



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 parents¹ 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,

Lancet HIV 2017

Published Online

August 23, 2017

[http://dx.doi.org/10.1016/S2352-3018\(17\)30133-9](http://dx.doi.org/10.1016/S2352-3018(17)30133-9)

See Online/Comment

[http://dx.doi.org/10.1016/S2352-3018\(17\)30153-4](http://dx.doi.org/10.1016/S2352-3018(17)30153-4)

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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

Parental HIV disclosure interventions have been tested in two clinical trials in high-income settings; one with adolescents⁶ 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 review¹³ 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-threatening 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 study¹⁶ 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,

See Online for appendix

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