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Strong effects of home-based voluntary HIV counselling and testing on acceptance and equity: A cluster randomised trial in Zambia

Knut Fylkesnes [a,*], Ingvild Fossgard Sandøy [a], Marte Jürgensen [a], Peter J. Chipimo [b], Sheila Mwangala [c], Charles Michelo [b]

[a] Centre for International Health, Faculty of Medicine and Dentistry, University of Bergen, 5020 Bergen, Norway
[b] Department of Public Health, School of Medicine, University of Zambia, Lusaka, Zambia
[c] University Teaching Hospital, Department of Pathology and Microbiology, Virology Laboratory, Lusaka, Zambia

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ABSTRACT

Home-based voluntary HIV counselling and testing (HB-VCT) has been reported to have a high uptake, but it has not been rigorously evaluated. We designed a model for HB-VCT appropriate for wider scale-up, and investigated the acceptance of home-based counselling and testing, equity in uptake and negative life events with a cluster-randomized trial. Thirty six rural clusters in southern Zambia were pair-matched based on baseline data and randomly assigned to the intervention or the control arm. Both arms had access to standard HIV testing services. Adults in the intervention clusters were offered HB-VCT by local lay counsellors. Effects were first analysed among those participating in the baseline and post-intervention surveys and then as intention-to-treat analysis. The study was registered with www.controlled-trials.com, number ISRCTN53353725. A total of 836 and 858 adults were assigned to the intervention and control clusters, respectively. In the intervention arm, counselling was accepted by 85% and 66% were tested ($n = 686$). Among counselled respondents who were cohabiting with the partner, 62% were counselled together with the partner. At follow-up eight months later, the proportion of adults reporting to have been tested the year prior to follow-up was 82% in the intervention arm and 52% in the control arm (Relative Risk (RR) 1.6, 95% CI 1.4–1.8), whereas the RR was 1.7 (1.4–2.0) according to the intention-to-treat analysis. At baseline the likelihood of being tested was higher for women vs. men and for more educated people. At follow-up these differences were found only in the control communities. Measured negative life events following HIV testing were similar in both groups. In conclusion, this HB-VCT model was found to be feasible, with a very high acceptance and to have important equity effects. The high couple counselling acceptance suggests that the home-based approach has a particularly high HIV prevention potential.

Introduction

Home-based health care strategies for improving coverage and outcomes have been shown to be feasible, and to some degree effective, in many settings and programmes. Such strategies include malaria management for effective treatment in Africa (Hopkins, Talisuna, Whitty, & Staedke, 2007; Kidane & Morrow, 2000), neonatal care (Bang et al., 2005), reduction of maternal mortality (Goldie, Sweet, Carvalho, Natchu, & Hu, 2010), sexual and reproductive health services for men and women (Bell, Mthembu, O'Sullivan, & Moody, 2007), and concurrent therapy for HIV and tuberculosis (Gandhi et al., 2009). Home-based antiretroviral treatment (ART) has been shown to be effective in reducing mortality and hospital admissions (Mermin et al., 2008), but has relatively low cost-effectiveness (Marseille et al., 2009).

Similarly, home-based HIV counselling and testing for household members of HIV-infected individuals has been reported to be feasible and have a higher uptake than clinic-based counselling and testing (Lugada et al., 2010). Voluntary HIV counselling and testing (VCT) of household members in their homes was introduced as part of population-based HIV surveys conducted in Zambia and Uganda (Fylkesnes, 2000; Fylkesnes, Haworth, Rosensvard, & Kwapa, 1999; Were, Mermin, Bunnell, Ekwaru, & Kaharuza, 2003). Later studies in multiple high HIV-prevalent populations in sub-Saharan Africa have consistently found that home-based provision to the general population is associated with high acceptance levels (Angotti et al., 2009; Bassett & Walensky, 2010; Bateganya, Abdulwadud, & Kiene, 2010;

* Corresponding author. Centre for International Health, Postboks 7804, 5020 Bergen, Norway. Tel.: +47 55588576.
E-mail address: knut.fylkesnes@cih.uib.no (K. Fylkesnes).

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Fylkesnes & Siziya, 2004; Helleringer, Kohler, Frimpong, & Mkandawire, 2009; Matovu, Kigozi, Nalugoda, Wabwire-Mangen, & Gray, 2002; Matovu & Makumbi, 2007; Mutale, Michelo, Jürgensen, & Fylkesnes, 2010; Obare et al., 2009; Tumwesigye, Wana, Kasasa, Muganzi, & Nuwaha, 2010; Were et al., 2003, 2006; Wolff et al., 2005); this includes a high uptake of couple counselling and testing, which represents an effective strategy for reducing sexually transmitted infections and HIV transmission within married or cohabiting couples (Allen, Serufilira et al., 1992, Allen, Tuce et al, 1992).

The only published cluster randomized trial on home-based VCT was conducted in an urban setting in Zambia within the framework of a population-based HIV survey. The acceptance was found to be 4.7 times higher among those randomized to home-based vs. clinic-based VCT (56.8% vs. 12.4%) (Fylkesnes & Siziya, 2004). High acceptance has also been found among rural residents (Mutale et al., 2010). Furthermore, there seems to be a strong economic case for home-based VCT strategies (Menzies et al., 2009; Negin, Wariero, Mutuo, Jan, & Pronyk, 2009).

The key roles of HIV counselling and testing (HTC) to expand access to prevention, linkage to treatment and support makes equitable access of great importance. Equity in health is an ethical concept based on the principle of justice, and is defined as "the absence of systematic disparities in health between social groups who have different levels of underlying social advantage/disadvantage" (Braveman & Gruskin, 2003). Health inequities are held to exist when already socially disadvantaged groups are systematically put at further disadvantage with regards to their health (Braveman & Gruskin, 2003; Whitehead, 1992). Higher socio-economic groups have been found to be more likely to use HTC than those of lower socio-economic position (Fylkesnes et al., 1999; Gage & Ali, 2005; Hutchinson & Mahlalela, 2006; Wringe et al., 2008), indicating that current service delivery contributes to social inequity. Regarding gender inequity, recent literature from sub-Saharan Africa indicates that previous inequities in HIV testing have been reversed after the introduction of routine testing, and males are now accessing HIV testing services less often than females, resulting in less or later access to treatment and poorer outcomes (Mills et al., 2011, Mills, Beyrer, Birungi, & Dybul, 2012; Njeru, Blystad, Shayo, Nyamongo, & Fylkesnes, 2011). The observed high acceptance among both men and women indicates that the home-based approach may achieve a more equitable service coverage than clinic based VCT (Helleringer et al., 2009; Mutale et al., 2010).

A systematic evaluation of how the HB-VCT model can be implemented on a full scale, has still not been undertaken (Bateganya et al., 2010). We have designed a model based on four core principles: (i) cultural relevance, (ii) maximising individual autonomy, (iii) emphasis on HIV prevention, and (iv) protection of confidentiality. The model was evaluated in a cluster-randomised trial in a rural setting with a high prevalence of HIV. In this paper we examine the acceptance, equity and negative life-events following HB-VCT compared with standard testing services.

Methods

The study consisted of community mobilisation, mapping of households and a baseline survey (May to September 2009), followed by the intervention (March–May 2010) and a follow-up survey (November 2010–January 2011). There was at least 6 months from the intervention to the follow-up survey, and more than 12 months from the baseline survey to the follow-up survey.

Study sites and participants

The study was conducted in 36 rural villages (clusters) in Monze district, Southern province of Zambia. The clusters were separated by corridors, i.e. a minimum of one village between clusters, to minimize potential contamination between intervention and control clusters. All cluster households were included to mimic a full scale intervention. Men and women aged 16 years or above residing in the study clusters were eligible for the study. The exclusion criterion was being deaf or mentally unfit to give informed consent. The selected communities were covered by two health clinics offering basic primary health services, including VCT and PMTCT. The distance to the nearest ART clinic varied from 1.5 to 12 km for the different clusters. However, the distance to the ART sites was shortened by the establishment of mobile ART services set up by an NGO (Chikuni Outreach Programme).

Sample size calculations were based an assumed baseline test rate of 20%. We intended to be able to measure a relative risk of 1.75 with 5% precision and 95% power. The intra-cluster correlation coefficient (ICC) used in the calculation was 0.026 based on previous HIV-related surveys in Zambia, and the estimated number of clusters of 50 individuals needed in each group was 14 (sample size of 1400, formula: design effect (DEFF) $= 1 +$ (cluster size $- 1) \times$ ICC). The cluster number was adjusted upwards to 18 in each group owing to an expected loss to follow-up of up to 30%.

Randomisation and masking

The clusters were matched into 18 pairs balanced on covariates from baseline survey data, and within each pair one cluster was randomly allocated to the intervention arm. The variables used for pair matching were: (1) proportion of men tested for HIV (because of a very high coverage of HIV testing among women through the PMTCT programme, a substantially higher proportion of women than men had been tested at baseline); (2) educational attainment; (3) distance to nearest health clinic; and (4) the size of the cluster (number of individuals eligible for the baseline survey). Randomisation was performed by a person who was blinded to the identity of the clusters by randomly selecting one cluster from each pair with computer. There was no overlap related to persons or activities between the team collecting baseline and follow-up data and the intervention team of counsellors and their supervisors.

Intervention and quality assurance

Both the intervention and control communities received standard care, comprising clinic-based VCT and routine HIV counselling and testing connected to antenatal care (both offered by the Government), and outreach VCT offered occasionally by NGOs. In the intervention arm, lay counsellors offered home-based VCT to all adult household members. This consisted of pre-test counselling, HIV rapid testing using the finger-prick method, and post-test counselling, all provided in the home during one session (one hour average duration). The participants were offered counselling in privacy, but couples were encouraged to be counselled and to disclose together. The counsellors used bicycles for transport and home visits were repeated until contact was achieved and attempts were made on week-days and weekends. The counsellors (four women and four men) were selected among already trained local lay counsellors. These lay health workers were individuals selected by the local communities for voluntary work at the clinics. Their educational background is a minimum of primary school. The main reasons for involving lay counsellors were the low costs and the limited number of local health care workers. The counsellors received supplementary training on general counselling principles, HIV testing, the principles on which the HB-VCT model was grounded, and their applications when approaching households. The training was carried out in workshops (10 days in total). Quality assurance of the counselling was addressed by counsellors from the

district's VCT team and the District Medical Officer. Two counsellors were responsible for regular supervision, and two counselling sessions were observed for each counsellor. The counsellors and supervisors met with the scientific coordinator once a week for reporting, clarifications and open discussions based on experiences.

Serial HIV testing was employed as per the Zambia national HIV testing algorithm to assess the feasibility of using the same testing algorithm in the home setting. The Abbott Determine HIV-1/2 test was used as a screening test, and the Uni-Gold HIV test was used as a confirmatory test. In cases of discrepancies between the screening test and the confirmatory test, the SD Bioline HIV-1/2 test was to be used as a tie breaker. Individuals with a positive result were referred to the nearest ART site and were provided with funds to cover transport costs. Guidelines on quality control, quality assurance, biosafety, kit storage, interpretation and handling of results, record keeping and confidentiality were adhered to as per national guidelines. External quality assurance of HIV testing was employed by the quality assurance team at the University Teaching Hospital Virology Laboratory, i.e. the national reference laboratory at the University Teaching Hospital, Lusaka. This involved proficiency testing and on-site evaluation procedures.

Post-exposure prophylaxis and necessary testing procedures were available at all times. Following receipt of HIV-positive results, some households were likely to experience conflicts. Active surveillance was established for reporting of adverse events during the intervention (counsellors were to report observed events directly to the supervisor). This reporting was modified in the period between the intervention and the follow-up survey in the sense that the lay counsellors went back to working at the clinics. All individuals visited in their homes by interviewers or counsellors were offered condoms and basic medicines (pain killers, Oral Rehydration Salts, de-worming agents for children) if needed.

Community mobilisation process

The core principles of the community mobilisation were consensus building, strategies rooted in the local culture, application of a dialogue approach, accountability and transparency. In-depth interviews and focus group discussions were conducted at the initial stage with local leaders (particularly the village Headmen) and community members to inform the research team of acceptable approaches to achieve trust. Consensus was reached on acceptable approaches for contacting households. Critical in this local context was that villagers would reject any participation unless the research team obtained support from the village leaders. The local radio station and cultural drama groups were used through all stages of the study (surveys and intervention) to raise preparedness for home visits by the research team. Furthermore, we partnered with well-known local HIV/AIDS activists and NGOs when raising awareness.

Data collection

Maps of all clusters and lists of eligible household members specifying age, sex, initials, and relation to the head of the household were made by visiting all households, and these lists were used by interviewers during the baseline and follow-up surveys and by counsellors during the intervention. The baseline questionnaire was piloted in a village close to the study area. The follow-up questionnaire included the same questions as the baseline, but the questionnaire for the intervention arm also contained some specific questions related to the intervention. In the baseline survey, data were collected with EpiHandy hand-held computers (version 165.528-142 RC). In the follow-up survey, the data were collected using paper questionnaires (due to technical difficulties with the hand-held computer software) and EpiData (version 3.1) was used for double data entry.

Outcomes and process measures

The primary outcomes of the trial were acceptance of counselling and testing, equity in uptake and negative life events following VCT. Acceptance of HB-VCT was measured in two ways; i) acceptance of counselling and ii) acceptance of testing. An additional measure was constructed to capture only voluntary counselling and testing based on the assumption that routine/opt-out testing, including PMTCT-related testing, includes less counselling and has less potential to lead to risk reduction because clients have not taken an equally active decision to opt for testing. Thus participants who reported PMTCT-related tests only during the previous year were not counted as counselled and tested according to this measure. Acceptance of couple counselling during the intervention was measured in the follow-up survey, and the definition of a couple was based on the question "Are you living with your regular partner or spouse?". Distribution of service uptake (i.e. acceptance of home-based counselling and testing or having been tested in the year prior to the follow-up survey) by educational attainment and sex was used to assess equity. Negative life events were measured by asking the following questions: "Have you in the last 6 months experienced the following" (response options yes/no): "Break-up of marriage; Break-up of a sexual relationship; Physical violence such as slapping, kicking, things thrown at you; Neglected or disowned by family; Loss of close family member". These indicator questions were similar to those employed in the study conducted by Grinstead, Gregorich, Choi, & Coates (2001).

Statistical analysis

PASW Statistic 18 and Stata/IC version 12.1 were used for the analysis. The proportions were estimated using survey data analysis in Stata (taking into account the design effect). Trial arms were compared with regards to i) past HIV test experience by background characteristics measured in the baseline survey, ii) the likelihood of being tested for HIV in the year prior to the follow-up survey (relative risk and 95% confidence interval), and iii) negative life events measured in the baseline survey (all participants included) and in the follow-up survey (restricted to individuals tested for HIV the year prior to the follow-up). A generalised linear log-binomial regression model was used to test differences between trial arms, i.e. accounting for pair-matching (inclusion of terms for matched pairs) and the design effect. The likelihood of being tested for HIV in the year prior to follow-up was first analysed by including individuals with valid information from both surveys (as per protocol), and then as intention to treat analysis (including all individuals eligible for participation in the baseline survey, with those lost to follow-up recoded as non-events, i.e. assumed not to have been tested). Additionally, potentially confounding and interaction effects of educational attainment, age and sex were assessed.

Study approval and ethical considerations

Study approval was obtained from the University of Zambia Biomedical Ethics Committee (UNZA-BREC) and the regional committee for Medical and Health Research Ethics in Western Norway. Individuals provided written informed consent for participation in each of the surveys and in the intervention separately. Strict confidentiality was maintained. A list that contained the unique participant numbers and initials, age, sex and location of the participants was used to identify individuals in the two surveys

and the intervention. The list, which was available only to the Principal Investigators, was used to link the various files. The data set used for analysis did not contain initials. This trial is registered with www.controlled-trials.com, number ISRCTN53353725.

Role of the funding source

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

Results

Participant flow

After the mapping of households and household members, 1694 individuals in 36 communities were eligible for recruitment in the baseline survey (Fig. 1). Eight individuals were ineligible due to deafness or mental disability. Among the eligible respondents, 1501 (89%) accepted the offer to be interviewed, 44 (2.6%) refused, 81 (4.8%) were absent, and for 38 (2.2%) individuals no reason was recorded, whereas technical problems led to loss of 30 (1.8%) completed questionnaires. After the pair-matched randomization, 836 of the listed individuals belonged to the intervention arm and 858 to the control. Baseline participation was 87% in the intervention arm and 90% in the control arm. A total of 97 of the 836 individuals in the intervention villages were not eligible for the intervention due to migration (including 33 temporarily relocated). In the follow-up survey, a total of 1410 were eligible, and a total of 1220 (87%) participated, i.e. 624 (88%) in the intervention arm and 596 (85%) in the control arm. Non-participation was due to refusal (52, i.e. 3.7%), absence (20, i.e. 1.4%) or unknown reasons (118, i.e. 8.4%). A total of 1120 (66%) individuals eligible at baseline participated in both the baseline and follow-up surveys, i.e. 565 (68%) in the intervention and 555 (65%) in the control communities.

Baseline characteristics

The average age of the participants was 35 years (SD = 16.2). Sixty five per cent were married, 22% single and 13% widowed, separated or divorced. The majority (57%) reported seven or more years in school whereas 9% reported no formal education. Few baseline differences were identified between the intervention and control clusters with regard to the most relevant socio-demographic characteristics and previous HIV testing (Table 1). The only statistically significant difference was a lower proportion of single individuals in the intervention communities reporting having been tested (13% vs. 23%, $p = 0.010$). Reporting of past HIV testing differed significantly by sex, and any lifetime HIV testing was reported by about 60% among females and 39% among males. The sex difference was also significant for testing during the year prior to the baseline. Among the women who were tested during the prior year, about 47% reported their most recent HIV test to be PMTCT-related. Women were more likely than men to consider the most recent test as mandatory (Table 1), and this was more often reported by those whose most recent test was related to PMTCT (42%). Moreover, close to 8% claimed not to have received counselling when last tested. Most tests (VCT and PMTCT) had been conducted in the nearest clinic, but outreach HTC was a third alternative reported by 18.2% and 19.6% in the intervention and control clusters, respectively (results not shown). Experience with testing in the year prior to the baseline survey increased with increasing educational attainment (Table 1).

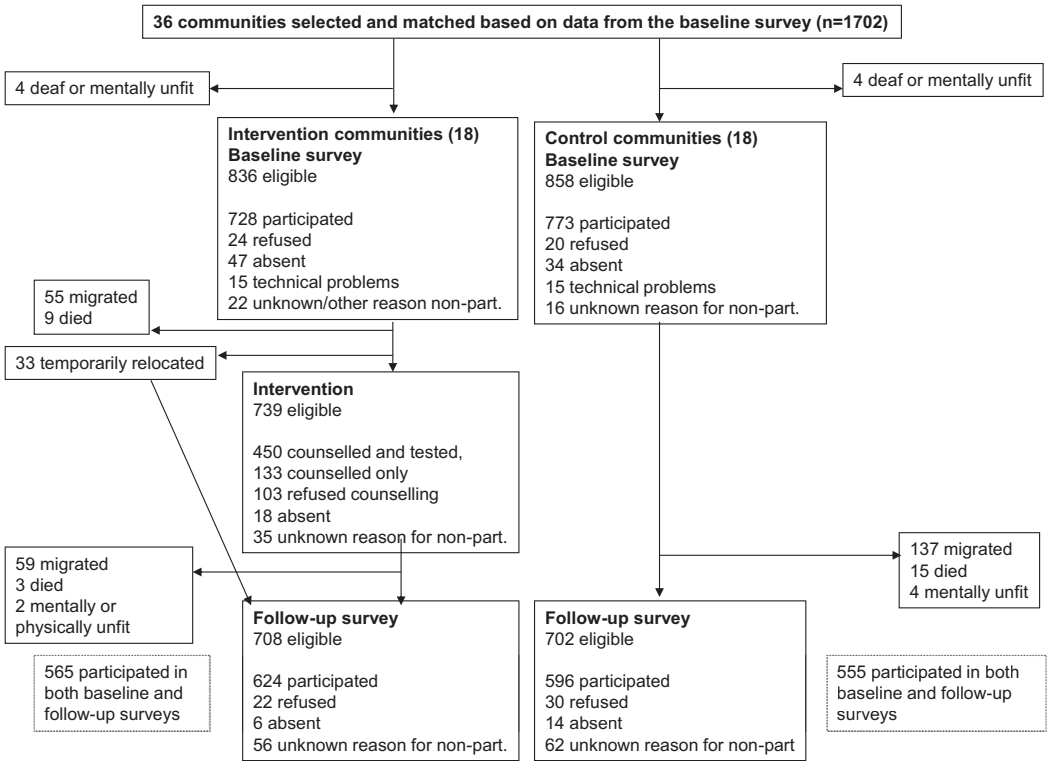

Fig. 1. Flow diagram of participation.

Table 1
Comparison of background characteristics in the intervention vs. control communities, as determined from the baseline survey.

	Intervention *n* (%)	Control *n* (%)	*p* value
Ever tested for HIV			
All	728 (51.1)	773 (49.6)	0.742
Men	335 (39.1)	351 (38.1)	0.811
Women	393 (61.3)	422 (59.0)	0.726
Tested previous year			
All	728 (31.2)	772 (28.2)	0.470
Men	335 (26.6)	351 (23.4)	0.350
Women	393 (35.1)	422 (32.1)	0.551
Last time tested was part of PMTCT			
All	372 (32.8)	383 (33.9)	0.866
Men	131 (7.6)	134 (7.5)	0.689
Women	241 (46.5)	249 (48.2)	0.740
Tested previous year by marital status			
Single	149 (12.8)	174 (23.0)	0.010
Married	482 (37.8)	497 (32.8)	0.374
Widowed	59 (25.4)	61 (14.8)	0.094
Separated/divorced	37 (27.3)	40 (15.0)	0.219
Tested previous year by age			
15–19	110 (12.7)	147 (22.5)	0.218
20–24	99 (35.4)	91 (34.1)	0.727
25–29	114 (44.7)	116 (31.9)	0.144
30–39	162 (38.9)	180 (31.7)	0.133
40–49	101 (29.7)	115 (32.2)	0.794
≥50	141 (24.1)	123 (18.7)	0.390
Tested previous year by years in school			
0	68 (14.7)	60 (11.7)	0.593
1–4	135 (34.8)	105 (22.9)	0.074
5–6	111 (27.0)	116 (25.9)	0.787
7	194 (29.4)	214 (30.4)	0.855
8–9	156 (35.9)	189 (32.3)	0.535
≥10	64 (42.2)	87 (35.6)	0.572
Experienced testing as mandatory last time tested			
All	374 (21.9)	383 (20.1)	0.637
Men	132 (7.6)	135 (10.4)	0.395
Women	242 (29.8)	248 (25.4)	0.368
Was not counselled last time tested			
All	372 (7.5)	383 (9.4)	0.491
Men	131 (9·2)	134 (9.7)	0.876
Women	241 (6.6)	249 (9.2)	0.412

Outcomes of the intervention

Acceptance of counselling was 85% and 66% accepted testing and received the test result, i.e. 133 (19%) accepted to be counselled only (Table 2). The HIV prevalence among individuals tested was 8.8% in men and 9.7% in women. Acceptance of counselling did not differ significantly by sex, age and educational attainment. When asked by the counsellors, having been previously tested was the main reason (60%) given for test refusal among the participants who accepted counselling only. Moreover, 13 persons (2%) reported being on ART. Amongst cohabiting respondents, 361 (62%) of those who were counselled at home reported to have been counselled together with the partner, and of those who were tested at home, 315 (70%) reported to have received the test together with their partner. Reasons given in the follow-up survey for refusing home-based testing were mainly knowledge of own HIV status and being reluctant to give blood. Five respondents reported to have refused counselling owing to distrust of the counsellor, and one person refused due to lack of support from the family.

In the follow-up survey, the proportion reporting to have been HIV tested in the prior year was substantially higher in the intervention than in the control arm (Table 3). Among men the overall proportions were 76% vs. 42% (RR 1.8, 95% CI 1.4–2.3). The difference in likelihood of testing during the year prior to follow-up among women (86% vs. 60%, RR 1.4, 95% CI 1.2–1.6) was smaller than among men (Table 3). The design effect for these two analyses was 2.1 for men and 1.6 for women. When PMTCT-related tests were excluded, however, the proportional differences between the intervention and control arms were similar for both sexes. Intention-to-treat analysis (including persons lost to follow up as non-cases) in Table 4, gave closely similar effects (or in some cases modestly stronger) compared to the per protocol analysis in Table 3.

The distribution of acceptance of HIV testing during the previous year by educational attainment tended to differ by arm, i.e. being tested was equally distributed in the intervention arm whereas it remained unequally distributed in the control arm (Table 3). The interaction between educational attainment and intervention arm was not significant when PMTCT-related tests were included in the analysis ($p = 0.096$). However, the interaction appeared significant when excluding PMTCT-related tests ($p = 0.036$), and this equity effect in uptake is illustrated in Fig. 2.

There were no significant differences between the arms in the proportions reporting negative life events in the follow-up survey between individuals tested for HIV during the year prior to the follow-up (Table 5). The level of negative life events at follow-up

Table 2
Acceptance of the HB-VCT during the intervention.

	Found & invited *n*	Accepted counselling[a]% (95% CI)	Accepted testing[b]% (95% CI)
Total	686	85.1 (79.2–91.0)	65.6 (59.2–72.0)
Men	318	84.0 (77.8–90.1)	64.2 (56.8–71.5)
Women	368	86.1 (79.7–92.6)	66.9 (59.4–74.3)
Age-group			
16–19	88	79.5 (67.5–91.6)	56.8 (43.0–70.6)
20–24	89	84.3 (75.9–92.6)	69.7 (58.7–80.7)
25–29	103	79.6 (70.5–88.7)	65.0 (53.2–76.9)
30–39	156	87.2 (79.9–94.4)	65.4 (55.8–75.0)
40–49	103	88.3 (80.2–96.5)	60.2 (49.6–71.8)
≥50	146	88.4 (79.1–97.6)	72.6 (60.2–85.0)
HIV prevalence			
Total	450		9.3 (5·7–13·0)
Men	204		8.8 (4·9–12·8)
Women	246		9.8 (5·4–14·0)

[a] The proportion of those found & invited who were counselled, i.e. tested & counselled or counselled only.
[b] The proportion of those found and invited who accepted testing.

Table 3
HIV tested the year prior to the follow-up survey.

	Intervention *n* (%)	Control *n* (%)	RR[a] (95% CI)
Tested previous year for any reason			
All	565 (81·6)	554 (51.8)	1.6 (1.4–1.8)
Men	255 (76·1)	261 (42.2)	1.8 (1.4–2.3)
Women	310 (86·1)	293 (60.4)	1.4 (1.2–1.6)
Tested previous year, PMTCT-related tests excluded			
All	565 (79.8)	554 (37.4)	2.1 (1.8–2.6)
Men	255 (75.9)	261 (34.5)	2.2 (1.7–2.8)
Women	310 (83.9)	293 (39.9)	2.1 (1.7–2.6)
Tested previous year by age-group			
16–19	64 (60.9)	81 (42.0)	1.4 (1.0–2.0)
20–24	69 (91.3)	57 (61.4)	1.5 (1.1–2.0)
25–29	90 (81.1)	78(57.7)	1.4 (1.1–1.8)
30–39	125 (88.8)	139 (60.4)	1.5 (1.3–1.7)
40–49	92 (85.9)	95 (61.1)	1.4 (1.1–1.7)
≥50	124 (77.4)	104 (29.8)	2.6 (1.7–3.9)
Tested previous year by years in school			
0	63 (79.4)	47 (27.7)	2.9 (1.5–5.7)
1–4	104 (76.9)	75 (36.0)	2.1 (1.4–3.3)
5–6	77 (77.9)	87 (59.8)	1.3 (1.0–1.7)
7	141 (87.9)	133 (58.7)	1.5 (1.3–1.7)
8–9	124 (83.9)	130 (55.4)	1.5 (1.2–1.9)
≥10	55 (78.2)	80 (56.2)	1.4 (1.1–1.8)

[a] Relative risk and 95% CI in the intervention arm vs. control arm; Denominator: individuals with valid data in both baseline and follow-up surveys.

Table 4
Intention-to-treat analysis: HIV tested the year prior to the follow-up survey with inclusion of respondents and persons lost to follow-up being coded as non-cases.

	Intervention *n* (%)	Control *n* (%)	RR[a] (95% CI)
Tested previous year for any reason			
All	836 (60.3)	858 (36.4)	1.7 (1.4–2.0)
Men	394 (56.1)	386 (30.1)	1.9 (1.4–2.5)
Women	442 (64.0)	472 (41.5)	1.6 (1.3–1.8)
Tested previous year, PMTCT-related tests excluded			
All	836 (59.0)	858 (26.5)	2.2 (1.8–2.7)
Men	394 (55.3)	386 (24.6)	2.3 (1.7–3.0)
Women	442 (62.2)	472 (28.0)	2.2 (1.8–2.8)
Tested previous year by age-group			
15–19	126 (34.9)	166 (22.3)	1.6 (1.1–2.2)
20–24	119 (57.1)	110 (35.5)	1.7 (1.2–2.4)
25–29	128 (59.4)	124 (40.3)	1.5 (1.0–1.1)
30–39	187 (67.4)	200 (46.0)	1.5 (1.2–1.8)
40–49	117 (74.5)	127 (48.0)	1.6 (1.2–2.0)
≥50	158 (65.8)	131 (25.1)	2.6 (1.7–3.9)
Tested previous year by years in school[b]			
0	68 (60.3)	60 (20.0)	3.0 (1.2–7.4)
1–4	135 (66.7)	105 (36.2)	1.8 (1.2–2.8)
5–6	111 (68.5)	116 (39.7)	1.7 (1.2–2.4)
7	194 (64.4)	215 (41.9)	1.6 (1.3–1.9)
8–9	156 (59.0)	189 (37.0)	1.6 (1.3–2.09
≥10	64 (57.8)	87 (34.5)	1.5 (1.0–2.5)

[a] Relative Risk and 95% confidence interval (CI).
[b] Information on education was limited to participants in either of the surveys.

was comparable or lower than the baseline level in the population, except for deaths of close family members, which tended to have increased in the intervention arm.

Quality of counselling and testing

The report from the external quality assurance team for HIV testing at the national reference laboratory in Zambia showed that all counsellors and supervisors received a Performance Proficiency Score of 100%. The counselling supervisory team (supervisors and local medical staff) concluded that the quality of counselling was acceptable.

Discussion

This is the first cluster randomised trial to evaluate a home-based VCT-model designed to be implemented on a full scale. The model was found to achieve a very high acceptance of counselling and testing of both individuals and couples, and in levelling off social inequities in uptake. The lay home-based counsellors achieved very high acceptance and rating of their counselling. The high acceptance of couple counselling identifies the home-based approach as having particular HIV prevention potential. A potential risk to client autonomy is inherent in this home-based approach since many might be particularly vulnerable to pressure by the counsellor when being visited at home. The implemented model therefore put a very high focus on the principle of maximising autonomy. In a wider scaling-up of the home-based approach, we believe that this principle is of vital importance to maintain the focus on human-rights and responsiveness.

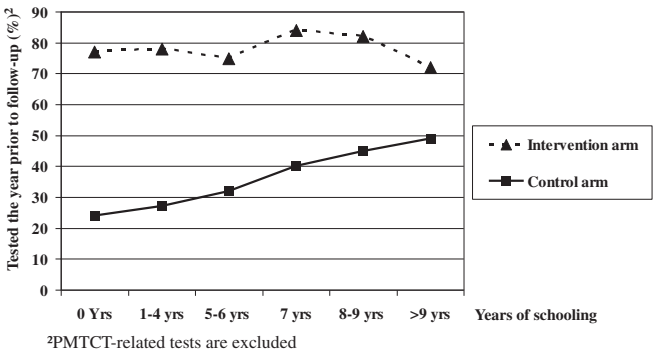

Fig. 2. Proportion of individuals being HIV tested during the year prior to follow-up by trial arm and educational attainment.

The HB-VCT intervention achieved a very high acceptance of both counselling and testing. This agrees with the findings from less robust studies from a variety of high HIV prevalence settings in Africa (Angotti et al., 2009; Fylkesnes & Siziya, 2004; Helleringer et al., 2009; Mutale et al., 2010; Tumwesigye et al., 2010). The previous randomised trial on HB-VCT in Zambia used nurse counsellors, but the current trial showed that it is feasible to offer home-based VCT of high quality and to achieve high acceptance using lay health workers. The high acceptance of lay counsellors being recruited from the study community contrasts with a finding from Malawi which indicated that use of counsellors not known to the community could be more beneficial in ensuring perceived confidentiality (Angotti et al., 2009). In our study the counsellors were selected by their communities for work at the local clinic, and it is likely that the selection procedure of counsellors was important in gaining the high local trust. This model is more suitable for scale-up in settings with an inadequate number of health care workers and constrained resources. Other studies have also documented high potential benefits of involving lay health workers within a range of health issues (Lewin et al., 2005; Lipp, 2011; Patel, Chowdhary, Rahman, & Verdeli, 2011).

The HIV prevalence has declined substantially during the last two decades among young well educated people in Zambia, whereas it has remained more stable among the less educated (Kayeyi, Sandoy, & Fylkesnes, 2009; Michelo, Sandoy, & Fylkesnes, 2006). The finding that the home-based model has potential to diminish social differences in HIV test uptake has important consequences for equitable treatment access, morbidity and survival. The home-based approach is also an effective strategy to counter gender inequities in access to testing and treatment arising due to the substantial scale-up in recent years of HIV testing of pregnant women (Njeru et al., 2011; World Health Organization et al., 2011). Moreover, the home-based approach achieved a very high uptake in a rural area where access to testing and treatment is usually lower than in urban areas (Glick & Sahn, 2007; Makwiza et al., 2009; Mutale et al., 2010). Scaling up the home-based VCT model thus has the potential to diminish important health inequities resulting from past insufficiencies in prevention, care and support efforts.

We observed very high levels of couple counselling and testing. This contrasts with findings from community-based VCT (Sweat et al., 2011), workplace VCT (Corbett et al., 2006) and antenatal clinics (Becker, Mlay, Schwandt, & Lyamuya, 2010; Byamugisha et al., 2011), where testing as couples has been rare. Couple VCT has been shown to reduce the incidence of HIV and other STIs through a reduction in sexual risk-taking in discordant couples (Allen et al., 2003, Allen, Serufilira et al., 1992, Allen, Tuce et al, 1992), possibly because of a safe context for disclosure and open communication about risk reduction strategies. Couple counselling was not encouraged during the mobilisation process, and it is not clear to what extent counselling of couples has been promoted in Zambia. Considering that several studies from sub-Saharan Africa have found that a substantial proportion of couples are HIV discordant (Kaiser et al., 2011; Lingappa et al., 2008), it follows that home-based VCT can be a particularly powerful tool in the prevention of horizontal HIV transmission.

Table 5
Comparison of negative life events experienced during the six months preceding the survey.

Life event	Baseline			Follow up		
	Intervention[a] ($n = 728$)	Control[a] ($n = 773$))	p-value	Intervention[b] ($n = 504$)	Control[b] ($n = 312$)	p-value
	n %	*n* %		*n* %	*n* %	
Break-up of marriage	6.2	6.5	0.878	4.4	4.5	0.987
Break-up of sexual relationship	9.6	9.4	0.867	7.7	6.4	0.393
Physical violence such as slapping, kicking, things thrown at you	6.7	6.7	0.937	6.2	6.1	0.825
Neglected or disowned by family	9.5	8.8	0.672	6.1	6.0	0.852
Loss of close family	50.9	48.6	0.369	57.3	51.9	0.135

[a] Denominator: all respondents in baseline.
[b] Denominator: individuals reporting to have been tested the year prior to follow-up.

Confidentiality was seen as critical for achieving high acceptance, and further home-visits to HIV-positive individuals and their families were avoided in order to prevent suspicions about who had received a positive result. The home-based counselling team provided funds to cover transport costs to the district hospital where antiretroviral treatment was available. The staff at the hospital was aware of the study and were ready to receive clients coming for CD4-testing. Additional counselling support was offered outside the home environment through the established system at the health clinic where the lay counsellor belonged to the support group. This may thus have been one of the advantages of using familiar lay counsellors. Compared to a home-based follow-up system, however, it is likely that there were needs for further counselling that were missed and that linkage-to-care might have been suboptimal. This is an area where further research is needed. It is noteworthy that no serious adverse events were recorded during the intervention, and the cautious approach might have contributed to this. Additionally, the follow-up survey identified no differences in negative life events that could be attributed to the home-based VCT, though it was not powered to detect differences.

Potentially, the intervention could have promoted test-seeking behaviours in the control arm and thus have attenuated the measured effect. An effort to prevent this type of contamination was made by allowing for corridors between clusters. It is still likely, however, that individuals in the control clusters were to some extent affected by the extensive community mobilization of this project and other ongoing promotional programmes in intervention and control areas. The most evident sign of contamination was in the use of outreach services which increased by about 10% for both men and women from baseline to follow-up. However, despite community VCT probably being easier to access than clinic-based VCT, there was no change in the educational profile of VCT users in the control arm. As for routine testing, it had been extensively scaled up in this district as part of the national PMTCT-programme (Njeru, et al., 2011), and the use of PMTCT is less likely to have been affected by the intervention owing to the very high coverage of antenatal care and the use of the opt-out consent approach (which is less likely to be influenced by personal motivation to be tested).

Of all eligible individuals, 34% were lost to follow-up owing to out-migration, absence or refusal. This loss was well balanced between the arms, however, and was not found to bias the effect estimate. We tried to reduce reporting bias relating to the intervention by avoiding any overlap between the team of interviewers and the counselling team, and we found that acceptance levels reported by the counsellors were similar to those reported by the survey participants. Another limitation was the lack of "blinding" of research assistants at the end.

In summary, the trial provides convincing evidence for home-based VCT being a feasible and equitable approach to achieve a high HIV test uptake without compromising client autonomy and confidentiality. Accordingly, our findings have important strategic implications. It seems reasonable to generalize the findings to similar contexts as they are supported by literature from multiple sub-Saharan settings, and hence the home-based model can be recommended for implementation on a wider scale. Another strategic implication relates to the high level of couple counselling. Men are "the forgotten half of the equation" in programmes on the prevention of vertical transmission and child health promotion (Mohlala, Boily, & Gregson, 2011). We think HB-VCT offers a golden opportunity to involve male partners in family planning and HIV prevention.

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