HIV-exposed, uninfected children are vulnerable before adolescence, and with this first controlled study of a psychological intervention focused on HIV and primary school-aged children in low-income and middle-income countries, we show positive outcomes of disclosure. These positive outcomes build on existing evidence, mostly from high-income settings, that suggests that increased disclosure about parental life-threating illness, undertaken in a developmentally sensitive manner, improves parent–child communication about health-related topics that are difficult to discuss. Increased communication and education of children about healthy behaviours, including HIV prevention, before behaviours are established could improve adolescent health behaviours in these high-risk children as they mature. Long-term follow-up and effectiveness research is warranted.

In view of this potential, more research on parental HIV disclosure should be encouraged globally. Several randomised controlled trials funded by the National Institutes of Health are investigating approaches to support parental HIV disclosure in diverse settings, including low-income and middle-income countries (predominantly in Asia) and in Africa, one of which focuses on disclosure to HIV-infected children in Namibia.

Contributors
TJR and RMB contributed to conceptualisation, funding, and supervision of this project, participated in the acquisition, analysis, and interpretation of data, and drafted and revised the manuscript. MC-B did the statistical analysis, contributed to the interpretation of findings, and drafted and revised the manuscript. AS and FT contributed to funding, participated in the acquisition, analysis, and interpretation of data, and revised the manuscript.

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