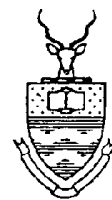# Study Protocol

<u>The Intervention with Microfinance for AIDS and Gender Equity Study (IMAGE Study) : An integrated community randomised trial of a structural intervention to prevent HIV and gender-based violence in South Africa</u>

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List of Acronyms

AIDS	Acquired Immune Deficiency Syndrome
BRAC	Bangladesh Rural Advancement Committee
CRT	Community Randomised Trial
DOH	Department of Health
HIV	Human Immunodeficiency Virus
IPV	Intimate Partner Violence
IMAGE	Intervention with Microfinance for AIDS and Gender Equity
LSHTM	London School of Hygiene and Tropical Medicine
MF	Microfinance
MFI	Microfinance Initiative
NGO	Non-Governmental Organisation
NHLS	National Health Laboratory Service
OMT	Oral Mucosal Transudate
PLA	Participatory Learning and Action
PRA	Participatory Rural Appraisal
PWR	Participatory Wealth Ranking
RADAR	Rural AIDS and Development Action Research Programme
RCT	Randomised Controlled Trial
SEF	Small Enterprise Foundation
SFL	Sisters for Life
STD	Sexually Transmitted Disease
TCP	Tšhomišano Credit Programme
UNAIDS	United Nations Joint Programme on AIDS
VCT	Voluntary Counselling and Testing for HIV
WITS	University of the Witwatersrand

1.   Background and Rationale

Substantial resources have been mobilised for research and programme development in efforts to combat HIV/AIDS in Africa. In the absence of an effective vaccine the main method of HIV prevention is behavioural change. Despite this, there have been few controlled studies on interventions that aim to change sexual behaviour in African contexts.[1]

Public health interventions for HIV/AIDS prevention have often focused on behavioural or biological risk in individuals. Condom use has been actively promoted as a rational means of protection, alongside educational interventions aimed at risk reduction. However, after more than two decades of concerted efforts in developing countries, evidence of success has been limited. Enhanced sexually transmitted disease (STD) treatment services [2] and Voluntary Counselling and Testing for HIV (VCT) [3] remain the only interventions that have been shown to prevent STD/HIV infections or change sexual behaviour in randomised controlled trials (RCTs). Many are beginning to question whether a continued reliance on technical individually-oriented interventions, while necessary and important, will be sufficient to reduce the level of disease in populations.

Structural Factors and Structural Interventions

Recent years have witnessed the emergence of a growing body of international research that seeks to examine the broader context in which individual behaviour takes place.[4-7] The concept of *structural factors* has been used to describe the physical, socio-economic, cultural, legal, or policy dimensions of the environment – and the way they interact to shape

vulnerability to disease.[8] Structural factors that influence HIV transmission have been well described.[9-11] Most can be grouped into three interconnected categories: (1) **poverty** and economic underdevelopment; (2) **mobility**, including migration, seasonal work, and the social disruption due to war and political instability; and (3) **gender inequalities**. In spite of the uniqueness of each local epidemic, similar structures and processes have helped shape transmission in areas as diverse as Africa, Asia, and Latin America.[9]

The case of South Africa illustrates well how these structural factors can fuel a rapidly growing epidemic. Land expropriation and migrant labour have eroded the fabric of communities, destabilised household and community life, and exacerbated gender inequalities. In addition, economic crisis has driven many women, either formally or informally, to exchange sex for resources as a means of survival.[12] Intimate partner violence (IPV), well documented in South Africa,[13,14] continues to affect women's vulnerability to HIV infection.[15,16] Refusing sex, inquiring about other partners, or suggesting condom use have all been described as "triggers" for IPV - yet all are intimately connected to the behavioural cornerstones of HIV prevention.[17-20] In South Africa as elsewhere, the interplay of all of these factors has critically impeded prevention efforts based on modifying individual risk.

However, despite broad recognition of the importance of structural factors in underlying the HIV epidemic, there is a serious deficiency in the design and testing of interventions to critically engage issues at this level.[6,8] *Structural interventions* attempt to alter the context within which health is produced or reproduced. Such interventions locate the source of public health problems in

the social, economic and political environments that shape and constrain individual, community, and societal health outcomes.[21] There remains some ambiguity in the published literature on the definition and scope of structural interventions, yet there is consensus that such interventions would aim to influence contextual or political-economic conditions that shape health outcomes.[9,22,23] Some authors emphasise policy-level interventions in this area, yet structural interventions may also be programmatic. A recent review of structural interventions found few published studies that describe and/or evaluate specific structural interventions in detail. Among these, most have been limited to targeted interventions developed for particular risk groups, such as female commercial sex workers, male truck drivers, and men who have sex with men.[9] Although some, such as the 100% Condom Program in Thailand,[24] have shed light on the potential impact of policy-level interventions, their broader relevance to other groups and settings remain largely unknown. Similarly, while examples of structural interventions have been described in developed countries, primarily the United States,[21,25] interventions of relevance to developing countries have been few. Thus, to date, calls for an "expanded response" to the HIV epidemic have not been matched by action, and the creation of such interventions has remained largely within the realm of theory.[26,27]

Evaluating Structural Interventions

Part of the limitation in engaging structural processes derives from the numerous challenges to measuring impact. Policy makers need evidence of

the causal links between structural factors and prevention outcomes yet more upstream interventions demand innovative methods of evaluation.[6,8,9]

Guidelines for the stages of development and evaluation of complex interventions to improve health are in their infancy and are largely derived from models of drug development.[28] Nevertheless, a growing literature points to the importance of experimental methods coupled to extensive process evaluation in the evaluation of such programmes. Community level interventions are most appropriately evaluated in community randomised trials (CRT),[29] though the number of communities may be small.[30] Such methodologies have been widely used in evaluations of STD-treatment interventions for the prevention of HIV in Africa,[2,31,32] although these trials have pointed to the limited generalisability of the results of CRTs,[30,33] strengthening calls for intense process evaluation. Evidence on structural interventions is urgently needed to inform debates about resource allocation for HIV prevention.

The IMAGE Study

This protocol describes the Intervention with Microfinance for AIDS & Gender Equity (IMAGE) Study – a programmatic structural intervention being conducted in rural South Africa where widespread poverty,[34,35] and entrenched gender inequity,[36,37] continue to fuel an explosive HIV epidemic.[38] This community randomised trial is among the first attempts to rigorously evaluate the role of a structural intervention in the prevention of HIV in Africa. It seeks to provide information on both outcomes and process that will be of

great use to HIV prevention programme designers, health policy makers and practitioners.

This document is organized as follows:

- Section 2 describes the intervention.

- Section 3 provides a theoretical framework for the project.

- Sections 4 - 14 give an in-depth description of the methodology of this study.

- Section 15 discusses the strengths and limitations of our trial design.

- Sections 16-21 provide details of informed consent, ethical approval, partners and funders of the IMAGE study and a brief timeline.

- Section 22 holds a reference list.

- The Appendices are listed at the end of this document, and are provided in a separate file.

2.   Intervention Design

Background and Theory

Microfinance initiatives (MFI) expand access to credit and savings services to support income-generating projects among disadvantaged groups. Programmes such as the Grameen Bank and the Bangladesh Rural Advancement Committee (BRAC) have reached large numbers of poor rural women. Recently there have been increases in funding for MFIs from large international donors, with large programmes now operational in Asia, Africa, South America and Eastern Europe reaching millions of borrowers.[39] Targeting women in these programmes aims to both increase cost efficiency (due to higher female repayment rates) and deliver more effective poverty alleviation (due to women's prioritisation of expenditure on family welfare).[40]

Reviews of a wide range of microfinance programme assessments report that microfinance initiatives (MFIs) have the potential to serve as "enabling strategies" among vulnerable communities. A USAID review of 40 programmes in 24 countries from Asia, Africa and Latin America suggests MF has the potential to achieve gains at the level of individuals and communities which include, and can go beyond, purely economic returns.[41]

In addition, several studies have demonstrated MF has the potential to enhance autonomy and resilience among women participants - where newly acquired economic and business skills translate to improvements in self esteem, larger social networks, and wider control over household decision-making.[41-46] In this respect, studies that have examined the relationship between microfinance and empowerment have suggested overall

improvements in women's confidence and co-operation, their ability to resolve conflicts, and their bargaining power in relations with family members.[47,48] Beyond their potential to reduce poverty and enhance the status of women, MFIs have been linked to specific health outcomes. A number of studies have suggested that participation in MF has the potential to lead to increased use of formal health care by participants,[49] improved nutritional status of children relative to non-participants,[50-54] and in some cases, reductions in infant mortality rates.[51] In relation to reproductive health, recent evaluations of the Grameen Bank and BRAC credit programmes in Bangladesh have demonstrated an increase in contraceptive acceptance and use among poor families in communities receiving microfinance, suggesting that women who control money and participate in family decisions may have more control over reproductive health decisions.[47,55-58]

In their Bangladesh study, Schuler and Hashemi noted that multi-variate analyses suggested that women in credit programmes were significantly more empowered than women in communities without such programmes (based on seven of eight empowerment indicators developed), and less likely than other women to be beaten by their husbands.[57] Subsequent analysis by the author and others qualified the findings through ethnographic research.[59] They found that, in rural Bangladesh, expanding women's access to economic opportunities and resources does not always make them less vulnerable to domestic violence. In some cases, bringing home a source of income that benefited husbands and families reduced poverty related stress, raised the woman's perceived value, and protected them from violence. A more recent study on the impact of microfinance supports gains in this more nuanced

definition of empowerment.[60] In other cases, conflicts developed over control of assets and earnings as women became more inclined to defend themselves against what they saw as unfair domination and exploitation. The authors recommended that positive impacts might be strengthened by raising awareness about the issue of domestic violence through training programmes for MF staff and clients, and finding ways to encourage collective, community-level responses against such violence. This echoes observations arising from the broader microfinance and empowerment literature, emphasizing the importance of incorporating an additional training or capacity-building dimension to financial services.

The body of experience described above suggests that MFIs might provide a vehicle for generating a structural-level response to HIV/AIDS. However, the links between microfinance and empowerment are not universal or straightforward, as reflected in current discourse within the field. While microfinance has the potential to stimulate positive change, concerns have been raised about the "double burden" placed on women participants, and that upsetting rigid gender norms may actually increase their vulnerability to conflicts and violence in the home.[40,61-63] Others suggest MF involvement does little to alter the status quo, and may actually reinforce traditional gender norms.[64] Furthermore, some have questioned the extent to which increasing women's access to credit automatically translates into their increased control over its use.[65] In this respect, there is increasing recognition that empowering individuals requires strengthening access to resources *and* building individual agency to use those resources, make decisions, and take leadership.[40,61,63] Hence, some authors have suggested that adding a gender sensitization or

training component to microfinance programs may play an important role in catalyzing the broader benefits of increased access to economic resources.[40,66]

Consequently, many microfinance practitioners are motivated to provide additional educational or training services for their clients.[67] Such services might include group-based trainings that seek to provide information and challenge norms relating to HIV, gender and sexuality. Interventions of this type have been recommended for the prevention of HIV and gender based violence in developing countries.[68] There is the potential for synergy in such an approach. Indeed the importance of locating HIV prevention interventions within programmes that enhance women's economic and social status has been stressed.[69] Microfinance programmes may offer the opportunity to conduct group-work with poor rural women within just such a context. This engagement with women in a safe, empowering setting might beneficially impact household and community environments in ways that reduce HIV transmission and intimate partner violence.

The IMAGE Intervention

IMAGE is a programmatic structural intervention with two components. These are;

1) **TCP** : Operation of a community-level, poverty-targeted *microfinance* programme (Tšhomišano Credit Programme (TCP), administered by the Small Enterprise Foundaton (SEF), Tzaneen, South Africa).

2) **SFL** : Conduct of a two phase participatory learning and action and community mobilisation programme for TCP participants ("Sisters for Life", administered by RADAR, South Africa).

The IMAGE intervention being evaluated in this study comprises making TCP available at the community level, and conducting SFL with all individuals who join this programme. Consequently, *IMAGE = TCP + SFL.*

Tšhomišano Credit Programme (TCP)

SEF is a development microfinance NGO operating in South Africa's Limpopo Province that disburses small loans for micro-enterprises owned by poor women. SEF's Tšhomišano Credit Project (TCP) is a group based lending programme established to cater specifically for the very poor.[70] The key components of the operation of TCP within its target communities are;

- Poverty-targeted recruitment. The poorest households in communities are identified through a process of Participatory Wealth Ranking and given the opportunity to participate in the IMAGE intervention. Interested women are requested to form a loan group of five members. Typically the average age of loan recipients will be approximately 40 years.

- Group formation and membership. A four-week process of group training and recognition is conducted before these women are eligible to receive loans. Upon enrolment to the programme, the

women receive individual loans but each is required to guarantee the repayment of her fellow group member's loans.

- Borrowing and repayment of loans. After groups have enrolled, group members may apply for individual loans. First loans cannot exceed ZAR500 (c.USD40; July 2004), and will be paid back over 5 or 10 fortnights. Later loans are dependent on good group repayment and business value. Loans must be used for the development of income generating projects. Group savings must also be kept.

- Centre Meetings. Repayment of loans occurs at a fortnightly meeting of up to 8 groups (40 individuals). These meetings are structured and run by the participants themselves, who elect a chairperson, treasurer and secretary. Attendance is compulsory, and meetings are used to discuss wider aspects of business development.

- Business assessment and training. Individuals' businesses are regularly assessed by TCP staff. Continued involvement with TCP, and in particular the size of later loans that individuals can apply for are dependent upon these assessments.

- Ongoing impact assessment. TCP staff constantly monitor their clients and conduct regular formal assessments of the impact which involvement with the programme is having. These impact assessments are used to guide ongoing programme operation.

Small Enterprise Foundation (SEF), the implementing MF partner in this project has successfully implemented their programme in South Africa since 1992. Microfinance practitioners recognise the reality that when loaning money to the poor, some proportion will likely be spent on consumption, as well as income generation. Therefore the poverty-focussed Tshomisano Credit programme (TCP) places a strong emphasis on the productive use of loans, regular loan utilisation checks, and linkage of loan size to business value, in order to ensure that loans are given on the basis of adequate productive return from the business. Both quantitative and qualitative data suggest that TCP's poorest members perform at least as well as the average performance for the microfinance programme as a whole. Moreover, formal impact assessments demonstrate a positive impact for TCP members. Analysis of the impact monitoring data base maintained by SEF demonstrates that these gains result from a combination of building a strong business that can provide a reliable and adequate income to meet basic household needs, along with the development of assets to protect this income and reduce vulnerability. These assets include savings, which provide a fund to use in the case of emergencies, and means of managing money to meet expenditure needs for business or household purposes. In addition, human assets, in terms of business, social and participation skills, assist the effective management of the business, and the development of other livelihood opportunities. Children's education and the health of the family also contribute to the long-term sustainability and protection of the livelihood gains. Finally, the development of social networks and relationships with other people,

strengthen the social "safety-net" and improve the chances of support from others during times of crisis.[71]

Sisters for Life (SFL)

Tšhomišhano Centre Meetings offer the opportunity to introduce a program of training and skills development relating to gender and HIV/AIDS. The Sisters for Life program (SfL) has been developed specifically for microfinance clients in South Africa.[72,73] Key components of the two-phase Sisters for Life programme are;

- Phase I is a structured series of ten 1-hour training sessions based on principles of Participatory Learning and Action (PLA), where topics include gender roles, gender inequality and cultural beliefs, sexuality and relationships, and domestic violence, as well as topics relating to HIV prevention (see Table 1). This phase is facilitated by a team of four specially trained facilitators. The sessions are held at the beginning of microfinance meetings (fortnightly) before financial business is discussed.

- Phase II is an open-ended program that aims to support participants in developing and implementing responses to gender based violence and HIV infection that are appropriate to their own communities.

- Up to five 'Natural leaders' are elected by each centre.

- 'Natural Leaders' from a number of centres are brought together for further training on leadership and community mobilization.

- Taking these skills back to their respective centres, they are responsible for developing an Action Plan with their centres, with the aim of implementing what they regard as appropriate responses to priority issues.

- There is continued involvement of facilitators in each centre. The fortnightly one-hour session at the beginning of microfinance meetings is retained to discuss ideas, progress and problems in planning and implementing local action plans.

Table 1: Sisters for Life – Phase 1 Training Curriculum

	Session	Goals	Activities
1	Introductions	1) Help participants and facilitators to get to know one another and to feel comfortable 2) Overview of program	▪ Introductions ▪ Overall goals and program ▪ Expectations and concerns ▪ Ground Rules
2	Reflecting on Culture	1) Consider traditional wedding songs, names, and proverbs about women, and explore their content and meaning 2) Understand how gender roles and conditioning are reinforced from an early age	▪ Wedding songs, names and proverbs ▪ Girls do's and don'ts
3	Gender Roles	1) Consider the differential work loads and responsibilities of women and men 2) Analyze how much of women's time is devoted to others and how much to themselves	▪ 24 Hours in a Woman's Day: map out hourly activities for a typical day
4	Women's Work	1) Explore the implications of women's heavy workloads on their health and well being 2) Understand the difference between "sex" and "gender" 3) Explore and challenge the notion of "culture" and how it reinforces gender roles and stereotypes	▪ Continued group discussions: 24 hours in a Woman's Day
5	Our Bodies, Our Selves	1) Become more comfortable speaking about the body, sexuality, and women's feelings in relation to these. 2) Explore women's understandings of their bodies, particularly in relation to menstruation and sexual intercourse	▪ Group discussion: defining "womanhood" and what it means to be a woman ▪ Body mapping: menstruation, sexual intercourse
6	Domestic Violence	1) Explore a range of experiences which constitute domestic violence 2) Explore attitudes, beliefs, and experiences of such violence 3) Understand how it is perpetuated, and link this to prior sessions on gender roles and culture	▪ Group discussion: forms of violence experienced or witnessed ▪ Role play: Mother-in-law speaking to daughter-in-law who has been beaten by her husband
7	Gender and HIV	1) Cover basic understanding of HIV/AIDS, including prevention, transmission, and myths 2) Explore reasons why women (especially young women) are at high risk 3) Link social context of women's risk to previous sessions on gender roles, culture, domestic violence	▪ Group discussion: HIV basic information ▪ Trends and statistics: women and HIV ▪ Who is at risk? Discussion of 2 stories
8	Knowledge is Power	1) Introduce VCT and where it is available 2) Prepare women for thinking about VCT, reasons for testing, and fears and concerns 3) Bring home the reality of HIV by speaking to a PWA	▪ VCT demonstration ▪ Visualization exercise: finding out HIV status of yourself or someone you love ▪ Disclosure session: PWA tells her story
9	Empowering Change	1) Explore why negotiating safer sex with a partner is difficult 2) Explore why speaking to youth about sex and HIV is difficult 3) Practice communication skills, and exchange strategies/personal experience	▪ Role play 1: Speaking to your partner about safer sex ▪ Role play 2: Speaking to a young person about sex
10	Way Forward	1) Summarize and link all previous sessions 2) Explore obstacles and opportunities for greater involvement of youth and men 3) Link Phase 1 to upcoming leadership training and Phase 2	▪ Review of previous sessions and appreciation of progress ▪ Group discussions: what can we change? What can't we change? ▪ Next steps and closure

Sisters for Life comprises two substantial and inter-related phases taking place in the context of regular and sustained peer-group contact, and broader community engagement. The *first phase* comprises 10 structured participatory training sessions that are integrated into fortnightly MF repayment meetings over a period of 6 months. These sessions are not one-off exercises, but rather set the stage for addressing a range of relevant topics that are continuously re-visited in the context of participants' everyday experiences. In between sessions, women are given "homework" assignments designed to encourage them to apply and reflect on what they have learned. Many of the skills taught (communication, conflict resolution, solidarity and support) are consistent with SEF's core microfinance principles and are subsequently role-modelled and applied in the context of the loan repayment meetings.

The knowledge and skills covered in the sessions are again re-enforced and applied in the *second phase* of Sisters for Life. "Natural leaders" are elected by their peers to participate in a further one-week training workshop on leadership and community mobilisation. This training refreshes the content and skills addressed in the initial 10 sessions, and further equips natural leaders to work with their loan centres to implement appropriate strategies within their own families and communities. Such strategies are determined by the loan centres themselves, and can range from personal projects (e.g. to communicate more openly with children about sex), to collective actions (e.g. organising a march against domestic violence). During this phase, the facilitators continue to give support to the natural leaders and loan groups,

who by now, represent well-established peer groups. The importance of such community-led peer education and the participation of local stakeholders is emerging as a guiding principle for HIV interventions which seek to go beyond information-giving to engage broader contextual factors such as gender inequalities.[5,27,74,75]

The content and methods used in Sisters for Life were piloted in the context of this specific study, and originate from training approaches and activities that have been applied in both urban and rural settings in South Africa. The first draft of the curriculum, comprising 8 sessions, was piloted with pre-existing SEF centres as well as local women's groups in order to field-test the content and delivery of the training. An evaluation was conducted, involving both the participants and the trainers. Based on this pilot, several changes were made: individual sessions were modified where necessary to conform to the 1-hour time limit; one session was divided into two parts to allow more time for discussion on gender roles and culture; an additional session focusing on the body and sexuality was created to make room for women's many questions and concerns regarding these issues, and "homework" assignments were created to build continuity between the fortnightly sessions and to encourage reflection on how the sessions might relate to ongoing experiences in the women's lives. After further field-testing, the final draft of Sisters for Life - now comprising 10 one-hour sessions - was then edited and compiled into a training manual (submitted alongside this protocol).

The experience gained in South Africa and elsewhere suggests that participatory, group-based training initiatives can challenge the traditional

norms that often inhibit discussion of gender and sexuality in many cultures. This in turn may play an important role in overcoming broader constraints to behaviour change. In a recent ICRW (International Center for Research on Women) review of ten HIV prevention initiatives in eight countries, all of which incorporated a strong gender focus, such peer-based interventions were found to foster critical analysis, collaborative learning, communication skills, problem-solving and peer support. These, in turn, were seen as critical steps in changing social norms – and an important addition to projects that focused on one-on-one educational interactions. The review further concluded that such peer-based initiatives can result in increased knowledge, skills, and social support, all of which are important aspects of empowerment. The report also stressed the importance of locating such interventions within the context of increased access to economic resources and highlighted the need to identify ways of linking group-based HIV prevention efforts to programmes that enhance women's economic and social status.[75]

In summary, recognising that behaviour change does not occur in a vacuum, and that individual decisions are framed within a broader social environment, the IMAGE intervention is designed to interact across multiple levels. Just as microfinance initiatives operate at the level of communities and households, as well as individuals, Sisters for Life attempts to go beyond individual-focused HIV prevention messages, to question and challenge the collective norms, attitudes, and beliefs that often constrain individual behaviour change. Addressing economic vulnerability while simultaneously encouraging groups to question and challenge gender norms, gender-based violence, and taboos

around discussing sexuality, the intervention aims to engage structural factors

that shape vulnerability to HIV/AIDS.

3.   Theoretical Framework and Aim(s)

This study is based on the hypothesis that participation of an individual woman in the IMAGE intervention has the potential to impact her capacity for independent decision making (*agency*). Potential benefits are also hypothesised in terms of household well-being, and intra-household power relations and communication patterns. Cumulatively, through the involvement of a large number of households, it is believed the programme has the potential to impact networks and relationships at community level, to shift community norms around gender and sexual behaviour issues and to stimulate community driven responses to such problems.

This complex set of potential impacts may confer **health-related benefits**. Whilst data are being collected on many aspects of potential impact, and on the context in which the study is being conducted, four specific hypotheses have been identified for detailed examination. These are;

a) that participation in the programme will decrease participants' risk of experiencing intimate partner violence;

b) that co-residence of a person aged 14-35 years with a programme participant will increase their use of condoms in non-spousal relationships;

c) that 14-35 year old residents of communities where the programme operates will,

a. increase their use of condoms in non-spousal relationships, and,

b. experience lower levels of new HIV infection.

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Consequently the **aims** of this study are;

i) to measure the difference in the health related outcomes described above between communities that do and do not have access to the IMAGE intervention;

ii) to thoroughly investigate the processes and causal pathways through which levels of gender-based violence, condom use and HIV infection are promulgated and change over time;

iii) to document the process of implementing the IMAGE intervention.

4.   Study site

The IMAGE study is a community-based trial. The study site comprises eight rural communities in the Sekhukhuneland region of South Africa, on the border of Mpumalanga and Limpopo Provinces. The eight communities encompass approximately 9800 households with a population of approximately 64000. Some population details are held in Table 2.

Table 2 : Population indicators for Sekhukhuneland IMAGE Study Site

Indicator	
Population < 15yrs [+]	45 %
Population > 64 yrs [+]	5 %
Adults with No Education [+]	35 %
Adult Unemployment Rate [+]	24 %
Adult Unemployment Rate (excluding students) [+]	42 %
Households reporting No Cash Income in 1996 [+]	34 %
Households collecting water from a public tap (outside the house / compound) [+]	47 %
HIV prevalence, 2000 (Limpopo Province) *	13%
HIV prevalence, 2000 (Mpumalanga Province) *	30%

[+] Enumeration area data from the 1996 Population Census, supplied by Statistics South Africa, Pretoria.
* South African National HIV Prevalence surveys. Department of Health, South Africa.

The area is characterised by high levels of labour migration (among both sexes) and an unemployment rate in excess of 40%. While ploughing the land remains a survival tactic for many families, few have land or livestock sufficient to depend solely on this for their livelihood.

The communities are served by one hospital and one health centre, while four communities have primary health care clinics situated inside their borders. Six of the study communities are widely electrified, while the remaining two small, inaccessible communities do not have widespread access to electricity. Water supply is one of the most problematic issues in the region. 47% of households report that their main source of water collection is a public tap in the village, with even these supplies being unreliable in many places.

Data on HIV were obtained from the Department of Health national HIV prevalence survey conducted among antenatal clinic attending women. The HIV prevalence in the Sekhukhuneland region among this group was 13.2% in 2000. This figure is similar to the figure for the largely rural Limpopo province. Although the study site borders Mpumalanga, it is likely that the higher HIV prevalence in that province reflects the higher proportion of urban residents. HIV education is largely limited to campaigns in schools and multi-media campaigns. HIV-related services were strengthened in all the local clinics in advance of the start of the IMAGE study. Available services include free condom distribution, the practise of syndromic STD management and the provision of voluntary counselling and rapid testing (VCT) for HIV.

5.   Design of evaluation strategy

The IMAGE study is a matched-community, randomised trial. Both quantitative and qualitative data will be collected before, during and after the implementation of the IMAGE intervention. Matched communities were the units of randomisation for the IMAGE study.

Quantitative data collection is based on following up three different cohorts in the study area (summarised in table 3 below). Exact recruitment criteria are given in Table 4. Data will be collected from individuals at baseline and then after 2 years (cohorts I and II) or 3 years (cohort III).

Table 3 : Three parallel cohorts within the IMAGE Study

Cohort	4 Intervention Communities	4 Comparison Communities	Key Health-related endpoint
I	Women who join IMAGE (direct participants in the intervention)	Women eligible to join IMAGE	a) 12 month experience of intimate partner violence (2 years)
II	People aged 14-35 living in the household of women in cohort I	People aged 14-35 living in the household of women in cohort I	b) Condom use with last non-spousal partner (2 years)
III	People aged 14-35 living in Intervention communities	People aged 14-35 living in Comparison communities	c) Condom use with last non-spousal partner (3 years) d) HIV incidence (3 years)

The qualitative and process assessment broadly adopts the three cohort framework outlined above, and seeks to document processes occurring within

loan groups and centres, in households and in communities that may further illuminate patterns noted in the outcome studies.

In the following sections we provide details of community matching and randomisation (section 6), recruitment (7), end-points (8), data collection and management (9), sample size and precision (10), data analyses (11-13), qualitative and process data collection (14) and strengths and limitations of the study design (15).

6.   Community matching, randomisation and blinding

Intervention was randomised at the level of matched community pair.

A 'community' was defined on the basis of generally accepted community borders. Such borders usually, but not exclusively, represent an area under the control of a single traditional leader (kgoši).

The study communities were matched on the basis of estimated size (small, medium, large) and a qualitative assessment of accessibility (accessible, inaccessible). The communities were then divided into four pairs, and were randomised to be either Intervention or Comparison communities within these pairs. The four pairs were small, inaccessible (1 pair); medium, accessible (2); large, accessible (1).

The names of the two matched communities within each pair were written on pieces of paper and folded up. These were then put in a bag, and one paper was blindly drawn from the bag. The name drawn was assigned as an

intervention community. The randomisation procedure was conducted in April 2001. All laboratory analyses will be performed blind as to which communities the samples come from. It was not possible to blind communities or the interviewer teams from allocation of the intervention.

There was no "placebo" or "usual standard of care" intervention in control communities. However, the IMAGE work was initiated within a South African Department of Health/WHO TB/HIV pilot programme – known as ProTEST. As one of four such sites in the country, the pilot accelerated the delivery of TB/HIV services within the public health sector – including access to voluntary counselling and testing services, improved prevention and management of opportunistic infections, and referral networks to more specialized care at secondary hospitals.

Prior to the initiation of the IMAGE study, there was a substantial effort to ensure the different components of the ProTEST initiative were in place and operational in all study villages. This included training more than 40 health workers in 12 clinics and providing ongoing mentorship and support, including the provision of ongoing mentorship and in-service training and the establishment of support groups over a 2-year period following the training. Ensuring this package of HIV services was running smoothly was a basic minimum before initiating the IMAGE work. There were no pre-existing clinical HIV services at the primary care level prior to initiating the work, and many areas of the province still remain without access to such services.

Extensive efforts were also made to ensure a package of information and HIV prevention material was made available to research subjects equally in all

communities involved in the IMAGE work. All research staff underwent a one-month training period prior to being involved in any field work. This included a 40 hour in-depth module on HIV/AIDS which included one-to-one counselling with the option of undergoing HIV testing. Research staff were trained to respond accurately to common questions posed by community members during the conduct of research. In addition, a structured HIV information session was undertaken at the end of each interview, and each respondent received a package of condoms.

While oral specimens collected for HIV were anonymous, voluntary counselling and testing was discussed with each participant in the research at the end of the interview. They were notified that VCT with the opportunity to receive same-day results was now available in the local community and a list of alternative clinics in other villages was provided on request.

The study team also felt the need to generate guidelines for a structured response for field staff encountering difficult social circumstances in the homes that they visited. In response to this, an inventory of local support services was compiled with the contact details of relevant community-based and institutional actors including the police, the local social worker, and relevant NGOs in the area. The list was given to research participants who required it, along with advice on whom to contact.

These procedures were formalized at the start of the research and are contained in the document "Field Worker Training Manual" under Young Persons Interview Closure (p72) and Ethical and Safety Issues (p75). This is available at www.wits.ac.za/radar, and is submitted alongside this protocol.

7.   Recruitment, inclusion criteria and individual matching

Generating a sample frame

A sampling frame comprising all households in all eight study communities was generated using Participatory Wealth Ranking (PWR). This involves community members drawing maps of their communities, generating lists of all households and assigning a relative wealth rank to all households to identify the poorest households. It is these 'poorest' households that are eligible to join IMAGE. This process is described in detail elsewhere.[76] The output of this process – which includes a list and computerised database of all households in the eight study communities, with a relative wealth rank and unique identifier number linked to a map – was central to recruitment procedures.

Recruitment to the IMAGE intervention

Recruitment to TCP is co-ordinated by a locally based fieldworker who visits the poorest (eligible) households within Intervention communities, as defined by PWR, and invites women to join the programme. Interested women are requested to get together with other women they trust to form a loan group of five women. The local fieldworker then begins a four-week process of group training and recognition before these women are eligible to receive loans.

Recruitment to the IMAGE evaluation

The inclusion and matching criteria, and recruitment procedures to both intervention and comparison cohorts are provided in detail in Table 4. The aim in each case is to assemble two comparable cohorts of individuals, one from intervention communities, the other from comparison communities.

Table 4 : Recruitment procedures to three parallel cohort studies for the IMAGE study

	'Intervention' Group	Recruitment within Intervention communities		Recruitment within comparison communities	
		Inclusion criteria	Recruitment procedure	Inclusion criteria	Recruitment procedure
Cohort I	Loan recipients	Joining the IMAGE programme	All consenting women joining the programme during a 15 month recruitment period will be interviewed *after* official recognition as a TCP group member, but *before* receiving a loan.	Female, Eligible to receive microfinance loan and residing in an IMAGE Comparison community. *Matching* : Matched on community pair, and age group (18-25, 26-35, 36-45, 46-55, 56+) to the index IMAGE participant.	When an IMAGE participant is enrolled, contemporaneously a household eligible to receive TCP loans and from the matched community-pair will be randomly identified from the sample frame using a computer. This household will be visited, and if there is a currently resident female in the same age group as the index loan recipient residing in the household she will be invited to join the study. If more than one potential match resides in the household, one woman is randomly selected on the spot, and invited to join the study. If no age-matched female is found, the next house on the household list is visited. This continues until a suitable respondent is found to seek consent from.
Cohort II	People in the households of loan recipients	14-35 years old at time of interview. Current residence* in the household of a woman who joins the IMAGE programme.	Consent for interview and sample collection will be sought from all 14-35 year olds currently residing in the household.	14-35 years old at time of interview. Current residence* in the household of the non-IMAGE participant selected for inclusion in Study I.	Consent for interview and sample collection will be sought from all 14-35 year olds currently residing in the household.
Cohort III	People in communities where IMAGE is operating	14-35 years old at time of interview. Household member* in a community where IMAGE is operating.	200 Households randomly selected from all Intervention communities. Consent for interview and sample collection will be sought from all 14-35 year olds, listed as household members.	14-35 years old at time of interview. Household member* in an IMAGE study community where IMAGE is not operating.	200 Households randomly selected from all comparison communities. Consent for interview and sample collection will be sought from all 14-35 year olds listed as household members.

* 'Current residence' denotes being listed as a household member AND also currently sleeping at home. 'Household members' are listed on the household roster but may also currently be sleeping away from the home.

8.   Health related endpoint(s) and follow up

Primary health-related endpoints for each cohort study have been identified.

Table 5 : Primary health related endpoints for three cohorts within the IMAGE Study

Study	Key Health Related Endpoints	Follow up
Cohort I	a) 12 month experience of intimate partner violence	End Year 2
Cohort II	b) Condom use with last non-spousal partner	End Year 2
Cohort III	c) Condom use with last non-spousal partner d) HIV incidence	End Year 3

The method to be used in assessment of these endpoints is given in detail below.

a) 12 month experience of IPV

Questions on the occurrence of IPV are to be asked in accordance with international guidelines for the collection of data on violence against women through survey methodology.[77,78] Guidelines seek to limit reporting biases, and put an emphasis on the safety of both respondents and interviewers in the process. In the IMAGE surveys, privacy and confidentiality will be guaranteed, while leading terms such as "abuse", "violence" and "rape" will be avoided. All interviews will be conducted by women from the local communities, in local languages, after an extensive period of training, and all will be trained in referral mechanisms.

Questions to be asked are based on those used in the recent WHO Multi-Country Study on Women's Health and Domestic Violence against Women. Specifically;

"I want you to tell me if any of the following things have happened to you with a sexual partner or spouse …

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?"

Each question will be asked for the time period 'Ever', and 'In the last 12 months'. A positive answer to a) or b) for the last 12 months at two-year follow up is taken to indicate "current" physical violence. A positive answer to c) or d) for the last 12 months at two-year follow up is taken to indicate "current" sexual violence. A positive answer to any of the above questions for the last 12 months, when asked at two-year follow up, is the primary health related outcome measure among IMAGE participants.

b) and c) Condom use with last non-spousal partner

As for questions on violence as outlined above, there are widely accepted guidelines available for asking questions on sexual behaviour[79,80]. In IMAGE data collection confidentiality is stressed throughout the interview process,

and the importance of honesty is discussed with the respondent. Interviews are conducted in a private place, and at a time, chosen by the respondent. Female interviewers will conduct all survey interviews in the IMAGE study, and interviewer training will ensure that they are sensitive to the needs and problems of respondents.

Condom use with non-spousal sexual partners is a key behavioural surveillance variable. In the IMAGE study respondents will be asked the following questions.

"How many of your partners in the last 12 months were Sexual partners that you are not married to and have never lived with?"[a]

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 sex with this person?"

The binary outcome of use / non-use of a condom the last time (within 1 year) individuals had sexual intercourse with a non-spousal partner, asked at follow up, will be the primary sexual behaviour outcome measure for two cohort pairs (Cohort II & III). Follow up is at Year 2 for Cohort II, and Year 3 for Cohort III.

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[a] An inconsistency has been noted during the review process for this protocol. In fact data is to be collected on **all partners** in the past 12 months. The manual states that "All the partners they will have had will fall into one of the two following categories .. Spouse - someone the respondent is married to, or living with as though they were married, or Non spouse – anyone else the respondent has had sex with." The emphasis in our protocol incorrectly emphasises that these non-spousal partners will never have been lived with, but in practise, we feel our data collection system is designed to capture all currently non-spousal partners.

d) HIV incidence

Oral Fluid Samples for the assessment of HIV status will be collected using the OraSure collection device at both baseline and follow up visits. Samples are then transported to the laboratory within 21 days of collection.

Qualitative determination of antibodies to Human Immunodeficiency Virus (HIV) type 1 and/ or 2 (anti-HIV-1, anti-HIV-2 and anti-HIV-1 group O) from collected samples will be performed with the Vironostika HIV Uni-Form II. In this procedure, the OraSure specimen vial is centrifuged and specimen is eluted from the collection pad. The eluate is diluted and added to the microelisa wells. Each microelisa well contains a horseradish peroxidase-labelled conjugate sphere of the same HIV-antigen mixture. Test samples are then incubated in the microelisa wells. With the presence of antibodies to HIV-1, HIV-2 or HIV-1-group 0 a solid phase antigen/anti-HIV/enzyme labelled antigen complex is formed. Following a wash procedure and incubation with substrate, colour develops which turns yellow when the reaction is stopped with sulfuric acid. If anti-HIV-1, anti-HIV-2 and/or anti-HIV-1 group 0 is present in the sample, an intense colour develops. However, when the sample is free of anti-HIV-1, no or low colour forms with the addition of substrate.

Oral fluid systems for detection of HIV are highly sensitive and specific[81] and have been used in Southern Africa for large scale studies.[82] The OraSure HIV-1 Oral Specimen Collection Device has been licensed by the U.S. Food and Drug Administration (FDA) for collection of oral fluid specimens when used alongside the Oral Fluid Vironostika HIV-1 Microelisa System, since

1994 (http://www.fda.gov/bbs/topics/NEWS/NEW00503.html) and is intended for use in subjects 13 years and older. Best available estimates of the sensitivity and specificity of the device / assay combination come from studies conducted in the U.S. and in Trinidad and Tobago. These studies report figures for both sensitivity and specificity in excess of 99%, from well-conducted studies with 673 and 474 true positive results respectively.[83,84] There remains a dearth of good data on this device / assay combination from sub-Saharan or South Africa and for use of the device under field conditions. Despite this, the technology has recently been used for a number of nationwide HIV prevalence surveys in South Africa. Along with other investigators in South Africa, we were attracted to using this device by its ease of use in the field, the relatively lower problems of perceptions of witchcraft/stigma associated with the collection of oral fluid over urine or blood in rural areas, the flexibility in its storage and transit, and the reports of high sensitivity and specificity associated with the device / assay combination.

We are not aware of any previous attempts to use this technology for the measurement of HIV incidence in a community randomised trial. Cumulative three-year HIV incidence will be the main biological outcome measure to be used among people aged 14-35 years from communities involved in the study (Cohort III).

9.   Quantitative Data Collection and Management

Survey tools will be used to collect data on primary outcome measures and on additional variables that may be considered contextual variables, potential confounders or potential pathway variables. See Appendix 1-3 for the primary survey data collection tools.

Data will be entered to and stored in purpose built Microsoft Access Databases. All questionnaires will be visually checked at least three times before data entry. After data entry, rigorous data cleaning procedures will be applied with reference to source data to solve inconsistencies wherever appropriate. Data backups are to be taken weekly on CD. All analyses will be performed on data that has been *de-linked* from source data through the removal of any text or unique identifier variables.

HIV test results are to be stored on a database at a laboratory in Johannesburg. No personal information is held in this file – only a code number. The code number links to a code number that is on the questionnaire of the individual. The individual young person questionnaire does not contain names of the participant. HIV sample results are not held to be in the office where questionnaires are held.

The individual questionnaire code number does refer to a household questionnaire that contains the name of the individual, and to a map that can be used by trained individuals to locate the person's household. Before any data is made available for analysis all data will be fully "de-linked". This process will remove all text from all computer databases, and exchange all code numbers for random numbers that do not link to any names or maps.

Data need to re-link the databases to maps and names will be held on a CD that is held under lock and key at two sites, both away from the site where fieldwork is based and where "hard-copy" questionnaires are held.

10.   Sample size and Precision

Community randomised trials require the definition of sample size at two levels – at the level of randomisation (communities), and at the level of data collection (individuals).

Sample sizes for the IMAGE study were decided on based on a combination of pragmatic and theoretical considerations. The ultimate aim was to conduct the highest powered study deemed to be feasible given resource constraints in terms of finance, time, expertise and institutional buy in for a research programme from a target driven microfinance organisation.

Community level

Four communities per arm (Total = 8), randomised within four matched pairs.

Individual level

Projected sample sizes for individuals to be enrolled within each of the three cohort studies are given in Table 5.

Table 5 : Projected enrolled sample sizes for three cohorts within the IMAGE Study

	N	
	Intervention communities	Comparison communities
Cohort I	450	450
Cohort II	750	750
Cohort III	1500	1500

Precision Estimates

The expected final sample sizes to be included in impact analyses on the key health related endpoints for the IMAGE study, details of the hypothesised effect sizes, and estimates of the precision with which effect sizes (presented in the form of risk differences) will be reported in the final IMAGE analyses are presented in Table 6. We see the value of this study more in terms of its provision of unbiased impact estimates rather than as a set of hypothesis tests. Therefore we provide estimated confidence intervals (range of likely values for the true effect) for a range of possible observed effects, rather than power calculations.

In a community randomised trial, the precision of estimations is based on the number of communities included in the study, the number of individuals within each community included and the size of the *intraclass correlation coefficient* (k or rho). Reported data on intraclass correlation coefficients for outcomes are rare, and thus a wide range of values for k has been provided. We expect

the value of k to be low (< 0.1) for condom use, and highest for HIV incidence which is known to cluster by community. Values of k for HIV prevalence / incidence from previous community randomised trials have varied from 0.16-0.49.[85]

Table 6: Estimated final sample size, details of calculations and precision estimates for effect sizes from the IMAGE Study

Cohort	Endpoint	Estimated final average sample size per community	Estimated Prevalence of endpoint measure		Effect Estimate	Estimate of precision of risk difference (95% Confidence Interval)			
			Control arm	Intervention arm	Risk Difference	k=0.1	k=0.2	k=0.3	K = 0.4
I	12 month experience of intimate partner violence	90 [based on estimated 20% loss to follow up]	10%	5%	5%	**0.0%-10.0%**	*-0.5%-10.5%[+]*	*-1.3%-11.3%[+]*	*-2.3%-12.3%[+]*
			10%	7%	3%	*-2.3%-8.3%[+]*	*-2.9%-8.9%[+]*	*-3.8%-9.8%[+]*	*-4.9%-10.9%[+]*
			5%	2.5%	2.5%	*-1.0%-6.0%[+]*	*-1.2%-6.2%[+]*	*-1.5%-6.5%[+]*	*-1.9%-6.9%[+]*
			5%	3.3%	1.7%	*-2.0%-5.4%[+]*	*-2.2%-5.5%[+]*	*-2.6%-6.0%[+]*	*-3.0%-6.4%[+]*
II	Condom use with last non-spousal partner during last year	98 [based on estimated 65% having a non spousal partner in last year, and 20% loss to follow up]	30%	60%	30%	**18.3%-41.7%**	**11.6%-48.4%**	**4.0%-56%**	*-3.9%-63.9%[+]*
			30%	50%	20%	**9.0%-31.0%**	**3.4 %-36.6%**	*-3.0%-43.0%[+]*	*-9.8%-49.8%[+]*
			30%	40%	10%	*-0.3%-20.3%[+]*	*-4.8%-24.8%[+]*	*-10.2%-30.2%[+]*	*-15.9%-35.9%[+]*
III	Condom use with last non-spousal partner during last year	195 [based on estimated 65% having a non spousal partner in last year, and 20% loss to follow up]	30%	60%	30%	**19.9%-40.1%**	**12.5%-46.5%**	**4.7%-55.3%**	*-3.4%-63.4%[+]*
			30%	50%	20%	**10.7%-29.3%**	**4.5 %-35.4%**	*-2.2%-42.2%[+]*	*-9.2%-49.2%[+]*
			30%	40%	10%	*-1.5%-18.5%[+]*	*-3.6%-23.6%[+]*	*-9.3%-29.3%[+]*	*-15.2%-35.2%[+]*
III	3yr cumulative HIV seroconversion	240 [based on estimated 10% HIV prevalence at baseline, 10% refusal rate and 20% loss to follow up]	6%	3%	3%	**0.5%-5.5%**	**0.2%-5.8%**	*-0.04%-6.4%[+]*	*-1.0%-7.1%[+]*
			6%	4.5%	1.5%	*-1.1%-4.1%[+]*	*-1.6%-4.6%[+]*	*-2.2%-5.2%[+]*	*-2.9%-5.9%[+]*
			3%	1.5%	1.5%	*-0.2%-3.2%[+]*	*-0.3%-3.3%[+]*	*-0.6%-3.6%[+]*	*-0.8%-3.8%[+]*
			3%	2.1%	0.9%	*-0.9%-2.7%[+]*	*-1.1%-2.9%[+]*	*-1.3%-3.1%[+]*	*-1.6%-3.4%[+]*

* Based on estimations of the variance of between community differences when an unpaired t-test is used for final analysis, on the basis of calculations provided by Hayes & Bennet (1999)[29].

[+] Figures in italics represent situations when the study would not find a statistically significant difference between Intervention and Comparison groups.

11.   Data analysis

Our approach to the primary statistical analysis of defined health-related outcomes in this protocol will be a two stage procedure, based on the basic principles for the analysis of cluster randomised trials as outlined by Donner and Klar.[86] The specific approach will be similar to that used in the Mwanza HIV prevention trial,[2] with modifications suggested in subsequent literature to maximise the statistical power while retaining the study's validity, in particular the use of an unpaired analysis.[87]

Each outcome defined in this protocol is binary at the level of the individual. At the cohort level, this binary outcome can be captured as a marker of cumulative risk (HIV seroconversion) or period prevalence (12 month experience of gender based violence or condom use at last sex with a non-spousal partner). The analytic procedure will be the same for each binary outcome variable.

The first stage will generate unadjusted results and will follow these steps;

- The proportion of individuals experiencing a positive outcome will be calculated for each outcome variable in each cohort for each village.

- The geometric mean of this figure will be calculated for Intervention and Comparison villages, and a point estimate summary risk / period prevalence ratio measure will be calculated as the ratio of these two figures.

- An unpaired t-test will be used to compare the logarithms of the risk / period prevalence figures and generate a statistical test of significance

for the comparison between intervention and comparison groups. A nonparametic test will be conducted to assess the robustness of the results

- 95% Confidence intervals will be calculated for the risk / period prevalence ratio on the basis of the cluster level variance.

The second stage of the analytic process will generate an adjusted risk / period prevalence ratio for each of the outcome measures, using the following steps;

- An individual level binary logistic regression model will be fitted in which the dependent variable is the binary outcome measure of interest, and independent variables include terms for a series of factors measured at baseline thought to be possible confounders (age, sex etc).

- This logistic regression model will be used to calculate the expected (E) number of individuals experiencing the outcome in each village.

- For each village the ratio of the observed (O) to expected (E) number of individuals experiencing the outcome will be calculated (O/E).

- The geometric mean of this O/E value will be calculated to generate a point estimate of the adjusted risk / period prevalence ratio.

- An unpaired t-test will be used to compare the logarithms of this O/E ratio between intervention and control groups, and appropriate 95%

confidence intervals will be constructed. A nonparametric test will be conducted to assess the robustness of the result.

We expect to report these results as the main outcome measures in the main outcomes paper. Further data analysis will be completed as required, and may include adjustments of effect for loss to follow up as has been reported elsewhere if this is deemed appropriate.[88]

12.   Subgroup and further data analysis

The result from a significance test on primary outcome variables will provide an important contribution to an understanding of IMAGE. Nevertheless, a broad portfolio of explanatory analyses on both baseline and follow up data is expected. Frameworks to guide analysis of data on process and mechanism of action will be developed. Such analyses will be framework driven, iterative and will use qualitative data to generate hypotheses to be explored in the quantitative data set. Such analyses will aim to contribute to a further understanding of both context and causality. These secondary or pathway outcomes will be analysed in a similar way to those outlined above.

13.   Stopping rules, interim analyses and data monitoring

No stopping rules, and no interim analyses are planned for the IMAGE study. There is no independent data monitoring committee.

14.   Qualitative and process data collection and analysis

The primary process modules are outlined in brief below.

IMAGE Attendance and TCP Monitoring

Attendance registers will be kept at all IMAGE sessions to quantify "exposure" to the intervention. Additionally, routine information collected by TCP will be integrated to the data collection systems. This includes details of business location, type and value, and loan size and repayment over the course of multiple loan cycles.

Sisters for Life Monitoring

In-depth monitoring of the process of implementation of SfL will occur within four loan centres. Data are to be collected in the form of flipcharts produced within training sessions, pre-designed report forms describing observed discussions, and semi-structured notes taken by a recorder during each session. After each training session a reflection meeting will be held with all trainers and a researcher, to analyse and describe information ready for transcription. Additionally, an end-term focus group meeting conducted by an external facilitator will allow IMAGE clients to review and discuss their own feelings about the sessions and possible impacts on perceptions and behaviour. The monitoring process will continue into the community mobilisation phase to capture the plans, discussions, progress and obstacles to this stage.

Key informants

Key informants will be identified from the Sisters for Life monitoring sessions. Ongoing participatory observation will be conducted within key loan groups and within the households of individuals from those groups. Using an ethnographic multi-methodological approach, data will be collected in field notes and recording of in-depth interviews, both of which will be transcribed for analysis.

PRA project with young people

Groups of young people will be formed within intervention communities. The process for this will be to identify an 'index' young person living in an IMAGE household and to encourage this person to recruit friends to join the group (a 'snowball' method'). Each group will comprise up to ten young people from both IMAGE and non-IMAGE households, and will meet regularly for interactive workshops.

In keeping with a participatory approach, participants will themselves collectively select topics of interest for the workshops. It is expected, however, that discussions will broadly cover the following areas:

  (1) Sources and content of information on sex

  (2) Communication with others on sexuality, relationships, and sexual health

  (3) Peer and family networks

  (4) Gender roles and expectations

(5) Relationships: hopes, perceptions, realities

(6) Perceptions of sexual health, local priorities, and health seeking

behaviour

A set of three introductory workshops will initiate the process and address sources of sexual information and communication available to young people; local priorities in reproductive health as perceived by participants; and differences between men and women in expectations and behaviour related to sexual relationships. Subsequent activities will be designed to reflect and further investigate issues raised during the introductory phase, and to document any changes occurring over time.

Data will be recorded in the format of field notes, flipcharts produced by participants, and synthesis reports for each type of workshop. In addition, workshops will be complemented with in-depth interviews with young people identified as "key informants" through workshops. These will be transcribed for analysis.

Community profiling

An ethnographic approach will be employed in the gathering of data on community context. A multi-methodological strategy will be employed, including in-depth interviews with local leaders, employers and civil society groups, and the construction of ongoing "village event" timelines and an extensive literature review.

15.   Strengths, limitations and interpretation of the IMAGE Study

The IMAGE study is a unique attempt to use rigorous evaluatory methodology that seeks to minimise bias in both selection of participants and collection of data, and to integrate this with an extensive process evaluation, to provide important lessons on the potential for a complex structural intervention to play a role in the prevention of gender-based violence and HIV infection.

The design of the IMAGE study has been carefully constructed with reference to limitations and strengths of previous research. Attention has been paid to issues of recall bias, selection bias and interviewer bias. Furthermore, the study aims to capture the complete impact of the programme by following up all women who enrol and capturing "diffusion" effects in the community at large. To our knowledge this comprehensive design is unmatched elsewhere in assessments of microfinance programmes. Most importantly, the study will add a new and important contribution to both the poverty alleviation and HIV prevention literatures through its examination of both issues together.

Nevertheless, there are limitations to the design of the programme reported. Firstly, impact will be measured after a maximum of only three years, so only changes that occur within this period will be captured. Secondly, longitudinal cohort studies traditionally suffer from problems related to cohort attrition, which are of particular relevance among a highly mobile population. It is likely that a significant number of study recruits will be lost to follow up over the three year programme operation, both decreasing statistical power and introducing bias since those who are lost to follow up often differ importantly from those who are not. Thirdly, as with many randomised trials of community

level interventions, the number of communities randomised in this study is low. Consequently, the study has relatively low precision with which it can estimate the effect size, particularly if effect sizes are small and / or the level of clustering of primary outcomes is high. Fourthly, the potential exists for a contamination effect to confound the results of the study. Such an effect occurs if impacts of the intervention are also felt in the comparison villages. Some of the IMAGE study villages are quite close to each other and this proximity of villages will need to be considered when interpreting outcomes, since changes in the behaviour of sexual partners from outside the participants own village (and perhaps in a differently allocated village) will impact the risk of infection of study participants. Fifthly, there remains the potential for there to be self-selection bias in the study, since it is likely that women who join a microfinance programme such as that being offered in this study differ in important ways from women who are eligible for, but do not join, such a programme.

Nevertheless, the study is the first use of a cluster randomised design to assess the impact of a microfinance intervention on any outcome. It is particularly ambitious as we are examining health as our primary outcomes as well as a whole range of variables (quantitative and qualitative) to capture possible pathways of action of the intervention. In settling on a design for the IMAGE study, research rigour had to be balanced not only against the usual time and resource constraints but against the difficulties of motivating a target-driven microfinance NGO to implement their programme in a manner conducive to research. Within these limitations we chose to implement a high coverage, high quality intervention alongside a detailed evaluation within a

small number of villages, four, per arm. The care taken with the implementation of intervention and it's random allocation will result in extremely useful unbiased estimates of impact even if the confidence intervals do not allow for conclusions about a significant effect or lack of effect. The study further provides a platform for an evolving evaluation of process that will provide additional information for policy makers on the mechanism of action and the feasibility, accessibility, acceptability and transferability of the strategy. As such it has the potential to produce a number of research outputs over the coming years, each of which will need to be considered alongside the others.

The validity, feasibility, generalisability and utility of randomised controlled trials of complex interventions should be considered.[89] The results from such trials can provide valid information and in this case it was feasible to randomly allocate the intervention to four communities. We would recommend care in generalising the results of this work and attempts to standardise the intervention described here for use in different contexts. We would advocate that the utility of the trial will come from an integrated analysis of data on outcomes and process, alongside a careful consideration of context.

16.   Informed consent procedures

Community agreement was obtained for involvement with the study in consultations with leadership groups in all eight communities prior to the start of the study. Liaison groups will be formed and feedback sessions organised to maintain ongoing channels of communication between researchers and the study communities.

Throughout the study individual level consent will be sought for engagement in any interview or sample collection process. In this context where literacy is not complete, consent will be given orally in response to a statement read to the potential research volunteer. A statement confirming that consent has been given is then signed by the interviewer. The consent statement will be read after the interviewer is satisfied that the volunteer has had the chance to ask any questions and fully understands the procedures to which they are consenting.

This informed consent process was designed to meet the needs of the diverse groups of people involved in the research in a uniform way. A standardized procedure is used to introduce the study to participating households, who are encouraged to interact and ask questions. Participants will then undergo a formal informed consent process where they are read a structured consent sheet, and have the opportunity to read it themselves if they choose to. The interview proceeds only once full informed consent has been obtained, and respondents are able to stop the interview at any time. These procedures are documented in the "Field Worker Training Manual" p.16-17

After the interview process, research subjects eligible for HIV testing will undergo a separate information session pertaining to the confidential anonymous oral specimen collection. This is followed by another formal consent procedure where the researcher reads the consent form and documents that verbal consent has been obtained. This process will take place in the local language, with subjects given the opportunity to read through the material if they are able. These procedures are documented in the

"Field Worker Training Manual" p.67 as outlined above. Field research staff undergo periodic monitoring using supervised interviews, with a particular emphasis on ensuring this consent process is adhered to.

The reasons for the oral consent process are several. First, literacy is a profound issue in the area – even amongst those who have attended school. This factor has been well acknowledged by the local ethical review committees (University of the Witwatersrand) and as such, 'witnessed consents' are an accepted alternative in such areas. In addition, within participating households several interviews are to be conducted with different household members, with each questionnaire requiring its own consent process - some with older individuals clearly unable to sign informed consent, and others with adults as young as 14 years old. Maintaining uniformity in the consent process is important to avoid confusion amongst research subjects and in this context, having a different consent procedures for the oral specimens alone was felt to unduly prejudice this component of the research.

Finally, in the context of the IMAGE Study adhering to the principles of informed consent will involve ensuring that a field manual is generated to create a protocol from these procedures, that field research staff are well trained and supervised, that the integrity of the process is maintained throughout, and that this is properly documented in each individual case.

17.   Informed consent forms and information sheets

See Appendix.

18.   Ethical approval

The study has been approved by ethical committees at both the University of the Witwatersrand, South Africa (Protocol Number M991108, approved 31/01/00), and the London School of Hygiene and Tropical Medicine (Reference number 598, approved 06/09/00).

In addition to those highlighted throughout this protocol, we highlight here a number of specific ethical issues that were considered prior to the initiation of the study.

Community advisory board;

The importance of community liaison cannot be overemphasized as a core component of community-based research. A number of efforts are to be undertaken by the IMAGE study team to ensure this happens effectively in the study area. This includes;

- Extensive meetings with leadership structures in all of the 8 villages to gather support for the programme prior to starting the research – both elected civic structures and traditional leadership. We have maintained contact with such structures throughout the research programme.

- Establishment of a more formal Community Liaison Group [this has occurred during 2003] comprising 2 members from each of 8 study communities. This group is brought together for a 40 hour training session which includes basic HIV/AIDS related information, the nature of the intervention and the purpose of the research. Following this, the Community Liaison Group provides a link between the IMAGE research team and the communities in which it operates. To date, they have

been involved in numerous activities around the conduct and dissemination of the work including the following.

- Facilitating the distribution of materials (in both English and local languages) describing progress in the study to key stakeholders in the villages.

- Contributing to a booklet entitled "Learning about HIV/AIDS and poverty in Sekhukhuneland", highlighting the baseline findings of the study, which was widely distributed

- Working with the IMAGE team in performing 'research feedback events' – using song, dance and drama, with the opportunity for a question and answer period, which were conducted in the local language in area study villages.

Rollout to control communities

A critical ethical imperative is that the provision of microfinance services be made available to all study villages at the end of the study period. The current planned expansion is to roll-out the full IMAGE intervention, including the training component, to comparison villages and to other villages in the Sekhukhuneland area beginning in the last quarter of 2004.

19. Partner Organisations

Rural AIDS and Development Action Research Programme (RADAR)

RADAR is a division of the School of Public Health, University of the Witwatersrand, Johannesburg with links to the London School of Hygiene and Tropical Medicine. RADAR is a programme of intervention research, encompassing both the clinical and social dimensions of HIV/AIDS, with the intent of developing model approaches to addressing the epidemic in rural African settings. Recent work has included involvement in the WHO ProTest initiative, through training and monitoring for VCT and clinical services for HIV/AIDS administered at the primary health care level in Limpopo Province, South Africa. RADAR is the lead partner in the ongoing IMAGE study.

RADAR is responsible for the design and implementation of Sisters for Life, and for all aspects of study design, data collection, data management, data analysis and reporting.

Small Enterprise Foundation (SEF)

SEF is a microfinance NGO operating in the South Africa's Limpopo Province. It started operating in 1992, disbursing small loans for micro-enterprises owned by poor women. It presently has over 16 000 active members.

Many of SEF's clients are those looking to expand small businesses, and therefore come from the ranks of the non-poor. The organization also has a poverty-focused initiative called the Tšhomišano Credit Project (TCP). It is this TCP programme that forms the basis for the microcredit component of the IMAGE Study.

SEF is responsible for the implementation of TCP for the current project. A SEF/RADAR joint management committee is responsible for dealing with all day-to-day aspects of the partnership.

London School of Hygiene and Tropical Medicine (LSHTM)

LSHTM is a UK-based public health institution that has been a core partner in the IMAGE Study since its inception. Through the Clinical Research Unit, Infectious Disease Epidemiology Unit, and Health Policy Unit, the collaboration brings together substantial interdisciplinary expertise to facilitate the design, implementation, evaluation and dissemination of this research.

National Health Laboratory Service (NHLS)

The Contract Laboratory Service (CLS) of the National Health Laboratory Service (NHLS) and the University of the Witwatersrand is based at the Johannesburg General Hospital. NHLS is an amalgamation of the National Institute of Virology, the South African Institute for Medical Research and the Provincial Laboratory Service. It is responsible for all public sector laboratory services in South Africa. The CLS coordinates lab services for the conduct of clinical and public health research in the country.

The CLS oversees the processing and quality control of all biological specimens collected as part of the IMAGE Study.

20.   Sponsors

Henry J. Kaiser Family Foundation is a US-based foundation that has been supporting the University of the Witwatersand in rural South Africa since the mid 1980s. Its current focus in the country is large scale HIV prevention programmes, including a large social marketing campaign called Love-life.

The Kaiser Foundation currently supports North-South collaboration between LSTHM and WITS University for all aspects of RADAR's clinical and social intervention research.

Department of Health (DOH), South Africa: The DOH at National and Provincial levels has been supporting RADAR's activities since 1998 through the ProTEST initiative – a 4–site pilot programme to develop operational models for the expansion of clinical services for HIV and TB in diverse area of the South Africa. In 1999, the DOH encouraged ProTEST sites to expand their approach to prevention, care and support to include a dimension of poverty alleviation in areas most in need.

Support from the DOH has been critical to establishing voluntary counselling and testing services in all clinical facilities in the region prior to commencing the IMAGE intervention. It also provides core support for the microfinance component of the IMAGE intervention.

Department for International Development (DFID), UK: The Microfinance Summit has set a target for the microfinance industry of enrolling 100 million of the world's poorest by the year 2005. Microfinance is felt to be an important component of DFID's sustainable livelihood strategy for better addressing the

needs of the poor in reaching their stated goal of poverty eradication. The Enterprise Development Innovation Fund of DFID was set up to explore innovative approaches to or applications of microfinance within diverse contexts.

DFID provides support for the evaluation of the IMAGE study and assists technical collaboration between LSTHM and WITS.

Ford Foundation: The mission of the Ford Foudation is to strengthen democratic values, reduce poverty and injustice, promote international collaboration, and advance human achievement. Ford supports over a dozen HIV-related prevention and mitigation programmes throughout sub-Saharan Africa.

The Ford Foundation's support for the IMAGE Study centres around the development of the Sister's for Life gender awareness and HIV intervention programme, dissemination of research results, and nurturing effective collaboration between LSHTM and WITS.

21.   Timeline

A full timeline for field activities is provided in the Appendix.

Data Collection Completion Date : December 2004

Reporting Date : December 2005

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Appendices

(see Attached Zip File)

1. Household Questionnaire

   - Collects data on household membership and socio-economic factors on all households of individuals included in Cohorts I, II and III.

2. Young Person Questionnaire

   - Collects data on communication, attitudes, sexual behaviour on all 14-35 year olds included in Cohorts II and III.

3. Senior Female Questionnaire

   - Collects data on agency and community norms, groups etc. on all individuals included in Cohort I.

4. Informed consent statement for HH interview

5. Informed consent statement for YP interview

6. Informed consent statement for SF interview

7. Informed consent statement for collection of Oral Fluid

8. Time Line 2001 – 2004

9. Sisters for Life Training Manual

10. Letter of support on informed consent procedures from Professor Cleaton Jones, Wits University.