

Effect of a structural intervention for the prevention of intimate-partner violence and HIV in rural South Africa: a cluster randomised trial



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Summary

Background HIV infection and intimate-partner violence share a common risk environment in much of southern Africa. The aim of the Intervention with Microfinance for AIDS and Gender Equity (IMAGE) study was to assess a structural intervention that combined a microfinance programme with a gender and HIV training curriculum.

Methods Villages in the rural Limpopo province of South Africa were pair-matched and randomly allocated to receive the intervention at study onset (intervention group, n=4) or 3 years later (comparison group, n=4). Loans were provided to poor women who enrolled in the intervention group. A participatory learning and action curriculum was integrated into loan meetings, which took place every 2 weeks. Both arms of the trial were divided into three groups: direct programme participants or matched controls (cohort one), randomly selected 14–35-year-old household co-residents (cohort two), and randomly selected community members (cohort three). Primary outcomes were experience of intimate-partner violence—either physical or sexual violence—in the past 12 months by a spouse or other sexual intimate (cohort one), unprotected sexual intercourse at last occurrence with a non-spousal partner in the past 12 months (cohorts two and three), and HIV incidence (cohort three). Analyses were done on a per-protocol basis. This trial is registered with ClinicalTrials.gov, number NCT00242957.

Findings In cohort one, experience of intimate-partner violence was reduced by 55% (adjusted risk ratio 0·45, 95% CI 0·23–0·91; adjusted risk difference –7·3%, –16·2 to 1·5). The intervention did not affect the rate of unprotected sexual intercourse with a non-spousal partner in cohort two (1·02, 0·85–1·23), and there was no effect on the rate of unprotected sexual intercourse at last occurrence with a non-spousal partner (0·89, 0·66–1·19) or HIV incidence (1·06, 0·66–1·69) in cohort three.

Interpretation A combined microfinance and training intervention can lead to reductions in levels of intimate-partner violence in programme participants. Social and economic development interventions have the potential to alter risk environments for HIV and intimate-partner violence in southern Africa.

Introduction

HIV/AIDS and intimate-partner violence are major public-health challenges in southern Africa. In South Africa alone, almost 30% of women who visited public antenatal clinics in 2004 were HIV positive.¹ National prevalence surveys suggest that women and girls make up 55% of all infections.² Furthermore, one in four South African women report having been in an abusive relationship,³ and violence has been identified as an independent risk factor for HIV infection.⁴

Underdevelopment, lack of economic opportunities for both sexes, and entrenched inequalities in the distribution of power, resources, and responsibilities between men and women (gender inequalities) create a risk environment that supports high levels of both HIV infection and intimate-partner violence.^{5–12} Structural interventions seek to affect risk environments by altering the context in which ill-health occurs.¹³ Such interventions address upstream determinants of health and have the potential to affect multiple endpoints.¹⁴ Although structural interventions are increasingly regarded to be important in the prevention of HIV infection and intimate-partner

violence, few have been rigorously assessed in developing countries.^{15–17}

Microfinance is a development method that provides loans to poor households for income generation. With nearly 100 million clients worldwide,¹⁸ such programmes have the potential to reduce poverty, empower participants, and improve health.^{19,20} Furthermore, the benefits of microfinance can diffuse to non-participants who reside in programme areas, lending support to the wider adoption of health practices.²¹

The Intervention with Microfinance for AIDS and Gender Equity (IMAGE) study combined a poverty-focused microfinance initiative that targeted the poorest women in communities with a participatory curriculum of gender and HIV education. Our aim was to determine whether the involvement of women in the programme would improve household economic wellbeing, social capital, and empowerment and thus reduce vulnerability to intimate-partner violence. We also aimed to assess whether such measures could raise levels of communication and collective action on HIV and gender issues within communities, and reduce the vulnerability of 14–35-year-old household and village residents to HIV infection.

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Methods

Study population

The study was done between June, 2001, and March, 2005, in South Africa's rural Limpopo province. Poverty remains widespread in the area,²² and unemployment rates exceed 40%.²³ There are high levels of labour migration, with 60% of adult men and 25% of women residing away from home for more than 6 months every year.²⁴

The number of villages included in the study was determined by the operational feasibility of delivering the intervention over a wide geographical area, the time required for cohort recruitment and follow-up, the need to enrol all eligible households in a village before expanding, and ethical concerns about withholding participation from comparison villages.

Eight villages were pair-matched on estimated size and accessibility, and one village from every pair was randomly allocated to receive the intervention. Randomisation was done at a meeting of the teams that assessed and delivered the intervention. Within every matched pair of villages, one village name was drawn blindly and assigned to the intervention group. Before the study, no village had access to microfinance. Health workers in government clinics that served all villages received training in HIV testing, care, and support before the study.

Quantitative data were gathered from three cohorts within intervention villages—women enrolled in the IMAGE programme (cohort one), household co-residents aged 14–35 years (cohort two), and a random sample of community residents aged 14–35 years (cohort three). Individuals were also recruited for the corresponding cohorts in the comparison villages. Eligibility criteria and methods of selection are shown in table 1. Recruitment

to the first two cohorts occurred during a 15-month period, with matched controls recruited during the same period. Interviews were generally done after programme enrolment but before loan disbursement. Follow-up interviews were done about 2 years later. Interviews for the third cohort were done at the beginning and end of the 3-year study period.

The study design was approved by ethical review committees at the University of the Witwatersrand (South Africa) and the London School of Hygiene and Tropical Medicine (UK). All participating individuals provided informed consent. A two-stage witnessed oral consent process was used—the first for the questionnaire and the second for HIV testing, where applicable. Permission to do the study was also sought from leadership structures in every village. A community liaison board was established to provide feedback on study progress and results. The intervention was administered in comparison communities on study completion.

Procedures

Precision estimates for measures of effect for primary outcome variables were calculated on the basis of projected sample size and for a range of values of outcome prevalence, magnitude of effect, and inter-cluster variance.²⁵ Briefly, these estimates were calculated on the basis of the projected sample size and for a range of values of outcome prevalence, magnitude of effect, and inter-cluster variance.²⁵ From the outset, we recognised that the study would have wide CI that would be unlikely to exclude unity. A randomised, controlled design, with multiple intervention and control communities, was used to generate unbiased effect estimates, which represents a substantial advance over previous assessments of structural interventions and microfinance

	Eligibility criteria		Number eligible	Follow-up criteria	
	Intervention villages	Comparison villages		Period	Criteria
Cohort one	Women who applied for loan	Age, sex, and village pair-matched controls. The sampling strategy was as follows: households from the pair-matched village that would have been eligible for the Small Enterprise Foundation if available were randomly sampled from the village list by use of a computerised household database until a household that contained an age and sex matched control was identified	860	2 years	All individuals eligible at baseline
Cohort two*	14–35-year-old individuals of either sex listed as currently sleeping in the household of loan applicants (de-facto residents)	14–35-year-old individuals of either sex listed as currently sleeping in the same household of control women	1835	2 years	All individuals successfully interviewed at baseline
Cohort three*	14–35-year-old individuals of either sex listed as resident in randomly selected households in intervention communities (de-jure residents)	14–35-year-old individuals of either sex listed as being a resident in randomly selected households in comparison communities. Households were randomly selected with a computerised household database	3881	3 years	All individuals eligible at baseline

*To maximise levels of exposure to the intervention, young people were eligible for follow-up in cohort two only if they were currently sleeping in the home and successfully interviewed at baseline. Individuals enrolled in cohort one who were aged less than 35 years were also recruited to cohort two. Individuals were eligible for follow-up in cohort three if they were residents of the household (but not necessarily sleeping there), irrespective of whether successfully interviewed at baseline.

Table 1: Eligibility and follow-up criteria

programmes. The study was also designed to assess both the consistency and congruency of observed changes in structural-level pathway variables and health outcomes, which are critical in interpreting the plausibility of intervention effects.²⁶

Key features of the IMAGE intervention are shown in the panel and described elsewhere.²⁷ Microfinance services were implemented by the Small Enterprise Foundation (SEF; Tzaneen, South Africa), which has more than 12 years' experience and 30 000 active clients. Their client base was exclusively women. SEF actively targets the poorest individuals, and about half the households in the study area were eligible to receive loans on the basis of SEF's wealth ranking criteria. Loans were administered for the development of income-generating activities with a group lending model. Businesses were run by individual women, but groups of five women guaranteed one another's loans. Group members repaid together to receive further loans.²⁸ One loan centre consisted of about 40 women (eight groups of five), who met every 2 weeks.

On the basis of participatory learning and action principles, a 12–15-month training curriculum called Sisters for Life (SFL) was implemented during loan centre meetings. SFL had two phases. Phase one consisted of ten 1-hour training sessions, and covered topics including gender roles, cultural beliefs, relationships, communication, intimate-partner violence, and HIV, and aimed to strengthen communication skills, critical thinking, and leadership. Since group-based learning can foster solidarity and collective action,²⁹ phase two encouraged wider community mobilisation to engage both young people and men in the intervention communities. Key women were selected by their centres for a further week of leadership training and subsequently worked with their centres to mobilise around priority issues including HIV and intimate-partner violence. SFL began once sufficient members were recruited to a loan centre (generally after 3–6 months) and was run in parallel with the microfinance intervention by a separate training team.³⁰ A qualitative research programme monitored delivery of the intervention. Process data were gathered through attendance registers, focus groups, financial monitoring systems, and questions on intervention acceptability.

Data were gathered by trained female facilitators through face-to-face structured interviews. Facilitators received 4 weeks of training, including technical, ethical, and safety considerations in doing research on sexual behaviour, HIV, and intimate-partner violence.³¹ Interviews were done in a safe location chosen by the respondent, with discussion of sensitive topics suspended when interruptions could not be avoided. Interviews concluded by providing local information on HIV counselling and additional support services.

Questionnaire design and outcome indicators were guided by postulated pathways of change and established

best practices, and further refined through local piloting and the use of qualitative data. Table 2 lists predefined primary and secondary indicators in order of postulated likelihood of change. Primary outcomes were distal, health-related endpoints: experience of intimate-partner violence—either physical or sexual violence—in the past year by a spouse or other sexual intimate (cohort one), unprotected sexual intercourse at last occurrence with a non-spousal partner in the past 12 months (cohorts two and three), and HIV incidence (cohort three). Secondary outcomes were defined before comparative analysis. The selection of such endpoints was guided by the distribution of indicators within the population as well as through qualitative data indicative of the local risk environment for HIV and intimate-partner violence. Thus, in cohort one, indicators of household economic wellbeing, social capital, and gender equity were obtained, whereas in

Panel: Intervention components and key features

Poverty-focused microfinance

Microfinance processes facilitated by one field worker in every village

- Identification of the poorest households with participatory wealth ranking
- Recruitment and group formation for credit guarantee and support (one group consists of five women)
- Individual borrowing and repayment of loans over 10 or 20 week cycles
- Centre meetings every 2 weeks (one centre consists of around 40 women in eight groups)
- Continuing business assessment and monitoring of effect

Sisters for Life gender and HIV training programme²⁷

Sisters for Life facilitated by a team of trainers working in all villages.

Phase 1: Structured training

Ten sessions done within centre meetings every 2 weeks (for about 6 months)

- Introductions
- Reflecting on culture
- Gender roles
- Women's work
- Our bodies, ourselves
- Domestic violence
- Gender and HIV
- Knowledge is power
- Empowering change
- Way forward

Phase 2: Community mobilisation

- Election of natural leaders from within centres (up to five per centre)
- External training for natural leaders
- Development of centre-based action plans responding to local priority issues
- 6–9 months of continued facilitation by training team

Indicator		Number of items for composite indices	Expected direction of change due to intervention
Cohort one (direct programme participants or matched controls)†			
Household economic wellbeing	Estimated value of selected household assets >2000 South African rand	9	Increase
	Membership of a savings cooperative (<i>stokvel</i>)	NA	Increase
	Greater food security	2	Increase
	Per person expenditure on clothing or shoes >200 South African rand per year‡	NA	Increase
	Attending school (among household members aged 10–19 years at baseline)	NA	Increase
Social capital	More participation in social groups	18	Increase
	Taken part in collective action	2	Increase
	Greater perception of community support in a time of crisis	4	Increase
	Belief that the community would work together toward common goals	3	Increase
Gender equity	More positive attitude to communal ownership	NA	Increase
	Empowerment		
	More selfconfidence‡	2	Increase
	Greater challenge of established gender roles	6	Increase
	Communication with intimate partner about sexual matters in past 12 months‡	NA	Increase
	Communication with household members about sexual matters in past 12 months‡	3	Increase
Vulnerability to violence	More progressive attitudes to intimate-partner violence‡	8	Increase
	Controlling behaviour by intimate partner in past 12 months§	4	Decrease
	Experience of intimate-partner violence in past 12 months§	4	Decrease
Cohort two (14–35-year-old household co-residents)			
HIV awareness	Communication with household members about sexual matters in past 12 months	NA	Increase
	Comfortable discussing sex/sexuality issues at home	NA	Increase
	Knowledge that a healthy looking person can be HIV positive	NA	Increase
	Having had an HIV test	NA	Increase
	Participation in collective action against HIV/AIDS	NA	Increase
Sexual behaviour	New sexual debut¶	NA	Decrease
	More than one sexual partner in past 12 months	2	Decrease
	Unprotected sexual intercourse at last occurrence with a non-spousal partner in past 12 months	2	Decrease
Cohort three (randomly selected community members)			
HIV awareness	Correct identification that a healthy looking person can be HIV positive	NA	Increase
	Having had an HIV test	NA	Increase
Sexual behaviour	New sexual debut¶	NA	Decrease
	More than one sexual partner in past 12 months	2	Decrease
	Unprotected sexual intercourse at last occurrence with a non-spousal partner in past 12 months	2	Decrease
HIV incidence	HIV seroconversion in individuals who were HIV negative at baseline¶	NA	Decrease

NA=not applicable. *Details of questionnaire items and reliability analyses for composite indices are in the webappendix. Items in bold are primary outcome measures in the study protocol. †In cohort one, data about variables relating to partners were restricted to women who reported an intimate partner during the previous 12 months. Outcome measures were prevalence measures estimated in all cohort members at both baseline and follow-up except: ‡data not obtained at baseline, §data gathered on married/living-as-married individuals at baseline and all individuals reporting an intimate partner in the previous 12 months at follow-up, ¶outcome measure was a cumulative risk measure in those negative at baseline.

Table 2: Outcome measures*

cohorts two and three, secondary indicators related to HIV awareness, access to testing, and sexual behaviour. Details of questionnaire items are available in the webappendix and webtables 1 and 2. For the main analysis, all outcome variables were coded to be binary at the individual level, requiring the application of cutoff

values in some cases. Where outcome variables combined data from several questions to measure an underlying construct, reliability coefficients were high (webappendix). Sensitivity analysis confirmed that conclusions were robust to whether data were used in continuous form or if different cutoff values applied.

See Online for webappendix and webtables 1 and 2

Participants aged 14–35 years were asked to provide an oral fluid specimen for HIV testing at baseline and at follow-up. Samples were obtained with the OraSure collection device (UCB group, Hoeilaart, Belgium) and analysed with the Vironostika HIV Uni-Form II assay (bioMerieux, Lyon, France). Analysis was blinded to the village of origin. Data from one interviewer raised quality concerns and were excluded from the analysis ($n=67$). Additionally, some samples gathered at baseline were stored for longer than recommended by the manufacturer before analysis ($n=448$). Sensitivity analysis showed that the inclusion of these samples did not affect the estimate of effect and they were retained in the main analysis.

Statistical analysis

Data were entered into a Microsoft Access database containing range and logic checks. Statistical analysis was done with Stata version 9.

Crude measures of effect with 95% CI were calculated, comparing the intervention group with the comparison group (prevalence or risk ratios). Calculations were done by entering the log of village level summaries into an analysis of variance model that included terms for intervention and village pair. When analysing data from cohort one and two, statistical weighting was applied to all village level summaries to account for differences in denominators between villages. Weights were inversely proportional to the variance of each measure. For one primary outcome variable (experience of intimate-partner violence in the past 12 months), no events were recorded in one village at follow-up, so 0.5 was added to allow calculation of a log prevalence.³² The risk difference was also estimated to examine the robustness of this finding.

Adjusted risk ratios (aRR) were calculated by generating standardised village level summaries.³³ aRR were calculated as the ratio of observed to expected outcomes predicted by fitting a logistic regression model on individual data with binary outcomes as dependent variables. Independent variables included village pair and age group in all models, marital status in cohort one, and sex in cohorts two and three. Since the study randomised only eight villages, adjustment for baseline imbalances was necessary. Consequently, a term for the baseline measure was also included in the model, with a missing value category assigned to individuals for whom baseline data were not available.

For primary outcomes, the coefficient of variance (k_m) for a matched pair design was estimated with baseline data.³⁴ HIV prevalence was used to estimate k_m for HIV incidence, since no baseline incidence data were available.

Some subgroup analyses were done. In cohort one, effect estimates were calculated separately for individuals who did or did not take out at least three loans and attended more than 70% of the SFL programme. For cohorts two and three, effect estimates were calculated for men and women separately. Significance tests of interaction were done.

All analyses were done on a per-protocol basis. The study protocol underwent peer review at *The Lancet* (03/PRT/24²⁵) and was registered at ClinicalTrials.gov with the number NCT00242957.

Role of funding source

The sponsors had no role in study design, data collection, analysis, interpretation, or writing this report. All authors had access to all the data. P Pronyk had final responsibility for the decision to submit for publication.

Results

The trial profile is shown in the figure. At baseline, 843 (98%) women in cohort one, 1455 (79%) of 14–35-year-old household residents (cohort two), and 2858 (74%) of randomly selected residents (cohort three) were successfully interviewed. 2-year follow-up rates were 90% and 84% in cohort one, and 75% and 71% for cohort two in the intervention and comparison groups, respectively. 3-year follow-up rates in cohort three were 58% in the intervention group and 63% in the control group. Data about the frequency of HIV infection were available for 1286 (64%) of individuals in cohort three who were confirmed as being HIV negative at baseline. Table 3 shows the baseline characteristics of the study population. Villages in the intervention and comparison groups were much the same in terms of size, distance to the nearest town, access to mains electricity, unemployment rates, and levels of migrancy. Access to a water tap was restricted in one intervention village. Women in the intervention group did not differ substantially from those in the control group in terms of sociodemographic traits. However, there was evidence at baseline that women in the intervention group were more often members of social groups ($p=0.01$) and savings associations (*stokvels*; $p=0.02$), were more likely to believe that the community would work together towards common goals ($p=0.06$), and more likely to report controlling behaviours by their partner ($p=0.01$) than women who were recruited as matched controls (table 4). There were no substantial baseline differences between intervention and comparison groups in cohorts two and three.

430 women, with an average age of 41 years, enrolled in the loan programme during the 15-month recruitment period. About 1750 loans were disbursed over the first 3 years of programme operation, valued at more than US\$290 000. Loans were most often used to support retail businesses selling fruit and vegetables, new or second-hand clothes, or tailoring businesses. Repayments were made in 99.7% of cases.

For primary outcomes at baseline, high coefficients of variance for cluster proportions were noted for intimate-partner violence (k_m 0.41) in cohort one and HIV (k_m 0.32) in cohort three. Lower values were reported for unprotected sexual intercourse (k_m 0.10 in cohort two, k_m 0.02 in cohort three).

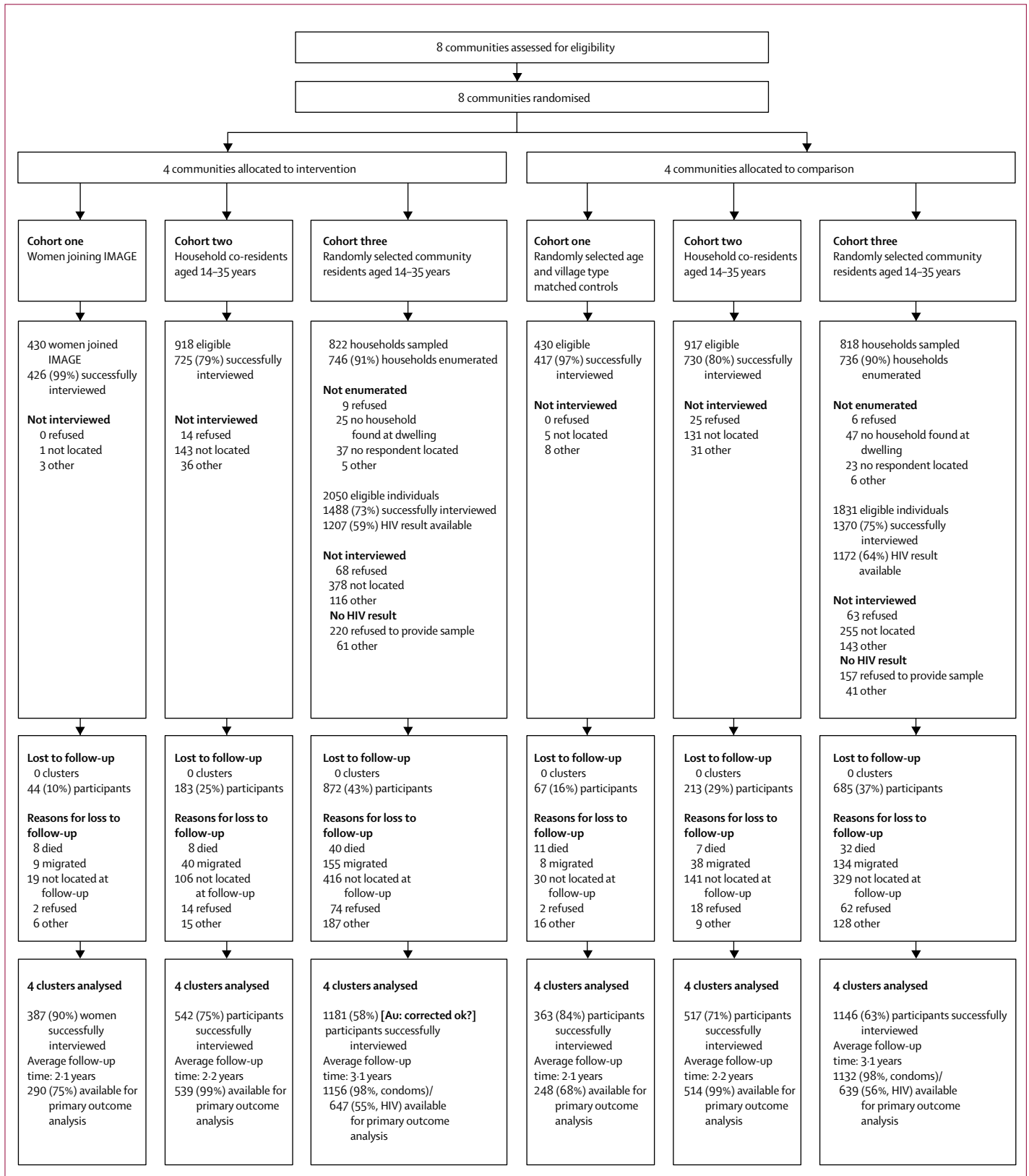


Figure: Trial profile

In women who were successfully followed-up, 301/387 (78%) had taken out three or more loans and most were still members of the programme. For those for whom data were available, 264/406 (65%) had attended more than seven training sessions. Qualitative data noted initial resistance to sensitive issues discussed in the training sessions, although this resistance had largely resolved by the end of the first phase. Although 58/387 (15%) of women reported that they were uncomfortable with some material, 348/387 (90%) felt the intervention had a major effect on their lives. 37 women attended the week of leadership training and had a central role in community mobilisation. Activities included numerous attempts to increase community awareness about HIV and intimate-partner violence through talking to children, partners, church leaders, and others. Staff at loan centres organised 40 village workshops, 16 meetings with leadership structures, five marches, two partnerships with local institutions, and formed two new committees targeted, respectively, at crime and rape within the community.

In cohort one at follow-up, adjusted point estimates of effect for 16 of the 17 indicators that were assessed suggested differences between intervention and comparison groups in the expected direction (table 4). Effect sizes were large, although CI did include unity for all but three indicators. Increased economic wellbeing in women in the intervention group was suggested by indicators of household assets (aRR 1.15, 95% CI 1.04–1.28), membership of *stokvels* (1.84, 0.77–4.37), and expenditure on food and clothing (1.23, 0.47–3.20), but not food security or school attendance by children in the household.

Furthermore, women in cohort one in the intervention group were more likely to report higher levels of participation in social groups (1.85, 0.95–3.61) and collective action (2.06, 0.92–4.49), and a greater sense of solidarity from their community in a time of crisis (1.65, 0.81–3.37) than women in the comparison group. There was less difference in the perception that community members would work together to solve common problems (1.11, 0.38–3.24) or the preference for communal ownership (0.97, 0.73–1.29) in the intervention group than in the comparison group.

Effect estimates for all measures of empowerment were in the expected direction for women in cohort one. The strongest effects were for holding attitudes that challenged established gender roles (1.57, 0.87–2.81), communication with household members about sexual matters (1.58, 1.21–2.07), and holding more progressive attitudes to intimate-partner violence (1.49, 0.86–2.60). There were smaller effects on improved selfconfidence (1.15, 0.83–1.60) and communication with partners about sexual matters (1.14, 0.90–1.44).

Women who took part in the IMAGE programme were more likely to report progressive attitudes towards gender violence (1.49, 0.86–2.60). The 538/750 (72%) women with an intimate partner during the previous year

	Intervention group	Comparison group
Villages		
Number of villages enrolled	4	4
Villages with mains electricity	3 (75%)	3 (75%)
Number of households	1310 (845–2256)	1147 (567–1512)
Distance to the main road (km)	9.1 (0–20)	8 (0–15.7)
Adult unemployment rate*	57% (55–59)	54% (51–60)
Proportion of population sleeping away from home	29% (22–37)	25% (21–32)
Proportion of households with access to water from a tap	53% (20–93)	75% (39–90)
Individuals		
Cohort one (direct programme participants or matched controls)		
Number of individuals interviewed at baseline	426	417
Age (years)†	41 (34–49)	42 (33–49)
Never married	104 (24%)	135 (32.1%)
Currently married	187 (44%)	174 (41.4%)
Divorced, separated, or widowed	135 (32%)	111 (26.4%)
Female-headed household	206 (48%)	231 (55%)
Had to beg for food or money in the past year	302 (71%)	305 (73%)
Cohort two (14–35-year-old household co-residents)		
Number of individuals interviewed at baseline	725	730
Women	450 (62%)	432 (59%)
Age (years)†	20.8 (16.9–26.4)	20.6 (16.9–26.0)
Never married	639 (88%)	636 (87%)
Currently married	76 (10%)	83 (11%)
Divorced, separated, or widowed	10 (1%)	11 (2%)
Student	355 (49%)	329 (45%)
Unemployed	260 (36%)	329 (45%)
Self-employed or employed	110 (15%)	70 (10%)
Sexually active men	187 (68%)	213 (71%)
Sexually active women	361 (80%)	344 (80%)
Cohort three (randomly selected community members)		
Number of individuals interviewed at baseline	1488	1370
Women	831 (56%)	783 (57%)
Age (years)†	20.9 (17.4–26.3)	21.0 (17.1–26.5)
Never married	1272 (85%)	1138 (83%)
Currently married	196 (13%)	208 (15%)
Divorced, separated, or widowed	19 (1%)	24 (2%)
Student	676 (45%)	652 (48%)
Unemployed	592 (40%)	510 (37%)
Self-employed or employed	217 (15%)	207 (15%)
Sexually active men	472 (72%)	418 (71%)
Sexually active women	676 (81%)	629 (80%)
HIV prevalence in men	26/509 (5%)	17/432 (4%)
HIV prevalence in women	91/679 (13%)	59/591 (10%)

Data are n (%), mean (range), or % (range), unless otherwise indicated. *Unemployment rate measured as proportion of all non-students aged 15–60 years classified as unemployed or in irregular work over past 12 months. †Data are median (IQR).

Table 3: Baseline characteristics of villages and individuals interviewed at baseline

	Baseline		Follow-up		Unadjusted risk ratio	Adjusted risk ratio
	Intervention group	Comparison group	Intervention group	Comparison group		
Cohort one (direct programme participants or matched controls)						
Estimated value of selected household assets >2000 South African rand	203/421 (48%)	183/412 (44%)	223/383 (58%)	176/359 (49.0%)	1.18 (0.87–1.60)	1.15 (1.04–1.28)
Membership in savings group (stokvel)	104/425 (24%)	49/420 (12%)	140/387 (36%)	55/363 (15%)	2.13 (0.92–4.94)	1.84 (0.77–4.37)
Greater food security	240/425 (56%)	190/422 (45%)	334/385 (87%)	304/361 (84%)	1.03 (0.83–1.28)	1.01 (0.81–1.26)
Per person expenditure on clothing or shoes >200 South African rand*	246/377 (65%)	182/339 (54%)	1.22 (0.46–3.23)	1.23 (0.47–3.20)
Children 10–19 years attending school†	882/1125 (78%)	833/1096 (76%)	654/1003 (65%)	630/985 (64%)	1.02 (0.93–1.12)	1.01 (0.97–1.06)
More participation in social groups	112/422 (27%)	53/416 (13%)	275/386 (71%)	133/363 (37%)	1.96 (1.02–3.78)	1.85 (0.95–3.61)
Taken part in collective action	167/407 (41%)	146/403 (36%)	290/383 (76%)	124/361 (34%)	2.22 (1.05–4.70)	2.06 (0.92–4.49)
Greater perception of community support in a time of crisis	300/419 (72%)	264/414 (64%)	306/387 (79%)	179/363 (49%)	1.68 (0.83–3.39)	1.65 (0.81–3.37)
Belief that the community would work together toward common goals	242/426 (57%)	171/419 (41%)	232/387 (60%)	184/362 (51%)	1.14 (0.39–3.36)	1.11 (0.38–3.24)
More positive attitude to communal ownership	259/426 (61%)	248/416 (60%)	227/387 (59%)	218/363 (60%)	0.97 (0.74–1.28)	0.97 (0.73–1.29)
More selfconfidence*	278/383 (73%)	227/358 (63%)	1.16 (0.83–1.61)	1.15 (0.83–1.60)
Greater challenge of established gender roles	158/423 (37%)	201/418 (48%)	233/381 (61%)	154/361 (43%)	1.54 (0.84–2.79)	1.57 (0.87–2.81)
Communication with intimate partner about sexual matters in past 12 months*†	260/288 (90%)	195/243 (80%)	1.14 (0.87–1.50)	1.14 (0.90–1.44)
Communication with household members about sexual matters in past 12 months*	331/383 (86%)	197/361 (55%)	1.60 (1.25–2.05)	1.58 (1.21–2.07)
More progressive attitudes to intimate-partner violence*	200/382 (52%)	128/361 (35%)	1.50 (0.81–2.75)	1.49 (0.86–2.60)
Controlling behaviour by intimate partner in past 12 months†	67/193 (35%)	40/178 (22%)	95/282 (34%)	101/242 (42%)	0.78 (0.34–1.82)	0.80 (0.35–1.83)
Experience of intimate-partner violence in past 12 months‡	22/193 (11%)	16/177 (9%)	17/290 (6%)	30/248 (12%)	0.50 (0.28–0.89)	0.45 (0.23–0.91)
Cohort two (14–35-year-old household co-residents)						
Communication with household members about sexual matters in past 12 months	339/724 (47%)	337/731 (46%)	357/542 (66%)	257/517 (50%)	1.34 (0.84–2.16)	1.32 (0.90–1.95)
Comfortable discussing sex/sexuality issues at home	355/724 (49%)	351/730 (48%)	336/541 (62%)	247/517 (48%)	1.36 (0.29–6.47)	1.35 (0.31–5.97)
Knowledge that a healthy looking person can be HIV positive	441/725 (61%)	413/730 (57%)	457/542 (84%)	387/517 (75%)	1.12 (0.85–1.47)	1.11 (0.86–1.42)
Having had an HIV test	90/725 (12%)	90/730 (12%)	98/542 (18%)	81/516 (16%)	1.16 (0.79–1.70)	1.18 (0.73–1.91)
Participation in collective action against HIV/AIDS	246/725 (34%)	225/729 (31%)	315/542 (58%)	211/517 (41%)	1.41 (0.68–2.93)	1.37 (0.67–2.82)
New sexual debut§	78/137 (57%)	70/132 (53%)	1.12 (0.94–1.33)	1.12 (0.93–1.36)
More than one sexual partner in past 12 months	95/724 (13%)	110/730 (15%)	98/540 (18%)	84/514 (16%)	1.08 (0.31–3.76)	1.16 (0.85–3.32)
Unprotected sexual intercourse at last occurrence with a non-spousal partner in past 12 months	326/724 (45%)	313/729 (43%)	259/539 (48%)	245/514 (48%)	1.03 (0.82–1.29)	1.02 (0.85–1.23)
Cohort three (randomly selected community members)						
Knowledge that a healthy looking person can be HIV positive	750/1488 (50%)	749/1370 (55%)	812/1179 (69%)	787/1145 (69%)	0.99 (0.77–1.27)	1.00 (0.80–1.25)
Having had an HIV test	166/1488 (11%)	150/1368 (11%)	268/1181 (23%)	242/1144 (21%)	1.08 (0.77–1.51)	1.09 (0.81–1.47)
New sexual debut§	380/461 (82%)	344/416 (83%)	1.00 (0.86–1.16)	1.00 (0.86–1.15)
More than one sexual partner in past 12 months	175/1481 (12%)	140/1365 (10%)	172/1175 (15%)	220/1139 (19%)	0.56 (0.06–5.23)	0.64 (0.19–2.16)
Unprotected sexual intercourse at last occurrence with a non-spousal partner in past 12 months	635/1481 (43%)	545/1365 (40%)	498/1156 (43%)	538/1132 (48%)	0.91 (0.68–1.22)	0.89 (0.66–1.19)
HIV incidences§	70/647 (11%)	72/639 (11%)	1.04 (0.67–1.61)	1.06 (0.66–1.69)

Data are risk ratio (95% CI) or those coded as having experienced outcome for an indicator/number for whom data were available (%). For more information, see webappendix. ..=no data. Primary outcomes are shown in bold. Adjusted risk ratios calculated on the basis of expected number of events from a logistic regression model on individual data with independent variables including age, village pair, marital status (cohort one only), sex (cohorts two and three only), and baseline measure except: *adjustment for most similar baseline variable since data not gathered at baseline, †no adjustment for marital status, ‡adjusted for lifetime experience of intimate-partner violence by current partner at baseline, or §cumulative risk measure so no adjustment made for baseline status.

Table 4: Estimates of effect on outcome indicators

experienced less controlling behaviour by these partners (0·80, 0·35–1·83), and there was a substantial reduction in intimate-partner violence in the previous 12 months (0·45, 0·23–0·91). Much the same result was noted when the effect estimate was calculated on the risk difference scale (adjusted risk difference –7·3%, –16·2 to 1·5). At baseline, data about intimate-partner violence were gathered from women married or living as married at baseline. At follow-up, data were also gathered for non-cohabiting partners. When the analysis was restricted to those women who reported on intimate-partner violence at both points, an effect of much the same magnitude was seen (aRR 0·39, 0·20–0·72; adjusted risk difference –7·7%, –11·5 to –3·8).

Most measures of effect were much the same in women who had taken three or more loans and attended 70% of the training sessions than in those who had participated less. However, there was some evidence of more pronounced positive effect on household communication (interaction test $p=0\cdot09$) and communal ownership ($p=0\cdot11$) among those with greater participation.

In household co-residents aged 14–35 years (cohort two) at follow-up, point estimates for five of the eight indicators were in the expected direction, but effect sizes were modest and CI wide. For the primary outcome of unprotected sexual intercourse at last occurrence with a non-spousal partner in the past 12 months, the relative risk was very close to unity (aRR 1·02, 0·85–1·23). The strongest evidence of effect related to household communication on sex or sexuality (1·32, 0·90–1·95). There was little evidence to suggest differences in effect estimates between men and women.

In cohort three at follow-up, point estimates of effect were in the direction expected for five of the six indicators, but effect sizes were small with wide CI. Fewer individuals in the intervention group reported more than one partner in the past year than did individuals in the comparison group (0·64, 0·19–2·16). In terms of primary outcomes, there was no difference in HIV incidence between intervention and comparison groups (1·06, 0·66–1·69) and there was little evidence that unprotected sexual intercourse at last occurrence with a non-spousal partner in the past 12 months was less common in the intervention group than it was in the comparison group (0·89, 0·66–1·19). There was also little evidence of consistent effect differences between men and women.

Discussion

The IMAGE study assessed the effect of a microfinance-based structural intervention on the prevention of HIV infection and intimate-partner violence. The intervention was both feasible to deliver and acceptable to programme participants. There was evidence for an intervention effect on household economic wellbeing, social capital, and empowerment. Furthermore, we estimated that, over a 2-year period, levels of intimate-

partner violence were reduced by 55% in women in the intervention group relative to those in the comparison group. There were more modest effects in young people not directly exposed to the intervention, and the incidence of HIV in this group was much the same in the intervention and comparison communities. This study provides encouraging evidence that a combined microfinance and training intervention can have health and social benefits, including reducing the levels of violence experienced by participants, although indirect effects, if any, on young people's HIV risk over the short term are more limited.

The study had several strengths. The prospective, matched cluster randomised design reduced recall and programme placement bias—both major limitations in the interpretation of previous poverty-reduction studies.³⁵ The study was informed by a prespecified framework and used extensive qualitative data, while the analysis controlled for secular changes that occurred during the study period and baseline imbalances. Our interpretation of the study results are shaped by the consistency of observed changes in predefined indicators and the congruency between pathway variables and health outcomes.²⁶

The study also had several limitations. Perhaps most important was the low precision of effect estimates, which was a result of the small number of clusters, a product of operational and ethical issues discussed earlier. A second weakness was the short duration of follow-up. Third, there might have been biased reporting, although the direction of such bias is difficult to predict. Higher levels of experiences such as violence might have been reported by programme participants since the training sought to increase sensitisation to these issues. Fourth, since programme participants self-selected to join the intervention, these individuals might have differed from those enrolled in the comparison group. We attempted to ensure that groups were much the same through age and village-type matching, and restricted entry in the comparison group to women who would have been eligible to join the programme. Nevertheless, some imbalances were seen at baseline. Fifth, although study communities were identified from locally recognised borders, they were not separated by large distances, thus the potential for contamination of control villages and underestimation of true effects remained. Sixth, individuals not successfully interviewed at baseline or follow-up might have differed from those included in the trial, although again the direction of such bias is not easy to predict. Finally, since programme participants were generally older women in whom sexual behaviour was not assessed, we are not able to comment on potential direct effects of the intervention on HIV risk.

The IMAGE study shows that to design and deliver an intervention that targets the structural determinants of HIV and intimate-partner violence in a southern African context is possible. Despite widespread recognition of

the role that structural factors have in relation to intimate-partner violence, HIV, and other health outcomes, such interventions have remained largely in the realm of theory. The assessment of such interventions is complex. We used an experimental design to generate unbiased estimates of effect despite practical constraints that restricted cluster numbers. The feasibility, ethics, and usefulness of such assessments remain important considerations in the assessment of structural interventions, and these factors need to be investigated further.^{14,36} Finally, our group is continuing to study the sustainability, transferability, cost, and relative benefits of the training and microfinance components of the IMAGE intervention.

Our findings also contribute evidence to ongoing debates about the role of microfinance in the alleviation of poverty. Participants represented the poorest women in every community, and enrolment in the intervention generated additional income for savings and expanded asset ownership. There was little effect on school enrolment, potentially the result of high enrolment rates in much of South Africa, with little room for measurable improvement. The small effect on food security could have arisen from overall increases in reported food security over the trial period, perhaps the result of the expansion of child and foster care grants in the area.

The data presented here also strongly suggest an intervention effect on women's empowerment and reduction of intimate-partner violence. Although this benefit cannot be assumed for all contexts, and the potential for violence to increase with changes in social and economic status has been suggested in some settings,³⁷ the study lends support to a growing amount of published work on the importance of women's economic participation in reducing gender inequity and violence.³⁸ Better understanding of the potential mechanisms for the effect on intimate-partner violence seen here and the relative contribution of the economic, social, and educational dimensions of the intervention are of central policy relevance in Africa and elsewhere.

There were modest intervention effects on levels of openness and communication about sexual matters and collective action in young people in participating households, yet the results of the trial suggest little effect on sexual behaviour and HIV infection rates during the short follow-up. Effects in this group would have to occur through diffusion from those receiving the intervention to the wider community via mentorship, education, or participation in community activities, or as a result of household economic gains. Because the time for direct IMAGE participants to receive the full intervention package of microfinance and training was, on average, 18 months, the opportunity for such diffusion to occur over the 2–3-year study was limited.

Structural interventions potentially have an important role in confronting the complex risk environment underlying high rates of intimate-partner violence and HIV

infection in southern Africa. Although some individuals suggest that addressing relations between economic underdevelopment, gender inequality, and HIV are the only sustainable solution,¹⁰ others argue that structural change takes too much time and could draw attention away from the basics of prevention.³⁹ This study suggests that, even in the short term, shifts in social and economic vulnerability, including reductions in intimate-partner violence, might indeed be achievable. Since poverty reduction, the promotion of gender equity, and combating HIV/AIDS remain pillars of the UN Millennium Development Goal framework, identifying strategies that achieve maximum synergy between behavioural and structural approaches is critical. Progress towards these targets will require creative partnerships between sectors.

Contributors

P Pronyk was the principal investigator of the study and project leader in South Africa, led the drafting of this manuscript, and contributed to all aspects of the study. J Hargreaves was responsible for the study design, field management of survey teams, data management, overall quantitative analysis, and assessment of process indicators. J Kim was responsible for the development and implementation of the training component of the intervention, the design, and validation of survey instruments for gender violence, and contributed to the analysis. L Morison contributed to the overall design of the study and provided major support for the statistical analysis. G Phebla was the team leader in South Africa for the qualitative component of the study. C Watts provided support to the training intervention, the design of survey methods, and the analysis. J Busza provided technical support to the qualitative research team. J Porter participated in the initial conceptualisation of the intervention, its design, and advised on most aspects of the study. All authors contributed to the drafting of this manuscript. All authors saw and approved the final version of the manuscript.

Conflict of interest statement

We declare that we have no conflict of interest.

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This appendix gives details of questionnaire items and their coding used to create binary primary and secondary outcome variables reported in the per-protocol analysis of the IMAGE study.

All primary outcomes used well-established measures that were defined in the study protocol. Indicators for secondary outcomes were also predefined before final analysis. The choice of indicators and the process undertaken to generate them were as follows:

- 1 Relevance to a pre-specified conceptual framework.¹
- 2 Extensive piloting of questionnaires to ensure questions comprising outcomes were both locally relevant and well-understood by respondents and the field research team.
- 3 A review of baseline quantitative data alongside interim analysis of concurrent qualitative data.
- 4 Reviews of the international literature from the economics/microfinance, social capital, and gender fields. More specifically, we refer to the following:
 - (a) Economics: indicators of economic well being were derived after piloting operational methods developed for doing poverty assessments in Africa by the Consultative Group to Assist the Poorest,² USAID,³ and the microfinance sector.⁴
 - (b) Social capital: dimensions of cognitive and structural social capital were derived from the World Bank Social Capital Assessment Tool and related advances where emerging best-practice is evolving for studies done in developing country settings.⁵⁻⁷
 - (c) Gender: Secondary intimate-partner violence outcomes (past year experience of controlling behaviour by an intimate partner, and attitudes towards the acceptability of intimate-partner violence) were drawn from the international WHO violence against women study instrument.⁸ These secondary outcomes were included because of quantitative and qualitative evidence suggesting that both are associated with risk of intimate-partner violence in a number of settings, including South Africa.⁸⁻¹⁰

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Effect of a structural intervention for the prevention of intimate-partner violence and HIV in rural South Africa: a cluster randomised trial

Cohort	Outcome variable	Questionnaire items	Number of items	Coding details to create binary outcome variables		Notes
				0	1	
One	Experience of intimate-partner violence in past 12 months	I want you to tell me if any of the following things have happened to you with a sexual partner or spouse (in the past 12 months)... (a) He pushed or shoved you. (b) He hit you with his fist or with something else that could hurt you. (c) He physically forced you to have sexual intercourse when you did not want to. (d) You had sexual intercourse when you didn't want to, because you were afraid of what he might do if you said no.	4	"No" to all items	"Yes" to any item	Exclusions: no intimate partner at follow-up Reliability coefficient: 0.87 Baseline data gathered in subgroup: data only gathered among married women at baseline.
Two and three	Unprotected intercourse at last occurrence with a non-spousal partner in the past 12 months	How many of your partners in the past 12 months were sexual partners that you are not married to and have never lived with? If the answer is greater than 0, then for up to the three most recent partners the following question is asked: Did you use a condom the last time you had sexual intercourse with this person?	2	Number of non-spousal partners in past year is zero OR Number of non-spousal partners in past year more than zero AND used a condom at last occurrence of sexual intercourse with all reported partners	Number of non-spousal partners in past year more than zero AND Did not use a condom at last occurrence of sexual intercourse with any reported partner	Only details of three partners are recorded for the previous 12 months
Three	HIV incidence	Estimated on the basis of laboratory assays done at baseline and follow-up	NA	Negative sample at baseline and follow-up	Negative sample at baseline, positive sample at follow-up	Exclusions: individuals with positive test at baseline and missing data at either time

Webtable 1: Primary outcome measures stipulated in the IMAGE protocol

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Cohort	Outcome variable	Questionnaire items	Number of items	Coding details to create binary outcome variables		Notes
				0	1	
One	Estimated value of selected household assets >2000 South African rand	Do people living in the household own any of the following items? Code the items as "new , <2 years old", "medium, 2–6 years old", "old, >6 years old" (a) Cars (b) Televisions (c) Hi-fis (d) Fridges (e) Bicycles (f) Cell phones Do people living in the household own any of the following livestock? (a) Cows (b) Goats (c) Chickens	9	Total value of assets listed <2000 South African rand	Total value of assets listed ≥2000 South African rand	Valuations: estimations of the value of each asset came from a small sub-study consisting of about 100 interviews done in 2002. Participants were asked to estimate the sale and purchase value of these items. Valuations for the calculation come from the average of estimated sale and purchase values across all interviews
One	Membership of a <i>stokvel</i>	Are you a member of a <i>stokvel</i> ?	1	"Not member"	"Leader", "Active member", or "Member"	Definition: a <i>stokvel</i> is an informal savings co-operative popular in rural South Africa
One	Greater food security	(a) During the past month, how often have most of the family had a meal that consisted of pap alone, bread alone, or worse? (b) While living in this house and during the past month have you or any of your own children gone without food or had a reduced amount to eat for a single day because of a shortage of food?	2	"Often" to any item	"Never", "Once only", or "A few times" to all items	
One	Per person expenditure on clothing or shoes >200 South African rand	Estimate the amount, in rand, that has been spent on clothing and footwear for this individual in the past year. Include tailoring costs and costs of items used to make or mend clothes at home. Summed over all individuals/household size.	1	Per person expenditure <200 South African rand	Per person expenditure ≥200 South African rand	Baseline: no data gathered at baseline. Nearest equivalent data is value of household assets
One	Attending school (among household members aged 10–19 years)	Is person X currently attending school? Data gathered on individuals aged 10–19 years at baseline.	1	"No"	"Yes"	
One	More participation in social groups	Index of group membership generated by summing total number of all social groups for which respondent reports being a member. Weighting doubled if an active member and trebled if leader of each group.	18	Score <5	Score ≥5	
One and two	Taking part in collective action	1) In the past 3 years, have you participated in a meeting, march, rally or gathering around HIV/AIDS awareness? 2) Have you ever been involved in the organisation of such a meeting or gathering?	2	"No" to all items	"Yes" to any item	Reliability coefficient*: 0.69

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One	Greater perception of community support in a time of crisis	Imagine that your house has been completely destroyed by a fire. In this question, we would like to know whether you feel you could turn to (people from the village you don't know at all) (a) To shelter you for 2 weeks while you make other long-term arrangements? (b) To borrow 50 rand to help you buy some clothes after the fire? How confident are you that you alone could raise enough money to feed your family for 4 weeks? This could be for example by working, selling things that you own, or by borrowing money (from people you know or from a bank or money lender) Would you say that your household's ability to survive this kind of crisis is better, the same or worse than it was 2 years ago?	4	"No" or "Don't know" to items (a) AND (b) AND "It would be possible/moderately confident", "Not confident at all", or "Don't know" to the last two questions.	"Yes" to item (a) or (b) OR "Very confident" to either of the last two questions	Reliability coefficient*: 0.60
One	Belief that the community would work together toward common goals	(a) If a community project does not directly benefit your neighbour but has benefits for others in the village/ neighbourhood, then do you think your neighbour would contribute time for this project? (if the community project is not ordered by the chief) (b) If a community project does not directly benefit your neighbour but has benefits for others in the village/ neighbourhood, then do you think your neighbour would contribute money (say about 10 rand) for this project? (if the community project is not ordered by the chief) (c) If there were a problem that affected the entire village/ neighbourhood, for instance lack of water or electricity or a major flood, which scenario do you think would best describe who would work together to deal with the situation?	3	"No" or "Don't know" to item (a) and (b) AND "Each person will deal with the problem individually" or "Neighbours among themselves", "Local government/municipal political leaders would take the lead", "All community leaders acting together", or "Other" to item (c)	"Yes" to item (a) or (b) OR "The entire village/ neighbourhood" to item (c)	Reliability coefficient*: 0.50
One	More positive attitude to communal ownership	Suppose a friend of yours in this village/neighbourhood faced the following alternatives, which one would he or she prefer most?	1	Own a plot of land entirely by themselves OR Don't know/ not sure	Own a much larger (threefold) plot of land jointly with one other person (not a family member)	

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One	More selfconfidence	(a) People often feel shy about speaking in public. If you were at a community meeting (eg, school committee), how confident are you that you could raise your opinion in public? (b) Neighbours often have similar problems (eg, around raising children). How confident do you feel about offering advice to your neighbour?	2	"Very confident and often do" to all questions	"Confident but would need to be encouraged to speak out" OR "not confident at all/ scared to speak in public and don't" to any question	No baseline data gathered: Nearest equivalent data on challenge of established gender norms
One	Greater challenge of established gender roles	In your own opinion, do you agree that... (a) A woman should do most of the household chores (cooking, cleaning), even if the husband is not working (b) If a man has paid lobola (bride payment), it means that his wife must always obey him (c) If a woman asks her husband to use a condom, she is being disrespectful to her husband (d) If a woman asks her husband to use a condom it means that she must be sleeping around with other men (e) A man needs to have many sexual partners, and the wife must just tolerate this (f) A woman should never divorce her husband, no matter what happens	6	"Agree" or "Don't know" to any item	"Disagree" to all items	Reliability coefficient*: 0.81
One	Communication with relationship partner about sexual matters in past 12 months	In the past 12 months have you spoken about sexual matters, and sexuality in general, with your own spouse or sexual partner(s)?	1	"No"	"Yes"	Exclusions: No intimate partner at follow-up Baseline data gathered in subgroup: Data only gathered from married women at baseline. No baseline data gathered: Nearest equivalent data gathered on partner giving advice (FF1002b)
One and two	Communication with household members about sexual matters in past 12 months	In the past 12 months, have you spoken about sexual matters, and sexuality in general with (a) your children, (b) your parents/guardians, or (c) other household members?	3	"No" to all items	"Yes" to any item	No baseline data gathered: Nearest equivalent data gathered on communication with children about sexual matters/sexuality
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One	More progressive attitudes to gender-based violence	In your own opinion, do you agree that... It is acceptable for a married woman to refuse to have sex with her husband if: (a) she doesn't want to (b) he refuses to use a condom (c) she is angry because he has other girlfriends (d) She is worried he might have AIDS A man has good reason to hit his wife if: (e) she refuses to have sexual intercourse with him (f) she asks him to use a condom (g) he finds out that she has been unfaithful (h) disagrees with him in public	8	"Disagree" with any item (a)-(d) OR "Agree" with any item (e)-(h)	"Agree" with all items (a)-(d) AND "Disagree" with all items (e)-(h)	Reliability coefficient*: 0.81 No baseline data gathered on some variables: data on attitudes to physical violence ([e]–[h]) not obtained at baseline
One	Controlling behaviour by relationship partner in past 12 months	In the past 12 months, In your relationship(s) with any of your partners has: (a) he kept you from seeing your friends? (b) he insisted on knowing where you are at all times? (d) he insulted or humiliated you in front of other people? (e) he boasted about girlfriends or brought them home?	4	"No" to all items	"Yes" to any item	Exclusions: no intimate partner at follow-up Reliability coefficient: 0.64 Baseline data gathered in subgroup: data only gathered from married women at baseline
Two	Comfortable discussing sexual matters/sexuality issues at home	In your household, do you feel free/open to discuss issues of sex and sexuality?	1	"No" or "Don't know"	"Yes"	
Two and three	Knowledge that a healthy looking person can be HIV positive	Do you think that a healthy looking person can be infected with HIV, the virus that causes AIDS?	1	"No" or "Don't know"	"Yes"	
Two and three	Having had an HIV test	I don't want to know the result, but have you ever had an HIV test?	1	"No"	"Yes"	
Two and three	New sexual debut	Have you ever had sexual intercourse?	1	"No"	"Yes"	Exclusions: individuals who report having had sexual intercourse at baseline
Two and three	More than one sexual partner in past 12 months	How many sexual partners have you had in the past year? Include both spousal and non-spousal partners	2	"None" or "one"	More than one	

*Reliability coefficient: Kuder-Richardson 20 coefficient describing agreement between binary indicators used to generate composite indicators at follow-up where appropriate.

Webtable 2: Secondary outcome measures stipulated after review of qualitative data

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