Effect of a cash transfer programme for schooling on prevalence of HIV and herpes simplex type 2 in Malawi: a cluster randomised trial

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Summary

Background Lack of education and an economic dependence on men are often suggested as important risk factors for HIV infection in women. We assessed the efficacy of a cash transfer programme to reduce the risk of sexually transmitted infections in young women.

Methods In this cluster randomised trial, never-married women aged 13–22 years were recruited from 176 enumeration areas in the Zomba district of Malawi and randomly assigned with computer-generated random numbers by enumeration area (1:1) to receive cash payments (intervention group) or nothing (control group). Intervention enumeration areas were further randomly assigned with computer-generated random numbers to conditional (school attendance required to receive payment) and unconditional (no requirements to receive payment) groups. Participants in both intervention groups were randomly assigned by a lottery to receive monthly payments ranging from US$1 to $5, while their parents were independently assigned with computer-generated random numbers to receive $4–10. Behavioural risk assessments were done at baseline and 12 months; serology was tested at 18 months. Participants were not masked to treatment status but counsellors doing the serologic testing were. The primary outcomes were prevalence of HIV and herpes simplex virus 2 (HSV-2) at 18 months and were assessed by intention-to-treat analyses. The trial is registered, number NCT01333826.

Findings 88 enumeration areas were assigned to receive the intervention and 88 as controls. For the 1289 individuals enrolled in school at baseline with complete interview and biomarker data, weighted HIV prevalence at 18 month follow-up was 1·2% (seven of 490 participants) in the combined intervention group versus 3·0% (17 of 799 participants) in the control group (adjusted odds ratio [OR] 0·36, 95% CI 0·14–0·91); weighted HSV-2 prevalence was 0·7% (five of 488 participants) versus 3·0% (27 of 796 participants; adjusted OR 0·24, 0·09–0·65). In the intervention group, we noted no difference between conditional versus unconditional intervention groups for weighted HIV prevalence (3/235 [1%] *vs* 4/255 [2%]) or weighted HSV-2 prevalence (4/233 [1%] *vs* 1/255 [<1%]). For individuals who had already dropped out of school at baseline, we detected no significant difference between intervention and control groups for weighted HIV prevalence (23/210 [10%] *vs* 17/207 [8%]) or weighted HSV-2 prevalence (17/211 [8%] *vs* 17/208 [8%]).

Interpretation Cash transfer programmes can reduce HIV and HSV-2 infections in adolescent schoolgirls in low-income settings. Structural interventions that do not directly target sexual behaviour change can be important components of HIV prevention strategies.

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Introduction

Two-thirds of HIV-infected people worldwide live in sub-Saharan Africa and 68% of new infections in adults occur in the region.[1] Women and girls are at particularly high risk; 60% of people living with HIV in sub-Saharan Africa are women. Furthermore, people aged 15–24 years account for an estimated 45% of new infections worldwide.[2] In this age group, women are more than twice as likely to be infected than are men. In Malawi, HIV prevalence in 2007 was 9·1% in young women, compared with 2·1% in young men.[3] Prevention of HIV in girls is one of the most essential challenges to reach a turning point in the epidemic.[4]

Schooling has been suggested to be a social vaccine to prevent the spread of HIV.[5] Although cross-sectional data[6,7] suggest a correlation between school attendance and HIV status, only two studies[8,9] have identified a possible causal link between school attendance and reduced risky sexual behaviour. Furthermore, although poverty, especially poverty of women, has been suggested as a major risk factor for HIV, evidence is mixed.[10–13] We are aware of only one cluster randomised trial[14] with biological outcomes of a structural intervention to prevent HIV in women. The Intervention with Microfinance for AIDS and Gender Equity (IMAGE) study[14] assessed a structural intervention that combined a microfinance programme with a gender and HIV training curriculum and showed no effect on HIV incidence. No studies causally link increased schooling or income with a reduction in HIV risk. However, this absence of clear and credible evidence is not restricted to interventions in education or social protection. A review of behaviour change interventions has shown that "the reality that current behavior change interventions, by themselves, have been limited in their ability to control HIV infection in women and girls in low- and middle-income countries".[15] No randomised controlled trial assessing a behavioural intervention has shown a significant effect on HIV incidence.[16]

Conditional cash transfer programmes aim to reduce current poverty and, by investment in the education of children, future poverty. As such, they have been popular in development economics since the late 1990s, especially in Latin America.[17,18] The programmes provide cash transfers to poor households with school-aged children (generally aged 6–18 years), often with the requirement that the children attend school regularly. Conditional cash transfer programmes can be an important component of social protection policy and evidence suggests that they have improved the lives of poor people.[19]

Because conditional cash transfer programmes increase household income and school enrolment, they are particularly suitable for investigation of the importance of education and poverty as risk factors for HIV. We assess the effectiveness of cash transfers in Malawi for reduction of the risk of HIV and herpes simplex virus type 2 (HSV-2) infections in never-married girls aged 13–22 years.

Methods

Study design and participants

We undertook this cluster randomised trial in Zomba district, which like most of southern Malawi is characterised by poverty, low school enrolment, and a high prevalence of HIV.[3,20] Zomba district contains 550 enumeration areas defined by the National Statistical Office of Malawi. Each enumeration area contains an average of 250 households spanning several villages. Zomba city includes 50 enumeration areas; the remaining 500 are in seven traditional authorities. Before the start of the trial we selected 176 enumeration areas from three different geographical strata: urban (Zomba city, 29 enumeration areas), near rural (<16 km from Zomba city, 119 enumeration areas), and far rural (≥16 km from Zomba city, 28 enumeration areas). The use of a 16 km radius was arbitrary and based mainly on transport costs. Of the 50 enumeration areas in Zomba city, 21 were excluded on the basis of advice from local experts who deemed these areas to be too affluent for the proposed intervention. In each of the two rural strata, with the exception of one traditional authority that was unsafe for field work, the study enumeration areas were randomly selected from all enumeration areas.

In the 176 sampled enumeration areas, each dwelling was visited to take a census of all never-married girls aged 13–22 years, which was used to define two cohorts: those enrolled in school at baseline (baseline schoolgirls), and those not enrolled in school at baseline (baseline dropouts). Because of their small number (about five per enumeration area), all eligible baseline dropouts were sampled to participate in the overall study. In the cohort of baseline schoolgirls, a subset of eligible individuals was randomly selected for the study. The sampling percentages for this cohort differed by geographical stratum and age group and varied from 14% to 45% in urban areas and 70% to 100% in rural areas. This sampling procedure yielded a baseline study sample of 4051 individuals of whom 3796 (94%) were enrolled and completed a baseline interview at the end of 2007. Of these study participants, 889 were baseline dropouts and 2907 were baseline schoolgirls. Table 1 shows eligibility criteria.

All participants provided written informed consent. We obtained additional consent from parents or legal guardians of all unmarried girls younger than 18 years. Informed consent for HIV, HSV-2, and syphilis testing was obtained separately at the time of specimen collection. The study design was approved by ethics review committees at the National Health Sciences Research Council (Malawi) and the University of California at San Diego (USA).

	Eligibility criteria			Household survey follow-up criteria		Voluntary counselling and testing follow-up	
	Intervention enumeration areas	Control enumeration areas	N	Period (months)	Criteria	Period (months)	Criteria
Baseline schoolgirls	Enrolled in school at baseline; eligible to return to standard 7 to form 2*	Enrolled in school at baseline; eligible to return to standard 7 to form 2	2907	12	All individuals successfully interviewed at baseline	18	Randomly selected subsample of baseline participants successfully interviewed in second household survey
Baseline dropouts	Not enrolled in school at baseline	Not enrolled in school at baseline	889	12	All individuals successfully interviewed at baseline	18	Randomly selected subsample of baseline participants successfully interviewed in second household survey

*Primary school year groups in Malawi are from standard 1 to standard 8 (generally for children aged 6–13 years); secondary school year groups are from form 1 to form 4 (generally for children aged 14–17 years).

Table 1: **Eligibility and follow-up criteria**

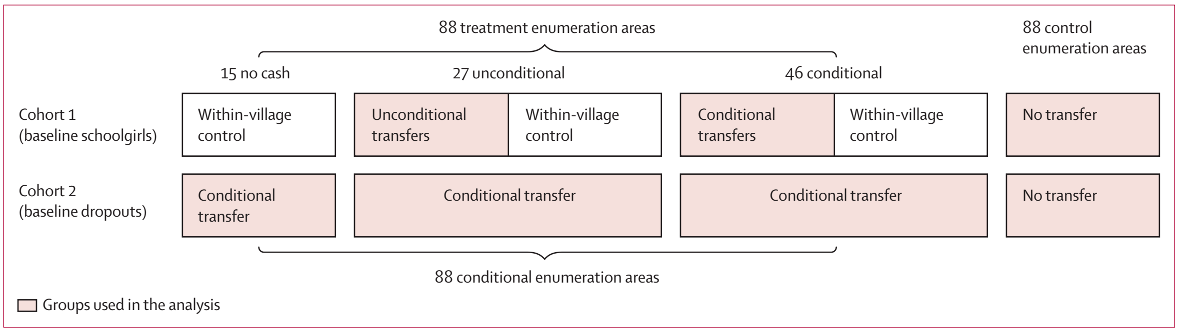

Figure 1: **Intervention groups**

Randomisation and masking

After baseline surveys were completed, the 176 geographic enumeration areas were randomly assigned (1:1) to intervention (cash transfer programme) or control groups (no programme). To reduce the possibility of crossover from the intervention group to the control group, participants were assigned to trial groups on the basis of the random assignment of the enumeration areas that they lived in. Randomisation within each geographical stratum ensured the assignment of equal proportions of enumeration areas from Zomba city, near rural, and far rural areas in the intervention and control groups. Within each of the three geographical strata, enumeration areas were assigned numbers from a computer-generated list of random numbers (with Stata, version 9.2). Each of the three lists of enumeration area identification numbers were sorted in ascending order and the enumeration areas in the first half of the list were assigned to the intervention group and the rest were assigned to the control group.

To assess whether any effects were simply due to increased household income baseline schoolgirls from the enumeration areas in the intervention group were further randomly assigned with computer-generated random numbers to one of two groups: one received conditional cash transfer offers and the other unconditional cash transfer offers. Baseline dropouts were assigned to receive conditional cash transfer offers in all intervention enumeration areas irrespective of the treatment status of the baseline schoolgirls within those areas.

To measure potential effects of the programme on untreated schoolgirls in treatment enumeration areas, the percentage of baseline schoolgirls invited to participate in the cash transfer programme in the intervention enumeration areas was randomly assigned with computer-generated random numbers to be equal to 0% (15 enumeration areas), 33% (15 conditional cash transfer enumeration areas, nine unconditional cash transfer enumeration areas), 66% (16 conditional cash transfer enumeration areas, nine unconditional cash transfer enumeration areas), or 100% (15 conditional cash transfer enumeration areas, nine unconditional cash transfer enumeration areas). In the 15 intervention enumeration areas where this share was 0%, no baseline schoolgirls were offered cash transfers, meaning that the only spillover of baseline schoolgirls would be from the baseline dropouts who were offered conditional cash transfers (figure 1). Analysis of secondary outcomes with the 12 month follow-up survey data, such as school enrolment, marriage and pregnancy, and sexual behaviour, showed no effects in this group of participants who did not receive cash transfer offers despite living in intervention enumeration areas (data not shown), and biological data were not collected from these study participants at the 18 month follow-up. Therefore, we did not include this group of 623 girls in the analysis of direct programme effects on HIV and HSV-2. The remaining 1225 sampled individuals in the 88 intervention enumeration areas (789 baseline schoolgirls and 436 baseline dropouts) were invited to participate in the cash transfer programme.

Codes for randomisation of the enumeration areas into trial groups, and for random assignment of baseline schoolgirls to participate in the cash transfer programme in the cash transfer enumeration areas, were written by one of the study investigators (SJB). These programmes were run by the programme field manager with Stata (version 9.2). The resultant enumeration area identification numbers and basic information about individuals selected to participate in the cash transfer programme in each intervention enumeration area were then provided to study staff, who enrolled participants.

Study participants were not masked to their assignment, but did not know what the comparison groups were because they were assigned at the enumeration area level. Trained counsellors who did home-based counselling and rapid testing for HIV, HSV-2, and syphilis were masked to the participant's group. Statistical analyses were done by the investigators who were not masked to the treatment status of the participants. However, the analysis was done according to the research design of primary outcomes, comparison groups, and covariates (age group and geographical strata) used for regression analysis. Because the primary outcomes were measurable and objective (HIV and HSV-2 test results) and regression adjustments were small, bias in analyses due to no masking was reduced.

Procedures

Panel 1 shows key features of the intervention design. Participants in the conditional cash transfer group received offers of monthly cash transfers dependent on regular school attendance during the previous month. In the unconditional cash transfer group, the offers were identical except that school attendance was not required. Participants in the control group received nothing. The intervention is summarised in the webappendix and described in detail elsewhere.[21] No other cash transfer programme existed in Zomba district before or during the study.

The primary outcomes were the prevalences of HIV and HSV-2 at 18 months, which were collected by home-based voluntary counselling and testing (VCT). Secondary outcomes included syphilis prevalence, school enrolment, self-reported marriage, pregnancy, sexual behaviour, and knowledge of HIV/AIDS. Data for the behavioural outcomes were collected at both baseline and 12 month follow-up (webappendix). We expected that school enrolment and HIV awareness would increase as a result of the intervention and that rates of marriage, fertility, and sexual activity would decrease.

See Online for webappendix

Data for biological outcomes were collected at follow-up at 18 months in 104 randomly selected enumeration areas with computer-generated random numbers. A detailed description of the VCT protocols is provided in the webappendix. Cost of voluntary counselling and testing was the main reason to reduce the number of enumeration areas in which biological data were collected. We expected that the intervention would reduce prevalence of HIV and HSV at follow-up. All behavioural and biological endpoints were pre-specified.

Biological data were not collected at baseline for two reasons. First, because HIV testing in Malawi was fairly rare at the start of our study (fewer than one in five baseline schoolgirls in control enumeration areas had ever been tested for HIV at baseline), and learning one's HIV status could change subsequent school enrolment decisions, we decided that HIV testing at baseline would have precluded the assessment of the effect of only the cash transfer programme on school enrolment and self-reported risk behaviours at 12 months.[22,23] Second, one of the primary aims of the study was to assess whether an intervention that aimed to increase school attendance could indirectly decrease exposure to HIV. To achieve this aim, the study participants could not think that the cash transfers were intended to reduce risky sexual behaviour and HIV or that they were tied to good behaviour in terms of sexual activity. Therefore, we judged that rapid testing at baseline would likely constitute a separate intervention and make it harder to argue that the study findings would be valid for a standard conditional cash transfer programme that promotes schooling exclusive of HIV counselling and testing. Thus, biological data were only measured 6 months after the 12 month follow-up surveys, but while the cash transfer programme was still ongoing.

Panel 1: Intervention details

Intervention

The Zomba cash transfer programme took place between January, 2008, and December, 2009. In both years, transfers were made on a monthly basis for a total of ten transfers per year.

Treatment groups

In the conditional group (baseline schoolgirls and baseline dropouts), each payment was received if the girl attended school for 80% of the days that school was in session during the previous month.

In the unconditional group (baseline schoolgirls only) payment was received if the girl attended the cash transfer points.

Split

Cash transfers split between guardian and girl.

Amounts

Household amount varied randomly (by use of computer-generated random numbers) by enumeration area, with monthly values of US$4, $6, $8, or $10. Girl amount varied randomly between individuals, with monthly values of $1, $2, $3, $4, or $5, decided by drawing numbers from an envelope.

Programme effects on untreated girls in treatment areas

Within treatment enumeration areas, a random subsample of baseline schoolgirls was not treated. The size of the subsample ranged from 0% to 100% per enumeration area.

Statistical analysis

Power calculations were done to establish the number of enumeration areas (and the number of participants in each enumeration area) needed to detect significant differences in school enrolment with 90% confidence and 80% power. Optimal Design software[24] was used for power calculations to account for the study's randomised, cluster design that aimed to assess effects for continuous and binary outcome variables. Separate power calculations were done for programme effects on HIV. With the assumption of a 4% prevalence (on the basis of analysis of data for unmarried women younger than 25 years in southern Malawi[3]) in baseline schoolgirls in the 52 control enumeration areas selected for collection of biological data, and with a 95% CI and an 80% power for analysis of the intervention's effect on HIV prevalence, we selected a sample size that would allow us to detect at least a 66% decreased HIV prevalence (2·3 percentage points) in the combined conditional and unconditional cash transfer programme groups versus the group receiving no cash transfers. The minimum detectable effect size was higher (3 percentage points) for each intervention group separately than for the control group because of the fewer clusters. The study was not powered to detect effects on HIV prevalence in baseline dropouts

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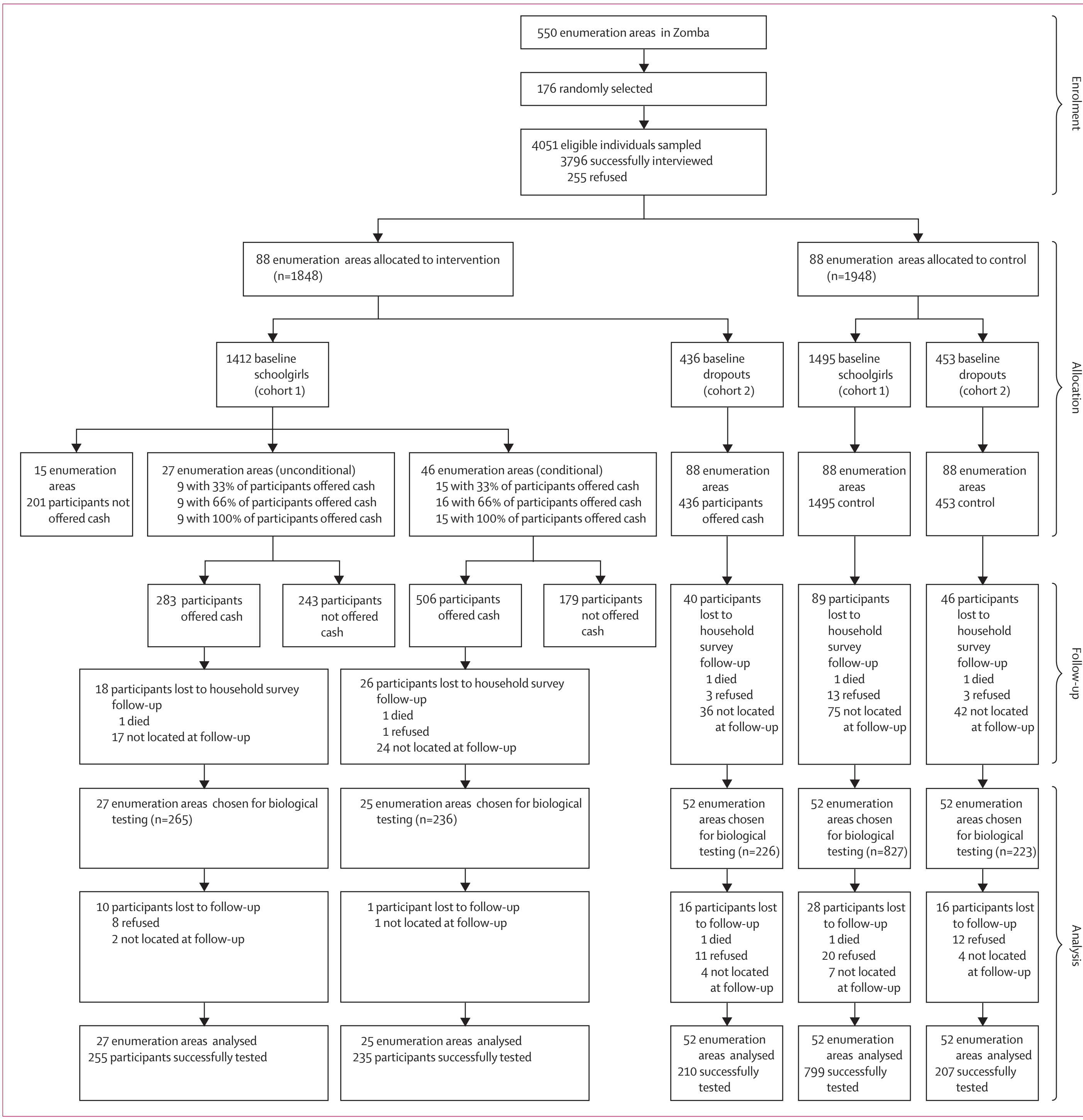

Figure 2: **Trial profile**

or heterogeneity of effects between the conditional and unconditional cash transfer programme groups.

We assessed, by intention to treat analysis, whether study outcome measures differed between the intervention (conditional and unconditional cash transfer programmes combined) and control groups; we analysed separately baseline schoolgirls and baseline dropouts. We also tested heterogeneity of programme effects on the prevalence of HIV and HSV-2 in the conditional and unconditional cash transfer groups by cash transfer size. We calculated unadjusted odds ratios (ORs) by fitting logistic regression models to individual follow-up data with treatment status as the only independent variable. We calculated robust standard errors, allowing for intracluster correlation. We used sampling weights to account for the fact that the probability of inclusion in the study varied by age and enumeration area geographical stratum. We calculated adjusted ORs with the same regression model with binary indicators for age (13–14 years *vs* 15–22 years) and geographical location as additional independent variables. Adjustments for baseline values were included for behavioural outcome measures. Stata (version 10.1) was used for the statistical analyses. The trial is registered, number NCT01333826.

	Control group	Intervention group		
		Pooled	Conditional cash transfer programme	Unconditional cash transfer programme
Enumeration areas sampled for biological data collection	52	52	25	27
Baseline schoolgirls				
Number of individuals	827	501	236	265
Ever had sexual intercourse	182 (19%)	130 (22%)	70 (22%)	60 (22%)
Ever pregnant	21 (3%)	16 (3%)	9 (3%)	7 (3%)
Age (years)	15·3 (1·9)	15·1 (1·9)	14·9 (1·8)	15·4 (1·9)
Age at sexual debut (years)	15·7 (1·7)	15·8 (1·8)	15·7 (2·0)	15·9 (1·7)
Highest grade attended	7·6 (1·6)	7·4 (1·7)	7·1 (1·7)	7·9 (1·6)
Mother alive	707 (85%)	423 (84%)	198 (85%)	222 (83%)
Father alive	601 (74%)	367 (75%)	176 (74%)	191 (76%)
Female-headed household	275 (32%)	141 (25%)	63 (26%)	78 (24%)
Household owns a radio	479 (59%)	309 (58%)	143 (53%)	166 (65%)
Household owns a television	130 (24%)	110 (30%)	40 (27%)	70 (34%)
Household has access to a mobile telephone	464 (61%)	303 (60%)	145 (60%)	158 (61%)
Electricity available in dwelling	86 (20%)	80 (26%)	31 (28%)	49 (24%)
Piped water available in dwelling	277 (47%)	183 (49%)	48 (41%)	135 (60%)
Baseline dropouts				
Number of individuals	223	226	..	..
Ever had sexual intercourse	151 (68%)	154 (68%)	..	..
Ever pregnant	98 (44%)	90 (40%)	..	..
Age (years)	17·6 (2·2)	16·8 (2·4)	..	..
Age at sexual debut (years)	16·4 (1·8)	15·9 (2·2)	..	..
Highest grade attended	6·2 (2·9)	5·8 (2·9)	..	..
Mother alive	175 (78%)	180 (80%)	..	..
Father alive	146 (66%)	144 (65%)	..	..
Female-headed household	93 (42%)	90 (39%)	..	..
Household owns a radio	118 (53%)	107 (47%)	..	..
Household owns a television	16 (7%)	24 (11%)	..	..
Household has access to a mobile telephone	103 (46%)	110 (49%)	..	..
Electricity available in dwelling	16 (7%)	24 (11%)	..	..
Piped water available in dwelling	64 (29%)	63 (25%)	..	..

Data are n (weighted %) or mean (SD). Sampling weights were used to account for variation in the probability of inclusion in the study according to age and stratum. All baseline dropouts received the conditional cash transfer intervention irrespective of the treatment status of baseline schoolgirls in their enumeration areas; thus, the conditional and unconditional cash transfer columns are not applicable to this cohort.

Table 2: **Baseline characteristics of participants**

Role of funding source

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

Results

Figure 2 shows the trial profile. At baseline 3796 individuals were successfully interviewed. Although 133 (7%) baseline schoolgirls and 86 (10%) baseline dropouts were lost to follow-up at 12 months, none of the enumeration areas had complete loss to follow-up. Rates were similar at the 18-month visit (figure 2). Of the 1777 individuals selected for biological testing, 71 (4%) were lost to follow-up because of either refusal to get tested (n=51) or not being located by the data collection teams (n=20). The number of participants lost to follow-up at 18 months did not differ significantly between the intervention and control groups (figure 2). All analyses of intervention effects on primary outcomes were done only in the 1706 individuals with both 12 month follow-up survey data and 18 month biomarker data. Table 2 shows the baseline characteristics of the participants selected for biological data collection for each cohort. Baseline characteristics in the intervention and control groups were similar (table 2).

In the cohort of baseline schoolgirls, weighted prevalence of HIV was 1·2% (seven of 490) in the combined intervention group versus 3·0% (17 of 799) in the control group at 18 month follow-up (adjusted OR 0·36, 95% CI 0·14–0·91; table 3). Weighted HSV-2 prevalence was 0·7% (five of 488) in the intervention group versus 3·0% (27 of 796) in the control group (0·24, 0·09–0·65; table 3). Self-reported sexual activity at 12 month follow-up was significantly lower in the intervention group for intercourse at least once a week with at least one partner, and for having a sexual partner aged 25 years or older (table 3). Individuals in the intervention group were also more likely to be enrolled in school during the 2008 school year than were those in control enumeration areas (table 3). The adjusted point estimates for the likelihood of marriage, pregnancy, sexual debut, and intercourse without consistent use of condoms with at least one partner did not differ significantly between intervention and control groups. Intervention and comparison groups did not differ significantly at follow-up for the prevalence of syphilis, HIV knowledge, having had an HIV test, or having received any health training about HIV/AIDS (table 3).

For baseline dropouts, although school re-enrolment was substantially higher and the likelihood of having been married at 12 month follow-up was lower in the intervention group than in the comparison group, the prevalence of

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	Baseline		Follow-up			
	Intervention group	Control group	Intervention group	Control group	Unadjusted odds ratio (95% CI)	Adjusted odds ratio (95% CI)
Baseline schoolgirls						
Enrolled during 2008 school year	..	..	419/484 (90%)	669/801 (84%)	1·67 (1·09–2·56)	1·62 (1·07–2·45)
Ever married	0/501 (0%)	0/827 (0%)	19/501 (3%)	45/827 (4%)	0·63 (0·31–1·28)	0·68 (0·37–1·28)
Currently pregnant	3/501 (<1%)	2/827 (<1%)	15/501 (3%)	35/827 (4%)	0·66 (0·33–1·30)	0·71 (0·35–1·41)
Sexual debut*	..	..	39/371 (8%)	100/645 (13%)	0·59 (0·33–1·05)	0·64 (0·38–1·07)
Had unprotected sexual intercourse	91/500 (16%)	107/825 (11%)	49/500 (8%)	63/826 (7%)	1·28 (0·78–2·09)	1·08 (0·67–1·75)
Had sexual intercourse once per week	16/500 (3%)	22/825 (2%)	22/299 (3%)	62/826 (7%)	0·44 (0·23–0·85)	0·46 (0·26–0·82)
Had a sexual partner aged ≥25 years†	..	..	4/502 (<1%)	20/827 (3%)	0·20 (0·07–0·59)	0·21 (0·07–0·62)
Had an HIV test	121/501 (22%)	174/827 (19%)	307/501 (54%)	470/826 (52%)	1·12 (0·74–1·68)	1·18 (0·83–1·69)
Knows that a healthy looking person can have HIV	443/501 (88%)	752/827 (90%)	454/501 (91%)	768/826 (92%)	0·94 (0·58–1·53)	1·00 (0·61–1·62)
Knows that HIV can be transmitted through breastfeeding	466/500 (93%)	785/827 (95%)	481/501 (97%)	786/827 (96%)	1·70 (0·84–3·43)	1·72 (0·89–3·34)
Received health training about HIV/AIDS†	..	..	398/501 (78%)	657/827 (80%)	0·89 (0·61–1·30)	0·90 (0·63–1·30)
HIV prevalence†,‡	..	..	7/490 (1%)	17/799 (3%)	0·39 (0·15–1·02)	0·36 (0·14–0·91)
HSV-2 prevalence†,‡	..	..	5/488 (<1%)	27/796 (3%)	0·23 (0·08–0·66)	0·24 (0·09–0·65)
Syphilis prevalence†,‡	..	..	1/491 (<1%)	4/800 (<1%)	1·20 (0·15–9·68)	0·92 (0·12–6·85)
Baseline dropouts						
Enrolled during 2008 school year	..	..	124/219 (57%)	27/220 (12%)	9·31 (5·31–16·3)	8·77 (5·08–15·1)
Ever married	0/226 (0%)	0/223 (0%)	37/226 (17%)	64/223 (29%)	0·50 (0·29–0·83)	0·48 (0·29–0·80)
Currently pregnant	11/226 (5%)	10/223 (5%)	16/226 (7%)	26/223 (12%)	0·59 (0·28–1·25)	0·55 (0·27–1·13)
Sexual debut*	..	..	18/72 (26%)	27/72 (38%)	0·57 (0·28–1·16)	0·70 (0·34–1·45)
Had unprotected sexual intercourse	133/222 (61%)	128/223 (57%)	59/225 (25%)	64/222 (29%)	0·75 (0·46–1·22)	0·74 (0·44–1·23)
Had sexual intercourse once per week	31/222 (14%)	28/223 (13%)	43/225 (19%)	66/223 (30%)	0·56 (0·34–0·91)	0·53 (0·32–0·86)
Had a sexual partner aged ≥25 years†	..	..	20/225 (8%)	23/223 (10%)	0·73 (0·40–1·34)	0·79 (0·42–1·50)
Had an HIV test	98/225 (43%)	104/223(47%)	163/225 (72%)	169/223 (76%)	0·84 (0·51–1·38)	1·00 (0·64–1·57)
Knows that a healthy looking person can be infected with HIV	198/225 (88%)	201/223 (90%)	204/226 (90%)	212/223 (95%)	0·45 (0·19–1·05)	0·51 (0·23–1·15)
Knows that HIV can be transmitted through breastfeeding	198/223 (89%)	210/223 (94%)	213/226 (94%)	214/223 (96%)	0·63 (0·25–1·56)	0·69 (0·26–1·81)
Received health training about HIV/AIDS†	..	..	130/226 (57%)	94/223 (42%)	1·82 (1·23–2·69)	1·91 (1·29–2·83)
HIV prevalence†,‡	..	..	23/210 (10%)	17/207 (8%)	1·30 (0·69–2·48)	1·37 (0·72–2·61)
HSV-2 prevalence†,‡	..	..	17/211 (8%)	17/208 (8%)	0·99 (0·46–2·10)	1·03 (0·47–2·23)
Syphilis prevalence†,‡	..	..	3/211 (2%)	2/208 (1%)	1·59 (0·27–9·50)	1·63 (0·27–9·95)

Data are n/N (weighted %) unless otherwise stated. Sampling weights were used to account for variation in the probability of inclusion in the study according to age and stratum. Adjusted odds ratios calculated with a logistic regression model of individual data with independent variables that include treatment status, age group, indicators for near rural and far rural strata, and baseline measure unless otherwise stated. HSV=herpes simplex virus. *Cumulative risk measure, so no adjustment made for baseline status. †No adjustment for baseline measure because data not collected at baseline. ‡Measured at 18 months, all others were measured at 12 months.

***Table 3:* Effects of cash transfer intervention on outcome measures**

HIV or HSV-2 did not differ significantly between the two groups (table 3). For self-reported sexual activity at 12 month follow-up, only intercourse at least once a week with at least one partner was significantly lower in the intervention group than in the control group (table 3).

Table 4 shows programme effects separately in the conditional and unconditional cash transfer programme groups, calculated with a subset of the outcomes included in table 3. These comparisons were of smaller treatment groups and therefore have less statistical power to detect effects for each of these intervention groups. Although some outcomes were significantly different compared with the control group in the conditional cash transfer group (HIV prevalence and had a sexual partner aged 25 years or older) and others in the unconditional transfer group (currently pregnant, had sexual intercourse once per week, and HSV-2 prevalence; table 4), only for currently pregnant do treatment effects differ significantly between the two intervention groups (table 4). In separate tests, we also analysed heterogeneity in programme effects on the prevalence of HIV, HSV-2, and syphilis by transfer size. The treatment effect did not vary by the

	Control group	CCT group	UCT group	CCT *vs* control (adjusted odds ratio [95% CI])	UCT *vs* control (adjusted odds ratio [95% CI])	Heterogeneity of odds ratios* (p value)
Enrolled during the 2008 school year	669/801 (84%)	207/229 (92%)	212/255 (87%)	2·08 (1·14–3·82)	1·22 (0·77–1·96)	0·14
Ever married	45/827 (4%)	14/236 (4%)	5/265 (2%)	0·93 (0·47–1·86)	0·36 (0·12–1·07)	0·11
Currently pregnant	35/827 (4%)	13/236 (4%)	2/265 (1%)	1·17 (0·56–2·43)	0·16 (0·04–0·68)	0·0121
Sexual debut†	100/645 (13%)	18/166 (7%)	21/205 (10%)	0·58 (0·29–1·15)	0·72 (0·37–1·40)	0·62
Unprotected sexual intercourse	63/826 (7%)	30/235 (9%)	19/265 (8%)	1·17 (0·67–2·05)	0·96 (0·50–1·83)	0·59
Had sexual intercourse once per week	62/826 (7%)	14/235 (3%)	8/264 (3%)	0·53 (0·26–1·07)	0·37 (0·16–0·85)	0·49
Had a sexual partner aged ≥25 years‡	20/826 (3%)	1/235 (<1%)	3/265 (1%)	0·08 (0·01–0·60)	0·36 (0·11–1·19)	0·19
HIV prevalence‡	17/799 (3%)	3/235 (1%)	4/255 (2%)	0·29 (0·09–0·98)	0·47 (0·14–1·59)	0·57
HSV-2 prevalence‡	27/796 (3%)	4/233 (1%)	1/255 (<1%)	0·37 (0·13–1·03)	0·08 (0·01–0·58)	0·16
Syphilis prevalence‡	4/800 (1%)	1/235 (1%)	0/256 (0%)	1·37 (0·20–9·41)	Undefined	..

Data are n/N (weighted %) unless otherwise stated. Adjusted odds ratios calculated with a logistic regression model of individual data with independent variables that include treatment status, age group, indicators for near rural and far rural strata, and baseline measure unless otherwise stated. Sampling weights were used to account for variation in the probability of inclusion in the study according to age and stratum. HSV=herpes simplex virus. CCT=conditional cash transfer. UCT=unconditional cash transfer. *Wald test of equality of adjusted odds ratios for the conditional and unconditional cash transfer interventions. †Cumulative risk measure, therefore no adjustment made for baseline status. ‡No adjustment for baseline measure because data not gathered at baseline.

Table 4: **Effect of conditional or unconditional cash transfers on baseline schoolgirls by outcome measures**

amount of cash transfers offered to programme participants (data not shown).

Discussion

The cash transfer programme decreased the prevalences of HIV and HSV-2 infection after 18 months in girls aged 13–22 years who were enrolled in school at baseline. These effects are supported by changes in self-reported sexual behaviour; we detected no effects on age of sexual debut or unprotected sex, but individuals in the intervention group chose younger partners than did those in the control group and sexual activity was less frequent with those partners.

Few randomised controlled trials have assessed behavioural interventions with biological outcomes, and none have recorded a significant effect on HIV (panel 2).[16] Our trial shows that an intervention without direct focus on sexual behaviour change can lead to meaningful reductions in HIV and HSV-2 infections. The cluster randomised study design ensured that crossover between treatment groups was minimised, and the data collected for a wide range of self-reported behavioural measures allowed us to verify and contextualise effects on biological outcomes. The percentage of study participants lost to follow-up did not differ between control, conditional, and unconditional groups, and was lower than that reported in similar studies.[25]

Our study had some limitations. The absence of baseline data for HIV and HSV-2 makes comparison of incidences between trial groups impossible. Thus, the programme effects on the 18 month prevalences of these infections are subject to scrutiny. However, several factors increase our confidence in the findings. First, participants in the intervention and control groups had similar characteristics at baseline. Although residual confounding due to unmeasured factors could have caused spurious findings, the balance across several baseline variables known to be associated with HIV infection makes this scenario unlikely. Second, block randomisation by geographical stratum helps to prevent bias that might be caused by differences in the underlying prevalence of HIV.[26] Third, the differences in biological outcomes between trial groups at follow-up are supported by changes in behavioural factors. Thus, the reported differences in the prevalences of HIV and HSV-2 are likely to be real rather than a result of selection bias.

The low event rate for biological outcomes, especially for HIV infection (seven in the combined intervention group *vs* 17 in the comparison group), means that the programme effects should be interpreted with caution. Furthermore, the study was not powered to detect heterogeneity of effects on biological outcomes between the conditional and unconditional cash transfer interventions, and had sufficient power to detect only very large effects on HIV in baseline dropouts because of the small size of this cohort. Further studies of cash transfer programmes are needed to confidently establish these effects and the channels through which they might operate.

The intervention was implemented for only 2 school years. The short duration of the programme might mean that the effects noted after 18 months might not be durable. However, the finding that cash transfers to school-aged girls and their families can reduce their risk of HIV infection while that support is ongoing is still important.

We did not collect data for men or for women older than 22 years. The risk of infection in older women might have increased in the intervention enumeration areas. However, survey data at 12 month follow-up showed no differences in behavioural outcomes between untreated girls in treatment enumeration areas and the

Panel 2: Research in context

Systematic review

We searched PubMed for full articles, systematic reviews, and meta-analyses published up to July 22, 2011, in any language with the search terms "HIV prevention" and "cash transfer" or "microfinance". Our search identified 17 results. Only one other cluster randomised trial of a structural intervention to prevent HIV in women with biological outcomes was identified. The Intervention with Microfinance for AIDS and Gender Equity (IMAGE) study[14] assessed a structural intervention that combined a microfinance programme with a sex and HIV training curriculum and noted no effect on HIV incidence.

Interpretation

Poor education, poverty, and gender inequalities are postulated to be important determinants of young women's vulnerability to HIV infection. However, to date, no randomised controlled trial of a structural intervention has shown a significant effect on HIV incidence.[16] The Zomba cash transfer programme reduced the prevalence of HIV and HSV-2 infection at 18 month follow-up in school-age girls who were enrolled in school at baseline. These effects are supported by changes in self-reported sexual behaviour. The findings suggest that financially empowering school-age girls and their families can have substantial effects on their sexual and reproductive health.

control group, which suggests that the risk of infection in this group is unlikely to have increased as a result of the intervention.

Undetected misclassification of HSV-2 status could have occurred, since no supplemental testing was done to confirm the results of the HSV-2 rapid tests. However, because counsellors were masked to the participants' intervention status at the time of testing, any misclassification of the test result would be non-differential by trial group and tend to bias results towards the null hypothesis of no difference in HSV-2.

The prevalence of HIV (3·7%) in unmarried women younger than 25 years in southern Malawi[3] was nearly identical to the overall HIV prevalence (3·8%) in the control group. Therefore, our sample of school-aged girls seems to be representative of the population in the study area. A valid question is whether our findings can be generalised to other areas in Malawi or other countries in southern Africa. Zomba district is characterised by high poverty, HIV, and school dropout in young women. Matrilocality is common in the study area, with married couples living with or near the wives' families. Transactional sex was also common in our study: roughly a quarter of participants who were sexually active at baseline reported that they started their relationship with their partner because they "needed his assistance" or "wanted gifts or money". Future studies are needed to assess whether cash transfer programmes can protect girls of this age from acquiring HIV in other settings.

By use of the average household transfer size (US$10 per month) and the high administrative costs of our cash transfer experiment, we calculated that the cost of averting a primary HIV infection is $12 500 in 2009 dollars. However, because intervention effect did not differ by transfer amount, we suspect that the minimum transfer amount of $5 per month would be equally effective. Combination of this amount with a more realistic administrative cost of about 15% of total programme costs for a scaled up cash transfer programme would yield a cost of only $5000 per HIV infection averted.

This study shows that a simple intervention that provided cash to unmarried schoolgirls (and their parents) decreased risky sexual activity and reduced their likelihood of being infected with HIV and HSV-2. Our findings suggest that financially empowering school-aged girls might have beneficial effects on their sexual and reproductive health. Our results indicate that cash transfer programmes could be attractive to policy makers in sub-Saharan Africa when they consider the full array of benefits that they might provide.

Contributors

CTM, BÖ, and SJB oversaw the design of the study and analysed the data. RSG, BÖ, and SJB oversaw the collection of biological data. All authors interpreted the data, prepared the report, and approved the final version.

Conflicts of interest

We declare that we have no conflicts of interest.

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