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A community-based child health and parenting intervention to improve child HIV testing, health and development in rural Lesotho (Early Morning Star): a cluster randomised controlled trial.

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Trial registration number ISRCTN16654287.

Summary

Background: When caregivers live in remote settings characterised by extreme poverty, poor access to health services and high rates of HIV/AIDS, their caregiving ability and children's development may be compromised. We aimed to test the effectiveness of a community-based child health and parenting intervention to improve child HIV testing, health and development in rural Lesotho.

Methods: We implemented a matched cluster-randomised controlled trial with 34 community clusters randomly assigned to intervention or wait-list control arms within a pair. Eligible clusters were villages with non-governmental organisation partner presence and an active preschool. Participants were caregiver-child dyads, where the child was 12-60 months old at baseline. The intervention consisted of eight group sessions delivered at informal preschools to all children in each village. Mobile health events were hosted for all intervention (n=17) and control (n=17) clusters, offering HIV-testing and other health services to all community members. Primary outcomes were caregiver-reported child HIV-testing, child language development and child attention. Assessments were conducted at baseline, immediately post-intervention (3 months post-baseline), and 12-months post-intervention. We assessed child language using one caregiver-report measure (MacArthur Communicative Development Inventory (CDI)) and used two observational assessments of receptive language (the Mullen Scales of Early Learning (MSEL) receptive language subscale, and the Peabody Picture Vocabulary Test (PPVT) 4th Edition). Child attention was assessed using the Early Childhood Vigilance Task (ECVT). Assessors were masked to group assignment. Analysis was by intention to treat. This trial was registered with ISRCTN.com, ISRCTN16654287.

Findings: Between Aug 8, 2015 and Dec 10, 2017, 1040 children (531 intervention; 509 control) and their caregivers were enrolled in 34 clusters (17 intervention; 17 control). Compared to controls, the intervention group reported significantly higher child HIV-testing at the 12-month follow-up (RR 1·46, 95% CI 1·29 to 1·65, p<0·001), but not immediately post-intervention. The intervention group showed significantly higher child receptive language on the caregiver report (CDI) at immediate (effect size 3·79, 95% CI 0.78 to 6·79, p=0·0275) but not at 12-month follow-up (effect size 2.96, 95% CI -.06 to 5·98, p=0·055). There were no significant group differences for the direct assessments of receptive language. Child expressive language and child attention did not differ significantly between groups.

Interpretation: Integrated child health and parenting interventions, delivered by trained and supervised lay health workers, can improve both child HIV testing and child development.

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Introduction

In low- and middle-income countries (LMICs) a large proportion of caregivers raise their children in conditions characterised by poverty, high rates of illness and poor healthcare access. This exposure places children at risk for poor health, educational failure, and adverse outcomes later in life.[1] In high HIV-prevalence countries, HIV poses a significant additional threat to the well-being of caregivers and to children's development.[2]

While there have been dramatic improvements in preventing HIV transmission to infants (notably vertical transmission prevention), there are still gaps where mothers and children are missed by the health system, lost to follow-up, or face limited testing opportunities after the postnatal period.[3] The lack of focus on HIV services for children after infancy has meant that children lag behind adults in terms of HIV outcomes, including rates of testing and treatment uptake.[4] Maternal HIV retesting and timely testing of HIV-exposed infants is critical in high burden settings[5] to reduce the 160,000 new infections among children yearly. Targeted HIV testing strategies such as index testing have shown to increase HIV yield, especially in older children. However, this depends largely on the availability of these strategies to remote and rural communities, and on uptake by the child's family.[6] Promoting testing of young children under five in high burden settings continues to be recommended by the WHO consolidated guidelines on HIV testing.[5]

HIV infection negatively affects child neurocognitive and motor functioning, and is associated with cognitive delay in children.[7] Children exposed to HIV but uninfected have lower mental and motor scores compared to children who are HIV unexposed and uninfected.[8] In addition, poverty and illness can compromise parental responsiveness and stimulation, and diminish opportunities for learning, all of which are predictors of poor cognitive development.[9] Threats to children's development should be addressed early, as a way to mitigate risks and improve outcomes into adulthood.[10] Importantly, children require nurturing care, a type of care that extends beyond preventing illness and malnutrition to include responsive interactions with caregivers.[11] Psychosocial interventions that assist parents to engage with their young children and provide learning opportunities can improve children's cognitive and language development.[12]

The challenge for LMICs is establishing feasible and effective mechanisms of delivering such interventions to at-risk and hard-to-reach populations, such as in remote and rural areas.[13] One solution is the provision of integrated intervention approaches, where early responsiveness interventions, health and/or nutrition components are combined to optimise delivery.[14] Integrated interventions provide opportunities for cost-saving,[15] increased efficiency of delivery through sharing of resources, and the potential for synergistic effects.[16] Finally, HIV stigma may prevent HIV testing, making a universal child development programme one way to support child HIV testing.

Lesotho is a small, mountainous country, landlocked by South Africa. Half the population lives below the poverty line (less than $1·90 a day),[17] a third of children under five are stunted and 10% are underweight.[18] The country also has the second-highest adult HIV prevalence rate globally, at 23·8%, and an estimated 16,000 children ages 0–14 years live with HIV.[17] Our study aimed to increase child HIV testing and improve early child development, through a community-based, integrated intervention, delivered by community

128 health workers (CHWs) to families with children aged one to five years living in Mokhotlong,
129 Lesotho.
130

Research in context

Evidence before this study

We searched for RCTs of early interventions implemented in LMICs that addressed child psychosocial stimulation, health and/or nutrition in some combined or integrated manner. Our review focused on studies that tested some combination of these components, not interventions providing only one component and assessing the outcomes across different domains (e.g., a purely nutritional intervention's effect on child cognitive/language/physical development).

We searched PubMed and Google Scholar for studies published between Jan 1, 2000, and May 1, 2017, with the search terms "early childhood development", "psychosocial stimulation", "health", "nutrition", "integrated interventions". Outcomes of interest were child development (cognitive, motor, language or socio-emotional) and child health (nutritional status or illness). Studies reported in languages other than English and non-randomised trials were excluded.

We identified 12 integrated interventions delivered in LMICs (a majority from the South-East-Asia Region and only two from the African Region). Only three studies included children older than two years, and no studies focused on children older than three. Three studies incorporated a psychosocial stimulation intervention into existing health or nutrition services, two of which focused on undernourished children attending these facilities. Six studies tested combinations of psychosocial and nutrition intervention components, while three studies tested integrated ECD, health and/or nutrition content delivered as part of one intervention. The focus of most studies was on psychosocial stimulation and nutrition. Only two studies included a health focus other than nutrition (content on hygiene in both studies).

All psychosocial stimulation interventions had positive effects on child cognitive development, most frequently child language. Only four studies reported improvements in child growth, and this mostly occurred through food/micronutrient supplementation. For the intervention that improved child growth without food supplementation, ECD, nutrition and health components were delivered as part of one integrated intervention. Only one study made use of local preschools to deliver the intervention. Three interventions included the use of children's books and encouragement for caregivers to use picture books with their children, which improved child language specifically, with the exception of one study.

Added value of this study

Integrated interventions are increasingly tested in LMICs, and several have shown beneficial effects on children's (cognitive) development. Most of these interventions focus on nutrition and psychosocial stimulation, and there is a striking lack of evidence on combined psychosocial and health (e.g., health messaging) interventions. Furthermore, most of these interventions focus on children younger than three years of age. Evidence

on centre-based strategies to deliver integrated interventions is lacking, especially for children three to six years of age. Our findings add to this evidence base by showing that an integrated intervention using a holistic approach can both improve HIV testing and enhance child development.

Implications of the available evidence

Improving outcomes for children living in the most remote and rural areas requires focused attention, informed by reliable data specific to these contexts.

Methods

Study design and participants

We conducted a pragmatic cluster-randomised controlled trial in the Mokhotlong district in north-eastern Lesotho. Mokhotlong has one of the highest concentrations of extreme poverty in Lesotho and the highest prevalence of stunting and underweight (48% and 16%, respectively) among children under the age of five.[18] The study included 34 community clusters (villages), with equal clusters assigned to intervention or control arms (17 in each) within the matched pair. Villages are situated within a remote, mountainous terrain with poor transport and road facilities.

Eligible clusters were villages with at least one active preschool centre, and where the local non-gonvernmental organisation (NGO) partner had a resident community volunteer (to facilitate with set-up and delivery of the intervention). Preschools were selected as the main platform for delivery, as the majority of villages in this setting have an informal preschool that can serve as a base to engage parents with young children, while circumventing the possible stigma associated with HIV-related health platforms. Preschools are mostly informal, operating out of community members' homes, without access to electricity or running water, and most without any toys or materials.

Participants were all caregiver-child dyads in which the child was 12-60 months of age at baseline. Within this age range, all children residing in the study villages were eligible for participation, regardless of whether or not they attended the village preschool. Following agreement from the local chief and community leadership in each village, trained recruiters went door-to-door to identify eligible caregiver-child dyads. Primary caregivers were included in the study if they were at least 18 years old, lived in the same house as the child for at least four nights per week, and consented to participate. All caregivers provided written informed consent at the time of baseline data collection after randomisation.

The study had research ethics approval from the Health Research Ethics Committee at Stellenbosch University (N14/09/127) and the Lesotho Ministry of Health Ethics Committee (#138-2014). The trial was registered on the International Standard Randomized Controlled Trial Number database (ISRCTN16654287), and the protocol was published (https://tinyurl.com/ycyh64dk).[19]

Randomisation and masking

Villages comprised clusters and were the unit of randomisation to minimise the risk of contamination. We identified all villages across the district's five community councils where the local NGO partner had an existing presence. We then listed villages that had an active preschool centre, resulting in a list of 51 eligible villages. Eligible villages were mapped to determine the size of the village (number of households and children younger than six), characteristics of the preschool/s (size; structure; resources) and characteristics of the village (housing type; access to water and electricity; number of shops and churches; sources of transport; distance from primary schools, secondary schools and health facilities; available government and nongovernmental services).[19]

Of the 51 villages, five were excluded because the preschool was no longer operational. Mapping data from the remaining 46 villages were used to stratify villages based on size and relative remoteness, to identify which villages could most closely be matched into pairs for randomisation. We identified 32 villages that could most closely be matched into 16 pairs based on community and preschool characteristics. Prior to baseline, clusters in each pair were randomly allocated to either arm, by an external statistician using a web-based randomisation programme. Each cluster was labelled with a letter, concealing any identifying information from the statistician. Clusters and participants were only informed that they would be receiving the intervention once the baseline assessments in that particular cluster had been completed. Allocation was concealed at the cluster and individual level.

The study was conducted in two phases to accommodate field work, while data collection was staggered to ensure that the time between baseline, intervention and follow-up periods would be comparable for control and intervention villages. Two weeks prior to the baseline start date in each village, data collectors visited each household to formally enrol eligible children (between the ages of 12 and 60 months). However, as baseline data collection progressed, the number of eligible children per cluster was slightly lower than identified during the mapping exercise. We selected an additional two villages from the 12 villages previously excluded during matching, resulting in a total of 34 villages (or clusters). Of the 34 clusters, two clusters each had two operating preschools, in which case the intervention was delivered through both schools.

Data collectors were masked to group allocation to minimise assessment bias. Due to the nature of the intervention, masking of participants and CHWs was not possible. Data collectors worked independently from the intervention teams, and were masked to group status. Assessments that required data coding after administration were conducted by independent coders in South Africa, all masked to group allocation.

Villages in the intervention condition received a group-based parenting intervention hosted at local preschools, followed by community-wide mobile health events open to all community members (see figure 1). The group-based parenting intervention consisted of eight weekly sessions, followed by a ninth top-up session one month later, followed by a monthly book drop-off for 10 months. Villages in the control condition were also invited to attend mobile health events and received a light-touch version of the parenting intervention after study completion. The light-touch intervention consisted of two delivery agents spending a full day in each village, hosting drop-in parenting group sessions that covered the key messages from the full intervention. Preschool teachers received a separate session

focused on techniques for engaging groups of children in shared reading activities. In addition, a "library" was set up in each village, available at a central location for all children to access.

[Insert Figure 1]

Sample size

We calculated that we needed to recruit at least 365 children across 12 clusters per arm to detect a small/medium effect size of 0·3 for the MacArthur Communicative Development Inventory (CDI) at 80% power with an intra-cluster correlation (ICC) of 0·05 at 12 months post-intervention. We used a higher ICC compared to other behavioural studies, due to the geographical isolation of the clusters.

Procedures

The group-based parenting programme (named *Mphatlalatsane* – Sesotho for "early morning star") consisted of three components (see Tomlinson et al.[19]): (1) Shared Reading (responsive caregiving), (2) Health (specific focus on HIV-testing and treatment), and (3) Growth (nutrition education). Sessions were delivered at the local preschool centre by a pair of trained CHWs. Caregivers attended with their children, and preschool teachers were also invited to participate. Parenting sessions provided training and practice in sensitive and responsive shared reading skills, combined with a participatory approach to address issues around HIV testing, health, and nutrition education. The intervention was developed in close collaboration with community stakeholders, and piloted in nine preschools before roll-out.

The health and nutrition component consisted of key educational messages and identifying available resources to enable positive health practices. Sessions covered topics on HIV prevention and treatment, barriers to HIV testing and disclosure, basic nutrition, child feeding practices, hygiene and sanitation, illness recognition and help-seeking. Local songs and metaphors were incorporated to convey key content. The shared reading component encouraged caregivers to engage with their children in a sensitive and responsive manner, facilitated through the use of picture books. This is well-established as an effective tool to promote children's language development and pre-literacy skills.[20] Reading skills were not needed, and the picture books provided a source for engagement and conversation tapping into the cultural traditions of storytelling, based on a successful programme previously used in South Africa.[21]

The intervention was delivered weekly to groups of 5-6 caregivers and their children in 2-3 hour sessions over eight consecutive weeks. As shared reading content differed slightly between younger and older children, groups were based on child age, with younger children (aged 12–30 months) and older children (aged 31–60 months) receiving the intervention separately. Children and caregivers received refreshments at each session. Session eight ended with a graduation where caregivers were presented with a certificate of completion and a copy of each of the six books used in the programme. The intervention team returned to each village four weeks later to deliver a ninth top-up session. For ten months thereafter, intervention villages received a monthly book drop-off at each preschool to encourage continued shared reading and parent meetings. Following completion of the parenting

sessions, local organisations were mobilised to co-ordinate community-wide health events open to the public. Events were located equidistantly between intervention and control villages, hosted in partnership with the Ministry of Health, Baylor International Pediatric AIDS Initiative, Touching Tiny Lives, GROW, the Child and Gender Protection Unit, the Food and Nutrition Coordinating Office, and PEPFAR-USAID. Services included nutrition assessments and vaccinations for children, general health consultations, birth document registration and HIV testing and counselling.

A team of two trained and supervised CHWs delivered the weekly parenting sessions, recruited and hired specifically for the study, and received a monthly salary. A group of local candidates were selected based on their experience working with children and facilitating group activities. Training began with a five-day workshop before the pilot, followed by a two-week training for the full intervention. A five-day refresher training took place after half the intervention villages had received the intervention. Training staff modelled affirmation, positive feedback, and supportive listening. The intervention was manualised, with materials available in English and Sesotho. The study team provided supervision, with a local supervisor hired and paid for through the project. Supervision activities included weekly group sessions, monthly site visits to observe and evaluate intervention sessions using a structured monitoring form, and daily check-ins via a WhatsApp group chat for technical and emotional support. Intervention sessions were video-recorded and used as learning opportunities during group feedback sessions.

We collected data at baseline, immediately post-intervention and 12 months post-intervention. At baseline, data collectors went door to door to formally enrol all eligible children and schedule baseline visits. No refusals were reported. Data collection took place in rented houses in each village to ensure a quiet and private space for the interviews and assessments. Caregivers were interviewed using a structured questionnaire, pre-programmed onto a mobile tablet device. Interviews were conducted in Sesotho with the child's primary caregiver. Questions covered household and caregiver demographics, as well as information about the index child such as care arrangements, child health and development, and parenting practices. Child assessments included measuring child attention and language, using standardised and translated instructions. Children received a snack and juice during their assessment session.

Data collectors, fluent in Sesotho and English, received extensive training in the administration of the interviews and assessments, with refresher training workshops conducted between data collection time-points. Interviews were audio-recorded, and assessments were video-recorded for quality control purposes. Data were checked in weekly batches to allow for constant data-quality monitoring.

Outcomes

As a pragmatic trial, the study had multiple primary outcomes. Primary outcomes were HIV testing of children, child language and child attention, with data collected at baseline, immediately post-intervention (equivalent to 3 months after baseline) and 12 months post-intervention. To measure child HIV testing, caregivers reported on whether their child had been tested for HIV since baseline. Child language was assessed using an adapted version of the MacArthur Communicative Development Inventory (CDI) short form,[22] the Mullen Scales

of Early Learning (MSEL) receptive language subscale, and the Peabody Picture Vocabulary Test (PPVT) 4th Edition. These measures have not been validated for use in Lesotho. All children completed the CDI and the MSEL, while children 30 months and older completed the PPVT. All measures were translated culturally and linguistically into Sesotho. All items and materials were reviewed for cultural appropriateness by a team of six local researchers familiar with the context. Inappropriate items were replaced by a conceptually similar and culturally relevant item. Two independent translators then translated the items from English to Sesotho. Any discrepancies between the two translated versions were discussed by the review team and resolved by consensus. The translated CDI, MSEL and PPVT were piloted with children across the study age range, and adapted through standard procedures.

Child attention was measured using the Early Childhood Vigilance Task (ECVT), a tablet-based assessment of focal attention.[23] The task consists of a seven-minute animated video, during which different cartoon characters appear and disappear across the screen at different intervals. The child's face is recorded for the full duration of the task to determine the percentage of time the child is focused on the screen. Five coders independently coded the ECVT assessments, while 30% were double-coded to determine reliability (inter-rater reliability was high r = .988).

Secondary outcomes were child HIV treatment uptake and adherence, child cognitive development and executive functioning, child growth, child emotional and behavioural functioning, parental discipline, parental stress, caregiver sensitivity and reciprocity, caregiver mental health and caregiver alcohol use.[19.] Here we present only the results from the primary outcome analysis (secondary outcomes will be reported separately).

Statistical analysis

Analyses were performed independently (by CL). Descriptive statistics such as means, standard deviations, and proportions were calculated for data collected across the three time-points. Baseline tables by arm were done to reflect the balance achieved through randomisation

To determine the statistical significance of the intervention the Fisher-Pitman permutation test for paired replicates was implemented using the cluster mean of the outcome and the exact p-value was calculated. For estimating the intervention effect for the continuous outcomes, mixed effects regression models were used with random effects for pair, village (cluster), family, and children, to take account of the clustering within each level. For each random effect, only intercepts were used resulting in a variance component setup. All three time-points (baseline, immediate, and one-year follow-up) were included in the analysis, and the intervention effect was assessed by the interaction effect between time and arm where time was implemented as a categorical variable using binary indicators for each of the post randomization time points. The phase of the study was included as a covariate. An intention-to-treat analysis was performed, and maximum likelihood estimation was conducted as the imputation strategy for missing data.

For estimating the intervention effect for the binary, test for HIV, outcome, a generalized linear regression model for the binomial family with log link function was used to estimate time-point specific relative risks and 95% confidence intervals. The standard errors where

estimated using a robust sandwich estimation approach to accommodate the various clustering effects in the study desig. Apart from the intervention and time effects the model took into account the phase of the study and matching as a stratification variable. The analysis for child HIV testing was based on children tested for HIV between baseline and the immediate post-intervention follow-up, and between the immediate post-intervention and the 12-month follow-up (at baseline caregivers were asked if their child has ever been tested for HIV). We used the Benjamini-Hochberg procedure to adjust for multiple comparisons (n=13) of the primary outcomes between the arms. An adjusted p value of 0·0308 was considered statistically significant, with a false discovery rate of 10%.

Role of the funding source

The study was funded by PEPFAR-USAID under the Orphans and Vulnerable Children Special Initiative. The aim of the initiative was to promote rigorous evaluation around child development interventions for children affected by HIV. The funders played a role in country selection and choice of methodology, but had no role in data collection, data analysis, data interpretation, or writing of the report, although GB (USAID) is a co-author on this manuscript. The corresponding author (MT) had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between August 8, 2015 and December 10, 2017, we randomly assigned paired villages to either the parenting intervention or the waitlist control within each of the 17 matched pairs. A total of 1040 children and their caregivers (531 in the intervention group and 509 in the control group) were enrolled into the study. All participants were black. No refusals were reported. At least 98% of participants completed the immediate and the 12-month post-intervention assessments (figure 2).

[Insert Figure 2]

At baseline, child age, gender, preschool centre attendance, orphan status, and caregiver education, marital status, HIV status, and household resources were similar between groups (table 1). However, we noted that children in the intervention group were healthier at baseline and had lower rates of HIV testing and a lower HIV prevalence. Unemployment and access to electricity were also lower in the intervention group.

[Insert Table 1]

Our primary outcome analysis showed that children in the intervention group demonstrated higher HIV testing rates at 12 months post-intervention (RR 1·46, 95% CI 1·29 to 1·65, p<0·001) compared to the control group. Child HIV testing immediately post-intervention were higher, but did not reach significance when adjusting for multiple testing (RR 1·32, 95% CI 1·07 to 1·62, p=0·2184). Immediately post-intervention, 30% of children in the intervention group had received an HIV test, compared to 23% of children in the control group. One-year post-intervention, 61·4% of children in the intervention group had received an HIV test, compared to 42·8% of children in the control group. At one-year post-intervention, the relative intervention effect was not significantly different from the intervention effect

observed immediately post-intervention (p=0·49). At the immediate post-intervention follow-up, one additional child (intervention arm) was identified as living with HIV. At the 12-month follow-up, a further two children (both in the intervention arm) were identified as living with HIV. At both follow up time-points, all children living with HIV were reported to be receiving ART.

We found that the intervention significantly improved child receptive language scores on one measure, namely the caregiver-report MacArthur CDI. Effects for receptive language on the CDI (words that a child understands) were evident immediately post-intervention (effect size 3·79, 95% CI 0.78 to 679; p=0·0275) but not evident at 12 months post-intervention (effect size 2.96, 95% CI 0.10 to 5·98; p=0·055). The linear mixed effects models, with interaction between group and time, show the mean CDI profiles are significantly different over time for receptive but not for expressive language (figure 3). , Group differences in CDI expressive language (words that a child understands and uses) did not reach significance at the immediate post-intervention time-point (effect size 2·559, 95% CI -0·47, 5.57; p=0·202) or at the 12-month post-intervention time-point (effect size 2·9, 95% CI -0·104 to 5·97; p=0·075) when adjusting for multiple testing. The observational measures of child receptive language (Mullen Scales of Early Learning receptive language subscale and the Peabody Picture Vocabulary Test) did not yield significant between-group differences at either time-point (although a positive trend towards the intervention group was noted for the PPVT immediately post-intervention). We found no effects of the intervention on child attention.

[Insert Table 2]

[Insert Figure 3]

More than 98% (n=523) of caregivers participated in the group-based parenting intervention. The majority of caregivers (94·6%; n=495 attended 75% of sessions, with 68·6% of caregivers (n=359) attending all eight sessions. Only 28 caregivers (5·3%) attended five or less sessions. The ninth top-up session was attended by 411 caregivers (78·6%).

In total, 20 community-wide health events were hosted across intervention and control sites, with 2932 people documented as accessing the services. A total of 825 people were tested for HIV during the events (32% of those tested were children under the age of 5). Only 3·6% of those who tested for HIV tested positive. In the intervention arm, 52·7% of caregivers (n=280) and 55·0% of children (n=292) attended the community health events. In the control arm, 22·0% of caregivers (n=112) and 21·0% of children (n=107) attended.

Discussion

We examined the effects of a group-based parenting intervention, combined with community health events, on child HIV testing, and child language and attention in remote rural community settings in Lesotho. A caregiver-directed, integrated intervention delivered by CHWs had meaningful impacts on child HIV testing, and some domains of child development. This was achieved in one of the poorest countries in the world, with challenging terrain, harsh weather conditions, and extremely high rates of HIV.

Caregivers face numerous challenges in accessing HIV testing and treatment for their children such as difficulties in transport to access difficult to reach health care facilities. Expanding coverage of HIV services beyond facility-based testing is important in high burden settings to ensure that all children are linked to services in a timely manner.[6] For remote communities, mobile health services are increasingly used to facilitate access to health services, particularly in terms of HIV testing and care.[24] Child health days in particular provide opportunities for improving coverage of key interventions, especially for slightly older children.[25] Our study demonstrates that accessible, flexible and responsive community-based programs can be effectively used to promote HIV testing of children as well as improving some domains of child development.

There was clear improvement in the receptive language domain in children who received the intervention when compared to controls on one measure of language, namely the caregiver-reported CDI. This is congruent with past research which demonstrates that increased stimulation of children by caregivers enhances child cognitive and language outcomes.[26] However, this finding should be interpreted with caution, as there were no differences detected on the direct measures of language, such as for the MSEL and PPVT. The fact that the intervention did not improve child attention was disappointing, given the large impact book-sharing had on child attention in our previous work.[21] This finding is important in that it reminds us that improving child development in contexts of high adversity is not like early innoculation, but rather requires ongoing strategic quality investments across the life course.

An important part of implementation is increased integration of existing interventions where local systems have the capacity, because of benefits such as optimisation of resource use, and potential additive and synergistic effects across multiple areas of development.[27] However, despite evidence that multi-sectoral co-operation and coordination results in improved human, social and economic development outcomes, there continues to be division between the health sector and other sectors supporting child development.[27]

This study has provided evidence that integrated interventions can be successfully implemented in remote, rural regions, and produce benefits across HIV and child development. There is no literature to the authors' knowledge which describes the effectiveness of integrated, group-based parenting interventions combined with community health events, that focus beyond child survival to child development and thriving in remote regions such as Lesotho. There is growing evidence that combined interventions are more effective than interventions using siloed approaches. Cluver and colleagues first described the concept of accelerators in making a case for accelerating progress towards the SDGs.[28] They found that parenting support, government cash transfers, and safe schools were associated with better outcomes than single focussed interventions.[28]

The intervention was delivered by CHWs in a group setting, a necessary condition given human resource limitations for these kinds of programmes at scale in rural settings. Attendance rates were high and sustained over the intervention period. The study's strengths are its high rates of retention and follow-up and its evaluation—using multiple methods—of domains of child functioning. The intervention used a manualised curriculum and systematic training for implementers (available for downloading at https://www.who.int/teams/social-

determinants-of-health/parenting-for-lifelong-health/programme-manuals). Caregivers were provided with opportunities to practise stimulation activities and receive feedback, which has been shown to increase effectiveness of parenting programmes.[29]

The study also had certain limitations. First, the MSEL and PPVT were adapted but not standardised for Lesotho. There was a lack of standardised child assessments and norms for this age group in this context. As such, we were only able to compare groups, which limited the interpretation of the clinical significance of the findings. Alternative assessment measures designed specifically for low-resource settings should be considered in future. The study also had a large number of primary endpoints which the statistical inference had to account for by using a stricter significance level.

Second, discordance between the caregiver-reported child language outcomes (CDI) and the directly observed language measures (MSEL and PPVT) could be a result of courtesy bias in the intervention arm. There are however other important factors to consider. The MacArthur-Bates group has invested substantial time in developing versions of the CDI for different languages and cultural contexts, whereas the MSEL and PPVT have not undergone similar processes. It is possible that the CDI performs better in different contexts as a result of the refinements that have been made to the measure over time. The CDI specifically measures vocabulary, whereas an assessment such as the MSEL measures the development of much more complex grammatical structures and broader cognitive skills. Improving a child's receptive and expressive vocabulary is likely easier to achieve within this kind of intervention, whereas more complex language or cognitive skills may be more difficult to shift without more specific input.

Lastly, expanding coverage while maintaining quality is a major issue.[29] The research group trained and supervised the delivery agents and provided extensive implementation support. For future scale-up, these activities would have to be performed by the Ministry of Health and/or Education and Training. One challenge will be how to transfer the overall responsibility for the programme from researchers to the district government staff. This field of work could benefit from a follow-up at school-entry of children and caregivers who had participated in an integrated intervention in early childhood. Given high rates of adversity and chronic poverty, future follow-up of this cohort will help to answer important questions regarding the duration of effects on child outcomes and potential long-term benefits of integrated programmes.[30]

The SDGs signified the beginning of a new era in global development and are marked by striving towards a healthier, more equitable and safer world by 2030.[31] Despite progress in narrowing the gap between rich and poor countries, there are still vast inequities in access to health services and resources between countries and rural and urban regions.[13] There is evidence which points to high HIV prevalence and high HIV incidence clustering in areas where health services fail to reach and engage vulnerable populations.[31] It is essential that rural contexts such as Lesotho are given priority, if we are to have any chance of improving outcomes for underserved children and families.

This study adds evidence to a limited body of research on the implementation and evaluation of an integrated group-based parenting intervention, combined with community

health days in deeply rural settings. It demonstrates that it is possible to reach the most remotely located communities and produce improved child language outcomes and HIV testing uptake when programme design and implementation are innovative in bringing health services to the most vulnerable, sensitive to context and culture, and make use of existing resources.

Contributors

MT = Mark Tomlinson, MaM = Marguerite Marlow, JS = Jackie Stewart, MoM= Moroesi Makhetha, TS = Tholoana Sekotlo, SM = Sebuoeng Mohale, CL = Carl Lombard, LM = Lynne Murray, PJC = Peter J Cooper, NM = Nathene Morley, SR = Stephan Rabie, SG = Sarah Gordon, AvdM = Amelia van der Merwe, GB = Gretchen Bachman, XH = Xanthe Hunt, LS = Lorraine Sherr, LC = Lucie Cluver, SS = Sarah Skeen

All authors had final responsibility for the decision to submit for publication. The original draft of the manuscript was written by MaM and then reviewed and edited by MT, AvdM, XH, LS, LC, and SS. MT, LS and LC were responsible for Funding Acquisition for the project leading to this publication. Project Conceptualisation was done by MT, SS, LM, PJC, LC, LS, and GB. MT, SS, LM and PJC developed the Methodology for the study. Project Administration was managed by MaM, MoM, NM, SR, and SG. The Investigation phase of the project was conducted by TS and SM, and managed by MoM, who was also responsible for Data Curation with MaM. Supervision of research activity planning and execution was done by SS and JS. MT, SS and CL directly accessed and verified the underlying data reported in the manuscript. Validation of study results was done by SS and MaM. Formal Data Analysis and Visualisation was done by CL.

Declaration of interests

We declare no competing interests.

Data sharing

The de-identified datasets generated during the study along with the statistical plan and analytic code can be made available from the corresponding author with publication on reasonable request. Data will be made available without identifiers, available only under a data-sharing agreement.

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