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Incentivising safe sex: a randomised trial of conditional cash transfers for HIV and sexually transmitted infection prevention in rural Tanzania

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ABSTRACT

Objective: The authors evaluated the use of conditional cash transfers as an HIV and sexually transmitted infection prevention strategy to incentivise safe sex.

Design: An unblinded, individually randomised and controlled trial.

Setting: 10 villages within the Kilombero/Ulanga districts of the Ifakara Health and Demographic Surveillance System in rural south-west Tanzania.

Participants: The authors enrolled 2399 participants, aged 18–30 years, including adult spouses.

Interventions: Participants were randomly assigned to either a control arm (n=1124) or one of two intervention arms: low-value conditional cash transfer (eligible for $10 per testing round, n=660) and high-value conditional cash transfer (eligible for $20 per testing round, n=615). The authors tested participants every 4 months over a 12-month period for the presence of common sexually transmitted infections. In the intervention arms, conditional cash transfer payments were tied to negative sexually transmitted infection test results. Anyone testing positive for a sexually transmitted infection was offered free treatment, and all received counselling.

Main outcome measures: The primary study end point was combined prevalence of the four sexually transmitted infections, which were tested and reported to subjects every 4 months: *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis* and *Mycoplasma genitalium*. The authors also tested for HIV, herpes simplex virus 2 and syphilis at baseline and month 12.

Results: At the end of the 12-month period, for the combined prevalence of any of the four sexually transmitted infections, which were tested and reported every 4 months (*C trachomatis*, *N gonorrhoeae*, *T vaginalis* and *M genitalium*), unadjusted RR for the high-value conditional cash transfer arm compared to controls was 0.80 (95% CI 0.54 to 1.06) and the adjusted RR was 0.73 (95% CI 0.47 to 0.99). Unadjusted RR for the high-value conditional cash transfer arm compared to the low-value conditional cash transfer arm was 0.76 (95% CI 0.49 to 1.03) and the adjusted RR was 0.69 (95% CI 0.45 to 0.92). No harm was reported.

ARTICLE SUMMARY

Article focus

- Existing prevention strategies have had a limited impact on the trajectory of the HIV/AIDS epidemic.
- Conditional cash transfers have been used successfully in a variety of settings to promote activities that are beneficial to the participants, such as school participation or health check-ups for children.
- This trial asks whether conditional cash transfers can be used to prevent people from engaging in activities that are harmful to themselves and others, such as unsafe sex.

Key messages

- We designed and evaluated a novel intervention that tests for risky sexual behaviour repeatedly over short time intervals, reinforcing learning about safer behaviour with cash transfer incentives conditional on testing negative for a set of curable sexually transmitted infections (STIs).
- After 12 months, the results from the adjusted model showed a significant reduction in the combined point prevalence of the four curable STIs tested every 4 months by nucleic acid amplification tests in the group that was eligible for the $20 payments, but no such reduction was found for the group receiving the $10 payments.
- The results suggest that conditional cash transfers used to incentivise safer sexual practices are a potentially promising new tool in HIV and STIs prevention. Additional larger study would be useful to clarify the effect size, to calibrate the size of the incentive and to determine whether the intervention can be delivered cost effectively.

ARTICLE SUMMARY

Strengths and limitations of this study

- This paper reports the results of a novel approach for HIV and STI prevention.
- Our study methodology is rigorous, and the results are likely to advance a global conversation about economic approaches to HIV/STI prevention.
- Our main outcome measure is the combined point prevalence of four STIs repeatedly tested by nucleic acid amplification tests over the course of the year and which have been incontrovertibly linked to risky sexual activity. These biological outcomes, however, cannot be used to infer the relative importance of STI treatment seeking behaviour versus other behaviour changes, such as increased condom use or reducing riskiness of partners.
- The results reported in this study are limited to a 12-month experiment and cannot address the sustainability of improvements in STI outcomes over a longer period, particularly after the conditional cash transfers have been discontinued.

Conclusions: Conditional cash transfers used to incentivise safer sexual practices are a potentially promising new tool in HIV and sexually transmitted infections prevention. Additional larger study would be useful to clarify the effect size, to calibrate the size of the incentive and to determine whether the intervention can be delivered cost effectively.

Trial registration number: NCT00922038 ClinicalTrials.gov.

INTRODUCTION

Innovative solutions for AIDS prevention are desperately needed. The Joint United Nations Programme on HIV/AIDS reported that five people are infected for every two placed on treatment, and, in 2009, approximately 2.8 million people were newly infected.[1] Large-scale behaviour change interventions aimed at promoting safer sexual practices have proven less effective and more unreliable at stemming the tide of the epidemic than hoped.[2 3] It has been far more difficult than was first anticipated to persuade high-risk populations to adopt safer sexual behaviours and practices that serve their longer term interests.

Conditional cash transfer programmes have become an increasingly popular approach for incentivising socially desirable behavioural change.[4] The principle of conditionality—making payments contingent, for example, on a minimal level of schooling attendance or preventive care use—distinguishes conditional cash transfer programmes from more traditional means tested social programmes. The evaluation of conditional cash transfer programmes has shown that they can be effective at raising consumption, education and preventive healthcare,[5] as well as actual health outcomes.[6] Similarly, 'contingency management' approaches have shown important substance abuse reductions by conditioning rewards on negative tests for drug or alcohol use.[7]

In the context of the staggering social, economic and human costs of the AIDS epidemic in sub-Saharan Africa, it is perhaps not as great a leap as it would first appear to apply the logic of conditional cash transfers to the private arena of human sexuality with the aim of incentivising safer sexual practices among high-risk populations. Numerous studies have documented the responsiveness of sexual behaviour to incentives, such as sex workers willing to forego condoms when clients pay extra,[8] and increases in transactional sex in the face of household financial difficulties.[9] Economic theory suggests several pathways through which risky sexual behaviours could be reduced by a conditional cash transfer programme that conditions payment on negative sexually transmitted infections (STIs) tests. Standard theory predicts that the incentives could operate by raising the implicit price of unsafe sex (risking losing the conditional cash transfer) or by bringing the rewards of risk avoidance much closer to the present (eg, a conditional cash transfer within weeks may be more powerful for some people than the spectre of developing AIDS many years in the future) or both. If the conditional cash transfer was sufficiently large, then this higher income could also relieve economic pressures on young women to engage in transactional sex; but even if incentives were small, recent behavioural economics research suggests that regular reminders of this new frame for viewing sexual behaviour could still 'nudge' individuals to overcome inertia and extricate themselves from unduly risky sexual relationships.[10] In Malawi, small financial incentives have already been shown to increase the uptake of HIV testing and counselling.[11] In the only prior study similar to ours, a follow-on Malawi intervention promised a single cash reward in 1 year's time for individuals who remained HIV negative, but this design had no measurable effect on HIV status.[12] By contrast, we used the above theory to design and evaluate a novel intervention that tests for risky sexual behaviour repeatedly over shorter time intervals, reinforcing learning about safer behaviour with conditional cash transfer incentives each time.

METHODS

Trial design

This study is an unblinded, individually randomised and controlled trial. It has three separate arms—a control arm with an allocation ratio of 50% and two intervention arms (low-value conditional cash transfer and high-value conditional cash transfer), with an allocation ratio of 25% each. No important changes to methods were implemented after trial commencement.

Participants

Inclusion criteria consisted of males and females, aged 18–30 years (and spouses starting at age 16 years and potentially older than 30 years), residing in one of 10 study villages within the Kilombero/Ulanga districts of the Ifakara Health and Demographic Surveillance

System[13] in south-west Tanzania. The villages consisted of eight rural villages and two semi-urban neighbourhoods in Ifakara town, with participants evenly distributed across the villages. On average across the 10 villages, approximately 20% of the 18–30 old residents were enrolled in the study. There were three exclusion criteria: being pregnant at the time of registration, having the intention to permanently migrate out of the Ifakara Health and Demographic Surveillance System area within the next year and unwillingness to participate if assigned to the control arm. HIV-positives were eligible for enrolment.

Interventions

The intervention arm was divided into two subarms—a low-value conditional cash transfer arm eligible for up to $30 over the course of the study (10 000 Tanzanian shillings or approximately $10 per testing round) and a high-value conditional cash transfer arm eligible for up to $60 (20 000 Tanzanian shillings or approximately $20 per testing round). Those amounts were determined based on focus-group discussions in neighbouring villages conducted before the intervention started, balancing sufficient incentive levels against concerns about scalability and potential coercion. All participants were tested for STIs at baseline and then every 4 months for 1 year. Participants in the two intervention arms were eligible to receive conditional cash transfer incentive payments if they tested negative for curable STIs at the 4-, 8- and 12-month testing rounds. STIs tested at all these incentivised rounds were *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis* and *Mycoplasma genitalium*, which are transmitted through unprotected sexual contact and therefore serve as a proxy for risky sexual behaviour as well as vulnerability to HIV infection.[14–17]

Individuals in the conditional cash transfer arms were not eligible for the cash award at the 4-, 8- and 12-month testing rounds if they tested positive for any of the following: *C trachomatis*, *N gonorrhoeae* and *T vaginalis*. Those converting from negative at baseline to positive at 12 months for syphilis or herpes simplex virus 2 were also ineligible to receive the 12-month conditional cash transfer. HIV testing was conducted at baseline and month 12, but payments were not conditioned on those results because of local ethical sensitivities. *M genitalium* results did not affect conditional cash transfer eligibility because there is some uncertainty around transmission pathways; however, it was included in the combined prevalence measure used as primary outcome to increase statistical power. Individuals in the intervention arms testing positive for any of the conditioned curable STIs did not receive the conditional cash transfer but were eligible to continue as a study participant in subsequent rounds after having been treated and cured of the infection. Individuals in the control arm were not eligible for conditional cash transfer, but all other study procedures were identical between the control and intervention arms. Anyone testing positive for a STI (regardless of arm) was offered counselling and free STI treatment (for self and partners) through health facilities of the District Ministry of Health serving the research communities. Individual pre-test and post-test counselling was provided to study enrollees at each testing interval, following Tanzania national testing guidelines. In addition, monthly group counselling sessions emphasising relationship skills training adapted from a subset of the Stepping Stones curriculum[18] were also made available to all study participants in all villages but were not mandatory.

Outcomes

The biological markers used in the study were selected both due to their likely prevalence levels in the study population and due to their status within the epidemiological literature as reasonable proxies for risky sexual behaviour. The primary outcome measure, as defined in the study protocol, is the round-specific combined point prevalence of the four STIs that were regularly tested—*C trachomatis*, *N gonorrhoeae*, *T vaginalis* and *M genitalium*—at months 4, 8 and 12. This measure of combined point prevalence was constructed at study design to ensure sufficient power to detect differences in the control and treatment groups in response to the conditional cash transfer intervention. For logistical reasons, *M genitalium* testing was not conducted at baseline. We also tested for HIV, herpes simplex virus 2 and syphilis at baseline and month 12.

All STI testing was conducted by the Ifakara Health Institute microbiology laboratory in Ifakara. All test results were available within 7–10 days and were returned to participants the following week. Ten per cent of all samples, and all positives, were sent to the University of California Chlamydia Laboratory for confirmation analysis (quality control).

Specimens for chlamydia, gonorrhoea, trichomonas and *M genitalium* were collected by a self-administered vaginal swab for women. Men provided a 'first-catch urine' (about 20–30 ml) sample. Specimen collection among women was always observed by a nurse at the testing station. For men, the specialised receptacle used to collect a urine sample was provided only after dropping off personal belongings upon checking into the testing section of the study station. Men were asked to urinate into the study receptacle in the vicinity of the study station. Detection used GenProbe Aptima (GenProbe Inc, San Diego, California, USA) nucleic acid amplification tests.

To test for HIV, herpes simplex virus 2 and syphilis, a single venous blood sample of approximately 5–10 ml was collected from each participant at baseline and month 12. For herpes simplex virus 2, we used the Focus HerpeSelect HSV-2 ELISA IgG assay (Focus Technologies, Cypress, California, USA) to detect serum antibodies. *Treponema pallidum* was identified using rapid plasma reagin with reactive tests confirmed by *T pallidum* particle agglutination assay. Active syphilis was defined as rapid plasma reagin+/*T pallidum* particle agglutination

assay+. For HIV, we used a series of three rapid tests for screening results (SD Bioline HIV-1/2 3.0; Standard Diagnostics, INC., Kyonggi-do, Korea), confirmation of positives (Determine® HIV-1/2; Inverness Medical Japan Co, Ltd, Tokyo, Japan), and tie-breaking (Uni-Gold HIV, Trinity Biotech plc. Bray, Ireland).

Sample size

Early study planning had initially assumed a sample size of 3000, which would have provided improved power for gender subgroup analysis in our main comparisons, but due to logistical fieldwork constraints the recruited sample size was reduced to approximately 2400. We present here the ex-post power calculations at this actual recruited sample size and actual infection rates, based on a comparison of combined STI prevalence rates of 12% between two equal-sized study arms for a single post-treatment measurement of proportions controlling for one baseline measure and assuming a two-sided alternative hypothesis. We calculated that a total sample size of 2400 individuals would be sufficient to provide at least 90% power to detect a one-third intervention-related reduction in STI point prevalence (significant at the 5% level) in both intervention arms combined. This sample size would also retain at least 80% power to detect a reduction in a single intervention arm (eg, the high-value conditional cash transfer arm) compared to the control arm, and if the prevalence was assumed to be as high as 20%, then this power rises to over 90%. Subgroup analysis by gender would not be powered at the 80% level for our main comparison of the high-value conditional cash transfer arm against controls assuming a 12% prevalence level, although it would retain approximately 90% power when comparing the combined arms against the control arm assuming 20% prevalence.

Randomisation

Individual-level randomisation took place at the study station after baseline interview and testing, with participants selecting coloured balls from an opaque bag. The randomisation took place in public view and in two stages with participants first randomly selecting one of four balls to determine their allocation to the intervention or the control arm. In order to study potential peer-effects, in randomly selected subvillages, the probably of selection in the intervention arm was 75% (three balls out of four) and in the other subvillages, it was 25% (one ball out of four); based on the distribution of participants across subvillages, we thus expected 48% of the overall sample to be randomised into the control arm. Participants randomised into the intervention arm were further invited to choose one of two balls from a second bag determining in which of the two intervention arms (low-value conditional cash transfers and high-value conditional cash transfers) they would be allocated. These highly transparent procedures were deemed necessary for acceptability of randomisation in a population with limited formal education. Participants were not blinded to arm assignment since awareness of their eligibility for the conditional cash transfer was a critical component of the intervention.

Spousal pairs were assigned the same intervention arm and the protocol prescribed for randomisation to occur after both spouses had enrolled.

Statistical methods

Each individual was coded as per their initial randomised assignment as per an intent-to-treat design. However, individuals who were not present at any given round were treated as missing and dropped from the analysis for that round due to lack of outcome data. We report sample means at baseline to verify the balance across the three study arms. Unadjusted outcomes at the three follow-up rounds are reported using RRs, that is, the probability of being positive for any STI in the intervention arm, divided by the probability of being positive for any STI in the control arm. RRs are calculated from logistic regressions using the *margins* and *nlcom* post-estimation commands in the *Stata V.12* statistical software package. We further report adjusted outcomes using RRs to account for residual variation across arms after randomisation. Adjustments have been made for standard socioeconomic variables, such as gender, education, age, marital status, income, socioeconomic status, subvillage and baseline STI status. Age and income are continuous variables, while the other adjustment variables are categorical. We cluster SEs both at the household and at subvillage levels, accounting for the possible correlation within couples and the variation in selection probability at that subvillage level. We present a subgroup analysis by gender. We used Stata V.12.1 (Stata Corp) for statistical analysis.

RESULTS

Participant flow

A total of 5370 individuals were randomly selected from the Ifakara Health and Demographic Surveillance System sample (figure 1). Eight hundred and sixty-four (16.1%) of those individuals were not found, six (0.1%) had died and 344 (6.4%) had migrated. Fieldworkers assessed for eligibility 4156 individuals: 173 (4.2%) did not meet the inclusion criteria, among them 35 (0.8%) were not in the study age range and 138 women (3.3%) were currently pregnant. Of those eligible, 133 (3.3%) explicitly refused to participate in the study and 168 (4.2%) declined for other reasons. All others (3682) were given an invitation to come to a study station the following week: 2409 (65.4%) registered for the study and were randomised into one of the three study arms, while 1273 did not come to the study station for registration.

Of the 2409 registered participants, 1124 (46.7%) were randomly allocated to the control arm. Among the participants, 1285 were randomly selected, in a first stage, to one of the two conditional cash transfer arms: 615 (25.5%) were randomly assigned in the high-value

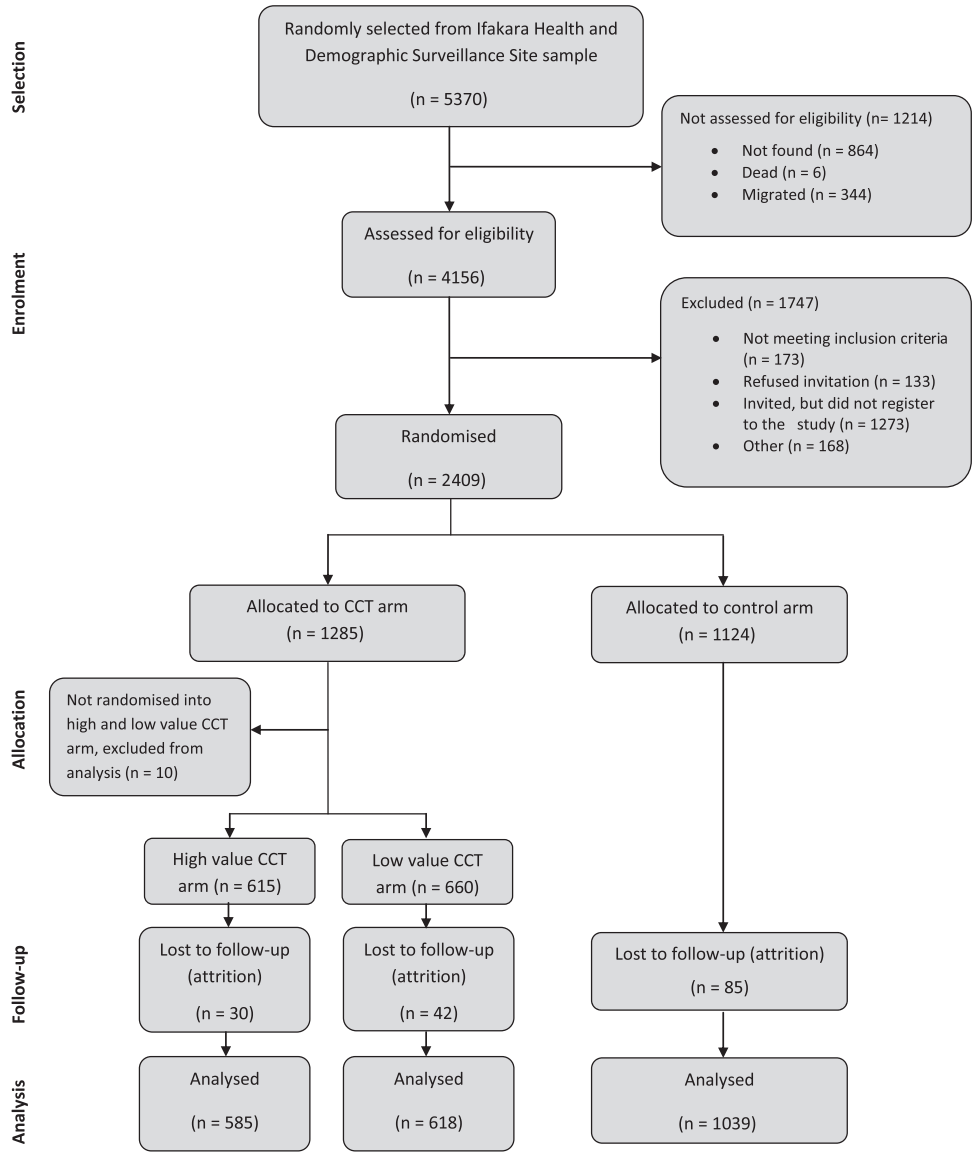

Figure 1 Participant flow diagram.

conditional cash transfer arm and 660 (27.4%) in the low-value conditional cash transfer arm. Ten (0.4%) individuals assigned to the intervention arms were intentionally dropped from the analysis since they failed to be further randomised in one of the two subarms. In the control arm, 967 were tested and interviewed at round 2 (attrition 14%), 983 (attrition 12.5%) at round 3 and 1039 (attrition 7.6%) at round 4. In the high-value conditional cash transfer arm, 570 were tested and interviewed at round 2 (attrition 7.3%), 567 (attrition 7.8%) at round 3 and 585 (attrition 4.9%) at round 4. In the low-value conditional cash transfer arm, 568 were tested and interviewed at round 2 (attrition 13.9%), 567 (attrition 14.1%) at round 3 and 618 (attrition 6.4%) at round 4. Overall, attrition was lower at round 4 because the field team made extensive additional effort to contact and interview attriters. Symptomatic individuals in all study arms were particularly encouraged to come to the study station in order to receive free STI treatment. Attrition was not predicted by any of the baseline STI results, except that HIV-positive individuals at baseline were more likely to be lost to follow-up, despite the fact the participants were clearly told that HIV status would not affect eligibility for conditional cash transfers.

Recruitment

Recruitment and baseline data collection took place from 10 February to 9 April 2009. The second, third and fourth rounds of interviews and testing took place from 9 June to 15 August 2009, 29 September to 5 December 2009 and 16 February to 1 May 2010, respectively. The conditional cash transfer intervention was stopped after 1 year, following the protocol.

Process

The intervention was well accepted and accessed by the study participants as indicated in the participant flow and the low attrition numbers. Furthermore, study participants randomised into the conditional cash transfer arms declared that the financial incentives motivated them to modify their behaviour. In the high-value conditional cash transfer arm, 317 (59.0%)

declared that the money motivated them 'very much' to change their behaviour and 67 (12.5%) stated that it motivated them 'somewhat'. In the low-value conditional cash transfer arm, those numbers are 194 (37.4%) for 'very much' and 107 (20.6%) for 'somewhat'.

Baseline data

Table 1 describes the baseline characteristics of the participants by study arm. The prevalence of the six STIs tested at baseline was distributed similarly across arms. Participants were also similar according to gender and education. However, individuals in the two intervention arms had slightly lower self-reported socioeconomic status, and individuals in the low-value conditional cash transfer arm also had a higher income.

We verified that there was no deviation from protocol that could have led to differential secondary spousal enrolment across arms: 604 out of the 2399 participants were spouses who joined the study after their spouse was initially invited. They were distributed as follows: 279 out of 1124 (24.8%) in the control arm, 156 (25.4%) out of 615 in the high-value cash arm and 169 (25.6%) out of 660 in the low-value cash arm. Tests for statistical differences with the control arm yielded p values of 0.673 for the high-value conditional cash transfer arm and 0.742 for the low-value conditional cash transfer arm, so differences across the three study arms in the percentage of spouses joining the study are minimal and not statistically significant.

Numbers analysed

Except for the 10 (0.4%) individuals who failed to be assigned to either the high or low-value conditional cash transfer arm, all participants tested and interviewed at the respective rounds were included in the analysis (refer to the sample sizes in tables 1 and 2). The reductions in sample size from the unadjusted (table 2) to the adjusted analysis (table 3) were from 2105 to 2077 at round 2, from 2117 to 2092 at round 3 and from 2242 to 2211 at round 4 due to missing data on covariates in the logistic regression model (table 2 results are similar when using the smaller samples from table 3).

Outcomes and estimation

Table 2 presents the unadjusted RR ratios compared to the control group. At months 4, 8 and 12 when the outcome is the combined point prevalence of the four curable STIs tested every 4 months by nucleic acid amplification tests (columns 1–3), the RRs are not statistically different at the 5% significance level. At month 12, the number of positives was 57 (9.7%) in the high-value conditional cash transfer arm, while it was 79 (12.8%) in the low-value conditional cash transfer arm and 126 (12.1%) in the control group. At month 12, this unadjusted analysis estimated a reduction in the RR of those four curable STIs for the high-value conditional cash transfer arm of 20% (95% CI 6% increase to 46% reduction). The RRs were also not statistically different at the 5% significance level in column 4 for the combination of syphilis prevalence and new cases of HIV and herpes simplex virus 2. Those three STIs were detected by serology performed only at baseline and round 4. For the combined point prevalence of chlamydia, gonorrhoea, trichomonas, *M genitalium* at month 12, the unadjusted RRs are not statistically different than 1 at 5% significance level when men and women are considered separately (columns 5 and 6). At month 12, for the combined point prevalence of the four curable

Table 1 Summary statistics at baseline, by arm

Variables	(1) Control	(2) High-value CCT	(3) Low-value CCT
Female	561 (49.9%)	314 (51.1%)	329 (49.9%)
Age	27.2 (5.6)	27.6 (5.4)	27.6 (5.7)
Education			
None	139 (12.4%)	70 (11.4%)	79 (12.0%)
Primary	863 (76.8%)	482 (78.4%)	660 (78.3%)
Secondary	122 (10.9%)	63 (10.2%)	64 (9.7%)
Married	842 (75.0%)	474 (77.1%)	476 (72.7%)
Low SES	582 (51.8%)	344 (55.9%)	377 (57.2%)
Yearly income	239 311 (425 091)	257 017 (531 370)	283 218 (534 399)
Chlamydia	21 (1.9%)	15 (2.4%)	16 (2.4%)
Gonorrhoea	8 (0.7%)	8 (1.3%)	6 (0.9%)
Trichomonas	130 (11.6%)	88 (14.3%)	79 (12.0%)
Herpes simplex virus 2	380 (33.9%)	226 (36.8%)	225 (34.2%)
Syphilis	17 (1.5%)	8 (1.3%)	15 (2.3%)
HIV	41 (3.7%)	17 (2.8%)	27 (4.1%)
N	1124	615	660

Data are represented in means (SD) or numbers (%).
Yearly income in Tanzanian Shillings (Tsh).
At baseline, 1000 Tsh = approximately 1US$.
Low SES corresponds to the lowest two ranks on a self-reported socioeconomic status scale from 1 to 7.
CCT, conditional cash transfer.

Table 2 Unadjusted outcomes: RR from logistic regression

	(1) Month 4 combined prevalence of four STIs tested by NAAT*	(2) Month 8 combined prevalence of four STIs tested by NAAT*	(3) Month 12 combined prevalence of four STIs tested by NAAT*	(4) Month 12 combined measure for three STIs detected by serology at baseline and month 12†	(5) Month 12 combined prevalence of four STIs tested by NAAT* men only	(6) Month 12 combined prevalence of four STIs tested by NAAT* women only
High-value CCT (95% CI)	1.06 (0.74 to 1.38)	0.86 (0.60 to 1.12)	0.80 (0.54 to 1.06)	1.09 (0.76 to 1.43)	0.70 (0.34 to 1.07)	0.85 (0.55 to 1.15)
Low-value CCT (95% CI)	0.97 (0.66 to 1.28)	0.80 (0.55 to 1.04)	1.05 (0.75 to 1.35)	1.03 (0.71 to 1.35)	1.25 (0.73 to 1.77)	0.94 (0.62 to 1.25)
Number positive	246 (11.7%)	260 (12.3%)	262 (11.7%)	232 (10.4%)	99 (9.0%)	163 (14.3%)
N	2105	2117	2242	2241	1105	1137
Number positives by study arm						
Control arm	112 (11.6%)	133 (13.5%)	126 (12.1%)	104 (10.0%)	47 (9.0%)	79 (15.2%)
High-value CCT	70 (12.3%)	66 (11.6%)	57 (9.7%)	64 (11.0%)	18 (6.4%)	39 (12.9%)
Low-value CCT	64 (11.3%)	61 (10.8%)	79 (12.8%)	64 (10.4%)	34 (11.3%)	45 (14.2%)

Robust SEs in parentheses, clustered at both the household and the subvillage levels.
The reference group for the computation of the RRs is the control group.
*Chlamydia, gonorrhoea, trichomonas, *Mycoplasma genitalium*.
†HIV, herpes simplex virus 2, syphilis.
CCT, conditional cash transfer; NAAT, nucleic acid amplification test; STI, sexually transmitted infection.

STIs tested by nucleic acid amplification tests, unadjusted RR for the high-value conditional cash transfer arm compared to the low-value conditional cash transfer arm was 0.76 (95% CI 0.49 to 1.03) and was 0.56 (95% CI 0.26 to 0.87) for men only.

Table 3 presents results from adjusted regressions. Adjustments have been made for gender, education, age, marital status, income, socioeconomic status, subvillage and baseline STI status. At months 4 and 8 (columns 1 and 2), the combined prevalence of the four STIs tested by nucleic acid amplification tests is shown to have RRs lower than 1 for the two conditional cash transfer arms compared to the control arm, but not significantly so. However, at month 12 (column 3) for the combined prevalence of the STIs tested by nucleic acid amplification tests, the adjusted model estimated a 27% reduction in the RRs for the high-value conditional cash transfer arm compared to the control arm (95% CI 1% to 53% reduction), while the RR is not statistically different from 1 for the low-value conditional cash transfer arm. At month 12, for the three STIs detected by serology (without having been tested at months 4 and 8), the RR for the low-value conditional cash transfer arm is 0.82 (column 4) but is not significantly lower than the control arm (95% CI 0.60 to 1.03). In a subgroup analysis by gender (columns 5 and 6), for the four STIs tested by nucleic acid amplification tests, the RRs for the high-value conditional cash transfer arm are 0.68 for men and 0.76 for women. Those two RRs are not significantly different from each other (as confirmed by test of interaction between gender and arm, where an interaction term for woman was not significant for either conditional cash transfer arm (p values 0.648 for high-value cash transfer arm and 0.391 for low-value cash transfer arm) and is not significantly lower than 1 at the 5% level. At month 12, for the combined point prevalence of the four STIs tested by nucleic acid amplification tests, adjusted RR for the high-value conditional cash transfer arm compared to the low-value conditional cash transfer arm was 0.69 (95% CI 0.45 to 0.92) and was 0.52 (95% CI 0.23 to 0.80) for men only.

DISCUSSION

After 12 months, the adjusted results showed a significant reduction in the combined point prevalence of the four curable STIs tested every 4 months by nucleic acid amplification tests in the group that was eligible for the $20 quarterly payments, but no such reduction was found for the group receiving the $10 quarterly payments. Such results were not found at earlier rounds nor for unadjusted results. Furthermore, the impact of the conditional cash transfers did not differ between men and women.

Limitation

Our main outcome measure is the combined point prevalence of four STIs repeatedly tested by nucleic acid amplification tests over the course of the year and which

Table 3 Adjusted outcomes: RR from logistic regression

	(1) Month 4 combined prevalence of four STIs tested by NAAT*	(2) Month 8 combined prevalence of four STIs tested by NAAT*	(3) Month 12 combined prevalence of four STIs tested by NAAT*	(4) Month 12 combined measure for three STIs detected by serology at baseline and month 12†	(5) Month 12 combined prevalence of four STIs tested by NAAT* men only	(6) Month 12 combined prevalence of four STIs tested by NAAT* women only
High-value CCT (95% CI)	0.92 (0.62 to 1.20)	0.90 (0.61 to 1.18)	0.73 (0.47 to 0.99)	1.03 (0.74 to 1.32)	0.68 (0.25 to 1.10)	0.76 (0.46 to 1.07)
Low-value CCT (95% CI)	0.94 (0.63 to 1.26)	0.85 (0.58 to 1.13)	1.06 (0.75 to 1.38)	0.82 (0.60 to 1.03)	1.31 (0.73 to 1.89)	0.98 (0.63 to 1.33)
Number positive	242 (11.7%)	258 (12.3%)	257 (11.6%)	227 (10.3%)	98 (9.0%)	159 (14.2%)
N	2077	2092	2211	2210	1093	1118

Results adjusted for gender, education, age, marital status, income, socioeconomic status, subvillage and baseline STIs.
Robust SEs in parentheses, clustered at both the household and the subvillage levels.
The reference group for the computation of the RRs is the control group.
*Chlamydia, gonorrhoea, trichomonas, *Mycoplasma genitalium*.
†HIV, herpes simplex virus 2, syphilis.
CCT, conditional cash transfer; NAAT, nucleic acid amplification test; STI, sexually transmitted infection.

have been incontrovertibly linked to risky sexual activity. These biological outcomes, however, cannot be used to infer the relative importance of STI treatment seeking behaviour versus other behaviour changes, such as increased condom use or reducing riskiness of partners. Furthermore, the lack of a clear result on the combined measure for the three STIs that were detected by serology only at baseline and month 12 (this measure primarily reflects herpes simplex virus 2 incidence, as HIV and syphilis prevalence were somewhat lower) is puzzling and merits further study. The contrasting result with the impact of the high-value conditional cash transfers on the four curable STIs that were tested by nucleic acid amplification tests could point to the importance of treatment seeking behaviour rather than safer sexual practices. However, the interpretation of herpes simplex virus 2 results is complicated by the fact that most transmission occurs via asymptomatic shedding by partners who may be otherwise low risk,[19] as well as the fact that it can be transmitted even in the context of appropriate condom use.[20] Furthermore, this study was not powered to directly examine HIV conversion, thus implications for HIV prevention remain speculative.

In order to study potential peer-effects, in randomly selected subvillages, the probably of selection in the intervention arm was 75% and in the other subvillages, it was 25%. This might have led to baseline imbalances. For this reason, we included subvillage indicator variables in the adjusted models. This might explain some of the differences between the results from the unadjusted and the adjusted models.

Finally, the results reported in this study are limited to a 12-month experiment and cannot address the sustainability of improvements in STI outcomes over a longer period, particularly after the conditional cash transfers have been discontinued. Nor can they address the possibility of adverse consequences to the extent that extrinsic incentives may reduce long-term intrinsic motivation to engage in safe behaviours after incentives are withdrawn. To address these questions, we will follow-up with study participants 1 year following the end of the intervention study, in the Spring of 2011, to assess whether improved outcomes have been sustained, or reversed, in the absence of a positive feedback mechanism in the form of STI testing and conditional cash transfers.

Generalisability

While these study results are important in showing that the idea of using financial incentives can be a useful tool for preventing HIV and STI transmission, it remains an initial study on a limited scale. Even though the study site is fairly representative of rural and small town environments in sub-Saharan Africa, this approach would need to be replicated elsewhere and implemented on a larger scale (in permutations requiring less administrative and laboratory capacity) before it could be concluded that such conditional cash transfer

programmes offer an efficient, scalable and sustainable HIV prevention strategy.

Interpretation

The results indicate that conditional cash transfers based on negative results of periodic screenings for incident STIs—an objectively measured marker for risky sexual behaviour—are a potentially useful tool for STI and possibly HIV prevention. The extraordinarily high social and economic cost of the current HIV and AIDS crisis suggests that prevention can be far cheaper than treatment, thus motivating the continued search for innovative and effective new prevention approaches, such as conditional cash transfers or other financial incentives.

The absence of significant impacts at rounds 2 (month 4) and 3 (month 8) suggests that the impact of the conditional cash transfer may take time to materialise, perhaps because it is not easy to extricate oneself from complicated sexual relationships, or perhaps because participants needed time to become accustomed to (and trust) the incentive mechanism. The comparison between the impacts of the conditional cash transfer intervention in the high-value conditional cash transfer arm to that in the low-value conditional cash transfer arm permits us to better understand at which threshold conditional cash transfers can be effective as an HIV and STI prevention tool. While the results showed a significant reduction in STI incidence in the arm that was eligible for the $20 conditional cash transfers every 4 months or up to $60 over 12 months, no such reduction was found for the arm receiving the $10 conditional cash transfers every 4 months or up to $30 over 12 months. This distinction must be interpreted with caution though because assignments were not masked, hence individuals in the low-value conditional cash transfer arm could have behaved differently than if they were to receive the same incentive in the absence of a higher conditional cash transfer arm. Both of these amounts represent a meaningful proportion of household income in a country where gross domestic product per capita was $440 in 2008, and particularly among our study participants who had mean individual annual earnings of approximately $250.

OTHER INFORMATION

Registration

This randomised control trial is registered at ClinicalTrials.gov, study identifier # NCT00922038.

Protocol

The study protocol was initially approved by the University of California; Berkeley's Institutional Review Board (Committee for Protection of Human Subjects) effective 17 December 2008; approval has been updated numerous times since to reflect protocol amendments, with the latest approval effective 11 October 2011. The Ifakara Health Institute Institutional Review Board initially approved the study on 24 July 2008. The latest amended approval is from 11 February 2010. Tanzania's National Institute for Medical Research approved the study 5 February 2009.

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Competing interests None.

Patient consent The article does not contain personal medical information about an identifiable living individual.

Contributors DdW, WHD, RN and CAM made contributions to each part of the project, planned and designed the study, conducted the analysis, interpreted the findings and contributed to the manuscript. The Ifakara Health Institute was the main implementing agency for the project: BJ and FA managed the Ifakara laboratory testing, AM led field operations, MAM facilitated operations, KS programmed the study systems and together with RA managed the database and SM was responsible for outreach to participating communities and health clinics. EG contributed to data analysis, LP conducted in-depth interviews and ZI was project director onsite in Tanzania. From University of California, San Francisco, JM and JS set up the Ifakara Health Institute laboratory, developed laboratory protocols and were responsible for quality control. SK, JJ and EM as senior investigators have contributed throughout the project and are leading subanalyses linked to the main study in their respective fields of expertise. All authors, external and internal, had full access to all the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis. DdW and WHD are the guarantors of the study.

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