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.

42   **Summary**

43   **Background:** When caregivers live in remote settings characterised by extreme poverty, poor
44   access to health services and high rates of HIV/AIDS, their caregiving ability and children's
45   development may be compromised. We aimed to test the effectiveness of a community-based
46   child health and parenting intervention to improve child HIV testing, health and development
47   in rural Lesotho.
48
49   **Methods:** We implemented a matched cluster-randomised controlled trial with 34 community
50   clusters randomly assigned to intervention or wait-list control arms within a pair. Eligible
51   clusters were villages with non-governmental organisation partner presence and an active
52   preschool. Participants were caregiver-child dyads, where the child was 12-60 months old at
53   baseline. The intervention consisted of eight group sessions delivered at informal preschools
54   to all children in each village. Mobile health events were hosted for all intervention (n=17) and
55   control (n=17) clusters, offering HIV-testing and other health services to all community
56   members. Primary outcomes were caregiver-reported child HIV-testing, child language
57   development and child attention. Assessments were conducted at baseline, immediately post-
58   intervention (3 months post-baseline), and 12-months post-intervention. We assessed child
59   language using one caregiver-report measure (MacArthur Communicative Development
60   Inventory (CDI)) and used two observational assessments of receptive language (the Mullen
61   Scales of Early Learning (MSEL) receptive language subscale, and the Peabody Picture
62   Vocabulary Test (PPVT) 4th Edition). Child attention was assessed using the Early Childhood
63   Vigilance Task (ECVT). Assessors were masked to group assignment. Analysis was by intention
64   to treat. This trial was registered with ISRCTN.com, ISRCTN16654287.
65
66   **Findings:** Between Aug 8, 2015 and Dec 10, 2017, 1040 children (531 intervention; 509 control)
67   and their caregivers were enrolled in 34 clusters (17 intervention; 17 control). Compared to
68   controls, the intervention group reported significantly higher child HIV-testing at the 12-
69   month follow-up (RR 1·46, 95% CI 1·29 to 1·65, p<0·001), but not immediately post-
70   intervention. The intervention group showed significantly higher child receptive language on
71   the caregiver report (CDI) at immediate (effect size 3·79, 95% CI 0.78 to 6·79, p=0·0275) but
72   not at 12-month follow-up (effect size 2.96, 95% CI -.06 to 5·98, p=0·055). There were no
73   significant group differences for the direct assessments of receptive language. Child expressive
74   language and child attention did not differ significantly between groups.
75
76   **Interpretation:** Integrated child health and parenting interventions, delivered by trained and
77   supervised lay health workers, can improve both child HIV testing and child development.
78
79   **Funding** United States Agency for International Development (USAID) and the President's
80   Emergency Plan for AIDS Relief (PEPFAR).

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.

131

132 **Methods**

133 **Study design and participants**

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

141

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

150

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

159

160 The study had research ethics approval from the Health Research Ethics Committee at
161 Stellenbosch University (N14/09/127) and the Lesotho Ministry of Health Ethics Committee
162 (#138-2014). The trial was registered on the International Standard Randomized Controlled
163 Trial Number database (ISRCTN16654287), and the protocol was published
164 (https://tinyurl.com/ycyh64dk).[19]

165

166 **Randomisation and masking**

167   Villages comprised clusters and were the unit of randomisation to minimise the risk of
168   contamination. We identified all villages across the district's five community councils where
169   the local NGO partner had an existing presence. We then listed villages that had an active
170   preschool centre, resulting in a list of 51 eligible villages. Eligible villages were mapped to
171   determine the size of the village (number of households and children younger than six),
172   characteristics of the preschool/s (size; structure; resources) and characteristics of the village
173   (housing type; access to water and electricity; number of shops and churches; sources of
174   transport; distance from primary schools, secondary schools and health facilities; available
175   government and nongovernmental services).[19]
176
177   Of the 51 villages, five were excluded because the preschool was no longer operational.
178   Mapping data from the remaining 46 villages were used to stratify villages based on size and
179   relative remoteness, to identify which villages could most closely be matched into pairs for
180   randomisation. We identified 32 villages that could most closely be matched into 16 pairs
181   based on community and preschool characteristics. Prior to baseline, clusters in each pair
182   were randomly allocated to either arm, by an external statistician using a web-based
183   randomisation programme. Each cluster was labelled with a letter, concealing any identifying
184   information from the statistician. Clusters and participants were only informed that they
185   would be receiving the intervention once the baseline assessments in that particular cluster
186   had been completed. Allocation was concealed at the cluster and individual level.
187
188   The study was conducted in two phases to accommodate field work, while data collection
189   was staggered to ensure that the time between baseline, intervention and follow-up periods
190   would be comparable for control and intervention villages. Two weeks prior to the baseline
191   start date in each village, data collectors visited each household to formally enrol eligible
192   children (between the ages of 12 and 60 months). However, as baseline data collection
193   progressed, the number of eligible children per cluster was slightly lower than identified
194   during the mapping exercise. We selected an additional two villages from the 12 villages
195   previously excluded during matching, resulting in a total of 34 villages (or clusters). Of the 34
196   clusters, two clusters each had two operating preschools, in which case the intervention was
197   delivered through both schools.
198
199   Data collectors were masked to group allocation to minimise assessment bias. Due to the
200   nature of the intervention, masking of participants and CHWs was not possible. Data
201   collectors worked independently from the intervention teams, and were masked to group
202   status. Assessments that required data coding after administration were conducted by
203   independent coders in South Africa, all masked to group allocation.
204
205   Villages in the intervention condition received a group-based parenting intervention hosted
206   at local preschools, followed by community-wide mobile health events open to all
207   community members (see figure 1). The group-based parenting intervention consisted of
208   eight weekly sessions, followed by a ninth top-up session one month later, followed by a
209   monthly book drop-off for 10 months. Villages in the control condition were also invited to
210   attend mobile health events and received a light-touch version of the parenting intervention
211   after study completion. The light-touch intervention consisted of two delivery agents
212   spending a full day in each village, hosting drop-in parenting group sessions that covered
213   the key messages from the full intervention. Preschool teachers received a separate session

214 focused on techniques for engaging groups of children in shared reading activities. In
215 addition, a "library" was set up in each village, available at a central location for all children to
216 access.
217
218 [Insert Figure 1]
219
220 **Sample size**

221 We calculated that we needed to recruit at least 365 children across 12 clusters per arm to
222 detect a small/medium effect size of 0·3 for the MacArthur Communicative Development
223 Inventory (CDI) at 80% power with an intra-cluster correlation (ICC) of 0·05 at 12 months
224 post-intervention. We used a higher ICC compared to other behavioural studies, due to the
225 geographical isolation of the clusters.
226
227 **Procedures**

228 The group-based parenting programme (named *Mphatlalatsane* – Sesotho for "early
229 morning star") consisted of three components (see Tomlinson et al.[19]): (1) Shared Reading
230 (responsive caregiving), (2) Health (specific focus on HIV-testing and treatment), and (3)
231 Growth (nutrition education). Sessions were delivered at the local preschool centre by a pair
232 of trained CHWs. Caregivers attended with their children, and preschool teachers were also
233 invited to participate. Parenting sessions provided training and practice in sensitive and
234 responsive shared reading skills, combined with a participatory approach to address issues
235 around HIV testing, health, and nutrition education. The intervention was developed in close
236 collaboration with community stakeholders, and piloted in nine preschools before roll-out.
237
238 The health and nutrition component consisted of key educational messages and identifying
239 available resources to enable positive health practices. Sessions covered topics on HIV
240 prevention and treatment, barriers to HIV testing and disclosure, basic nutrition, child
241 feeding practices, hygiene and sanitation, illness recognition and help-seeking. Local songs
242 and metaphors were incorporated to convey key content. The shared reading component
243 encouraged caregivers to engage with their children in a sensitive and responsive manner,
244 facilitated through the use of picture books. This is well-established as an effective tool to
245 promote children's language development and pre-literacy skills.[20] Reading skills were not
246 needed, and the picture books provided a source for engagement and conversation tapping
247 into the cultural traditions of storytelling, based on a successful programme previously used
248 in South Africa.[21]
249
250 The intervention was delivered weekly to groups of 5-6 caregivers and their children in 2-3
251 hour sessions over eight consecutive weeks. As shared reading content differed slightly
252 between younger and older children, groups were based on child age, with younger children
253 (aged 12–30 months) and older children (aged 31–60 months) receiving the intervention
254 separately. Children and caregivers received refreshments at each session. Session eight
255 ended with a graduation where caregivers were presented with a certificate of completion
256 and a copy of each of the six books used in the programme. The intervention team returned
257 to each village four weeks later to deliver a ninth top-up session. For ten months thereafter,
258 intervention villages received a monthly book drop-off at each preschool to encourage
259 continued shared reading and parent meetings. Following completion of the parenting

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

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

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

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

300 **Outcomes**

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

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

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

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

332 **Statistical analysis**

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

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

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

354 estimated using a robust sandwich estimation approach to accommodate the various
355 clustering effects in the study desig. Apart from the intervention and time effects the model
356 took into account the phase of the study and matching as a stratification variable. The
357 analysis for child HIV testing was based on children tested for HIV between baseline and the
358 immediate post-intervention follow-up, and between the immediate post-intervention and
359 the 12-month follow-up (at baseline caregivers were asked if their child has ever been tested
360 for HIV). We used the Benjamini-Hochberg procedure to adjust for multiple comparisons
361 (n=13) of the primary outcomes between the arms. An adjusted p value of 0·0308 was
362 considered statistically significant, with a false discovery rate of 10%.
363
364 **Role of the funding source**

365 The study was funded by PEPFAR-USAID under the Orphans and Vulnerable Children Special
366 Initiative. The aim of the initiative was to promote rigorous evaluation around child
367 development interventions for children affected by HIV. The funders played a role in country
368 selection and choice of methodology, but had no role in data collection, data analysis, data
369 interpretation, or writing of the report, although GB (USAID) is a co-author on this
370 manuscript. The corresponding author (MT) had full access to all the data in the study and
371 had final responsibility for the decision to submit for publication.
372
373 **Results**

374 Between August 8, 2015 and December 10, 2017, we randomly assigned paired villages to
375 either the parenting intervention or the waitlist control within each of the 17 matched pairs.
376 A total of 1040 children and their caregivers (531 in the intervention group and 509 in the
377 control group) were enrolled into the study. All participants were black. No refusals were
378 reported. At least 98% of participants completed the immediate and the 12-month post-
379 intervention assessments (figure 2).
380
381 [Insert Figure 2]
382
383 At baseline, child age, gender, preschool centre attendance, orphan status, and caregiver
384 education, marital status, HIV status, and household resources were similar between groups
385 (table 1). However, we noted that children in the intervention group were healthier at baseline
386 and had lower rates of HIV testing and a lower HIV prevalence. Unemployment and access to
387 electricity were also lower in the intervention group.
388
389 [Insert Table 1]
390
391 Our primary outcome analysis showed that children in the intervention group demonstrated
392 higher HIV testing rates at 12 months post-intervention (RR 1·46, 95% CI 1·29 to 1·65,
393 p<0·001) compared to the control group. Child HIV testing immediately post-intervention
394 were higher, but did not reach significance when adjusting for multiple testing (RR 1·32, 95%
395 CI 1·07 to 1·62, p=0·2184). Immediately post-intervention, 30% of children in the intervention
396 group had received an HIV test, compared to 23% of children in the control group. One-year
397 post-intervention, 61·4% of children in the intervention group had received an HIV test,
398 compared to 42·8% of children in the control group. At one-year post-intervention, the
399 relative intervention effect was not significantly different from the intervention effect

400   observed immediately post-intervention (p=0·49). At the immediate post-intervention
401   follow-up, one additional child (intervention arm) was identified as living with HIV. At the 12-
402   month follow-up, a further two children (both in the intervention arm) were identified as
403   living with HIV. At both follow up time-points, all children living with HIV were reported to
404   be receiving ART.
405
406   We found that the intervention significantly improved child receptive language scores on
407   one measure, namely the caregiver-report MacArthur CDI. Effects for receptive language on
408   the CDI (words that a child understands) were evident immediately post-intervention (effect
409   size 3·79, 95% CI 0.78 to 679; p=0·0275) but not evident at 12 months post-intervention
410   (effect size 2.96, 95% CI 0.10 to 5·98; p=0·055). The linear mixed effects models, with
411   interaction between group and time, show the mean CDI profiles are significantly different
412   over time for receptive but not for expressive language (figure 3). , Group differences in CDI
413   expressive language (words that a child understands and uses) did not reach significance at
414   the immediate post-intervention time-point (effect size 2·559, 95% CI -0·47, 5.57; p=0·202) or
415   at the 12-month post-intervention time-point (effect size 2·9, 95% CI -0·104 to 5·97; p=0·075)
416   when adjusting for multiple testing. The observational measures of child receptive language
417   (Mullen Scales of Early Learning receptive language subscale and the Peabody Picture
418   Vocabulary Test) did not yield significant between-group differences at either time-point
419   (although a positive trend towards the intervention group was noted for the PPVT
420   immediately post-intervention). We found no effects of the intervention on child attention.
421
422   [Insert Table 2]
423
424   [Insert Figure 3]
425
426   More than 98% (n=523) of caregivers participated in the group-based parenting intervention.
427   The majority of caregivers (94·6%; n=495 attended 75% of sessions, with 68·6% of caregivers
428   (n=359) attending all eight sessions. Only 28 caregivers (5·3%) attended five or less sessions.
429   The ninth top-up session was attended by 411 caregivers (78·6%).
430
431   In total, 20 community-wide health events were hosted across intervention and control sites,
432   with 2932 people documented as accessing the services. A total of 825 people were tested
433   for HIV during the events (32% of those tested were children under the age of 5). Only 3·6%
434   of those who tested for HIV tested positive. In the intervention arm, 52·7% of caregivers
435   (n=280) and 55·0% of children (n=292) attended the community health events. In the control
436   arm, 22·0% of caregivers (n=112) and 21·0% of children (n=107) attended.
437
438   **Discussion**
439   We examined the effects of a group-based parenting intervention, combined with
440   community health events, on child HIV testing, and child language and attention in remote
441   rural community settings in Lesotho. A caregiver-directed, integrated intervention delivered
442   by CHWs had meaningful impacts on child HIV testing, and some domains of child
443   development. This was achieved in one of the poorest countries in the world, with
444   challenging terrain, harsh weather conditions, and extremely high rates of HIV.

445

446   Caregivers face numerous challenges in accessing HIV testing and treatment for their
447   children such as difficulties in transport to access difficult to reach health care facilities.
448   Expanding coverage of HIV services beyond facility-based testing is important in high
449   burden settings to ensure that all children are linked to services in a timely manner.[6] For
450   remote communities, mobile health services are increasingly used to facilitate access to
451   health services, particularly in terms of HIV testing and care.[24] Child health days in particular
452   provide opportunities for improving coverage of key interventions, especially for slightly
453   older children.[25] Our study demonstrates that accessible, flexible and responsive community-
454   based programs can be effectively used to promote HIV testing of children as well as
455   improving some domains of child development.
456

457   There was clear improvement in the receptive language domain in children who received the
458   intervention when compared to controls on one measure of language, namely the caregiver-
459   reported CDI. This is congruent with past research which demonstrates that increased
460   stimulation of children by caregivers enhances child cognitive and language outcomes.[26]
461   However, this finding should be interpreted with caution, as there were no differences
462   detected on the direct measures of language, such as for the MSEL and PPVT. The fact that
463   the intervention did not improve child attention was disappointing, given the large impact
464   book-sharing had on child attention in our previous work.[21] This finding is important in that
465   it reminds us that improving child development in contexts of high adversity is not like early
466   innoculation, but rather requires ongoing strategic quality investments across the life course.
467

468   An important part of implementation is increased integration of existing interventions where
469   local systems have the capacity, because of benefits such as optimisation of resource use,
470   and potential additive and synergistic effects across multiple areas of development.[27]
471   However, despite evidence that multi-sectoral co-operation and coordination results in
472   improved human, social and economic development outcomes, there continues to be
473   division between the health sector and other sectors supporting child development.[27]
474

475   This study has provided evidence that integrated interventions can be successfully
476   implemented in remote, rural regions, and produce benefits across HIV and child
477   development. There is no literature to the authors' knowledge which describes the
478   effectiveness of integrated, group-based parenting interventions combined with community
479   health events, that focus beyond child survival to child development and thriving in remote
480   regions such as Lesotho. There is growing evidence that combined interventions are more
481   effective than interventions using siloed approaches. Cluver and colleagues first described
482   the concept of accelerators in making a case for accelerating progress towards the SDGs.[28]
483   They found that parenting support, government cash transfers, and safe schools were
484   associated with better outcomes than single focussed interventions.[28]
485

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

492   [determinants-of-health/parenting-for-lifelong-health/programme-manuals](). Caregivers were
493   provided with opportunities to practise stimulation activities and receive feedback, which has
494   been shown to increase effectiveness of parenting programmes.[29]
495
496   The study also had certain limitations. First, the MSEL and PPVT were adapted but not
497   standardised for Lesotho. There was a lack of standardised child assessments and norms for
498   this age group in this context. As such, we were only able to compare groups, which limited
499   the interpretation of the clinical significance of the findings. Alternative assessment measures
500   designed specifically for low-resource settings should be considered in future. The study also
501   had a large number of primary endpoints which the statistical inference had to account for
502   by using a stricter significance level.
503
504   Second, discordance between the caregiver-reported child language outcomes (CDI) and the
505   directly observed language measures (MSEL and PPVT) could be a result of courtesy bias in
506   the intervention arm. There are however other important factors to consider. The MacArthur-
507   Bates group has invested substantial time in developing versions of the CDI for different
508   languages and cultural contexts, whereas the MSEL and PPVT have not undergone similar
509   processes. It is possible that the CDI performs better in different contexts as a result of the
510   refinements that have been made to the measure over time. The CDI specifically measures
511   vocabulary, whereas an assessment such as the MSEL measures the development of much
512   more complex grammatical structures and broader cognitive skills. Improving a child's
513   receptive and expressive vocabulary is likely easier to achieve within this kind of intervention,
514   whereas more complex language or cognitive skills may be more difficult to shift without
515   more specific input.
516
517   Lastly, expanding coverage while maintaining quality is a major issue.[29] The research group
518   trained and supervised the delivery agents and provided extensive implementation support.
519   For future scale-up, these activities would have to be performed by the Ministry of Health
520   and/or Education and Training. One challenge will be how to transfer the overall
521   responsibility for the programme from researchers to the district government staff. This field
522   of work could benefit from a follow-up at school-entry of children and caregivers who had
523   participated in an integrated intervention in early childhood. Given high rates of adversity
524   and chronic poverty, future follow-up of this cohort will help to answer important questions
525   regarding the duration of effects on child outcomes and potential long-term benefits of
526   integrated programmes.[30]
527
528   The SDGs signified the beginning of a new era in global development and are marked by
529   striving towards a healthier, more equitable and safer world by 2030.[31] Despite progress in
530   narrowing the gap between rich and poor countries, there are still vast inequities in access to
531   health services and resources between countries and rural and urban regions.[13] There is
532   evidence which points to high HIV prevalence and high HIV incidence clustering in areas
533   where health services fail to reach and engage vulnerable populations.[31] It is essential that
534   rural contexts such as Lesotho are given priority, if we are to have any chance of improving
535   outcomes for underserved children and families.
536
537   This study adds evidence to a limited body of research on the implementation and
538   evaluation of an integrated group-based parenting intervention, combined with community

539 health days in deeply rural settings. It demonstrates that it is possible to reach the most
540 remotely located communities and produce improved child language outcomes and HIV
541 testing uptake when programme design and implementation are innovative in bringing
542 health services to the most vulnerable, sensitive to context and culture, and make use of
543 existing resources.
544
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552 All authors had final responsibility for the decision to submit for publication. The original
553 draft of the manuscript was written by MaM and then reviewed and edited by MT, AvdM, XH,
554 LS, LC, and SS. MT, LS and LC were responsible for Funding Acquisition for the project
555 leading to this publication. Project Conceptualisation was done by MT, SS, LM, PJC, LC, LS,
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557 Administration was managed by MaM, MoM, NM, SR, and SG. The Investigation phase of the
558 project was conducted by TS and SM, and managed by MoM, who was also responsible for
559 Data Curation with MaM. Supervision of research activity planning and execution was done
560 by SS and JS. MT, SS and CL directly accessed and verified the underlying data reported in
561 the manuscript. Validation of study results was done by SS and MaM. Formal Data Analysis
562 and Visualisation was done by CL.
563
564 **Declaration of interests**

565 We declare no competing interests.
566
567 **Data sharing**

568 The de-identified datasets generated during the study along with the statistical plan and
569 analytic code can be made available from the corresponding author with publication on
570 reasonable request. Data will be made available without identifiers, available only under a
571 data-sharing agreement.
572
573 **Acknowledgements**

581

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