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Empowerment for positive living: Evaluating the impact of a microfinance intervention on clinical, economic, and behavioral outcomes among people living with human immunodeficiency virus (HIV) in Uganda

Submission date
08/07/2013

Recruitment status
No longer recruiting

Registration date
24/09/2013

Overall study status
Completed

Last Edited
02/09/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) affects all aspects of family life, including household economics, food security, relationships, school participation and survival. Microfinance (provision of financial services such as loans, savings, insurance and training to people living in poverty) has been called the most important economic intervention of the twenty-first century in the fight against poverty. The linkage between HIV /AIDS and poverty has highlighted the need to evaluate microfinance interventions as a possible tool in managing the HIV/AIDS epidemic.
We are carrying out a study of Ugandans living with HIV to assess if microfinance can improve patients quality of life, clinical outcomes, household investment and livelihood security outcomes.

Who can participate?
This study aims to recruit 2000 Ugandan men and women ≥ 18 years who are currently accessing care at The AIDS Support Organization, the largest community-based AIDS organization in Africa and currently providing clinical care and antiretroviral therapy to more than 100,000 HIV+ patients.

What does the study involve?
The Empowerment for Positive Living (EPL) cash grant intervention will provide cash transfers of 350,000 Ugandan shillings (about $130 USD) to about 1500 clients over a two-year period. The beneficiaries will be active TASO clients (HIV-positive individuals) living in two rural areas of Uganda, Masindi and Soroti.
Individual clients will be randomly allocated to one of four groups, each group containing about 500 clients:
1. In the unstructured grant group, clients are told that they have been chosen to receive a cash

grant to improve their overall welfare, but they are not given any guidance on how the money should be spent. Recipients learn about enrollment in the program through individual notification, and grants are distributed at a subsequent meeting that will take place at the TASO Masindi and Soroti Centers.
2. In the grant + planning group, recipients are told that they have been chosen to receive a grant to improve their overall welfare. Counselors then follow a script which guides a discussion of ways to budget their money and plan the optimal use of their cash grant, One week later, clients complete the second portion of this mental planning component, which revisits their previous discussion and reviews the clients plan, and then receive the grant.
3. Clients in the pure control group do not receive a cash grant. They continue to have their regular meetings with TASO counselors throughout the project, but do not receive any cash grant.
4. Clients in the control expectations group do not receive a cash grant in the first year of the project, and continue with their regular meetings with TASO counselors. However, they are told that they will be phased in about a year later, after the first round of cash grants is completed. However they are told that they will receive the cash grant about a year later, after the first round of cash grants are administered to the other arms.

What are the possible benefits and risks of participating?
The intervention has no effect on the participants regular access to care and treatment. For those randomized to the microfinance arm, potential benefits include financial management training and income generation. There are no anticipated risks for participants or their households.

Where is the study run from?
This study will recruit participants who are accessing care from TASO Masindi and TASO Soroti, in Uganda.

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in August 2013 and participants will be enrolled in the study for 2 years.

Who is funding the study?
Canadian Institute for Health Research (CIHR).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Microfinance opportunities to improve quality of life and clinical outcomes among HIV+ patients in Africa: A randomized trial

Study objectives
This study is designed to evaluate whether receiving a microfinance grant of approximately $130 USD per person improves clinical, economic, and behavioral outcomes among people living with HIV in Uganda. It is hypothesized that participants who receive a microfinance grant will have better health and economic outcomes compared to those without microfinance grants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Innovations for Poverty Action, 02 May 2013
The AIDS Support Organization, 23 Jan 2013
University of Ottawa, Canada, 05 Sep 2013

Primary study design
Interventional

Study design
Open-label multi-site randomized trial with blinded analysis

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
HIV / AIDS

Interventions
The Empowerment for Positive Living (EPL) cash grant intervention will provide cash transfers of 350,000 Ugandan shillings (approximately $130 USD) to approximately 1500 clients over a two-year period. The beneficiaries will be active TASO clients, and hence HIV+ individuals, living in two rural areas of Uganda, Masindi and Soroti.

Individual clients will be randomly assigned to one of four arms, each containing approximately 500 clients:
1. In the unstructured grant (UG) treatment, clients are told that they have been chosen to receive a cash grant to improve their overall welfare, but they are not given any guidance on how the money should be spent. Recipients learn about enrollment in the program through individual notification, and grants are distributed at a subsequent meeting that will take place at

the TASO Masindi and Soroti Centers.
2. In the grant + planning (GP) treatment, recipients are told that they have been chosen to receive a grant to improve their overall welfare, and counselors then follow a script which guides a discussion of ways to budget their money and plan the optimal use of their cash grant, likely temptations and social pressures that might lead them to misuse the money, and strategies making sure the grant is used effectively. One week later, clients complete the second portion of this mental planning component, which revisits their previous discussion and reviews the clients plan, and then receive the grant.
3. Clients in the pure control (PC) group do not receive a cash grant. They continue to have their regular meetings with TASO counselors throughout the project, but do not receive any infusion of capital.
4. Clients in the control expectations (CE) group do not receive a cash grant in the first year of the project, and continue with their regular meetings with TASO counselors. However, they are told that they will be phased in approximately a year later, after the first round of cash grants is completed.

The total duration of the intervention is 2 years, follow-up for all arms will be 2 years.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Quality of Life will be measured using the culturally adapted version of the Medical Outcomes Study (MOS-HIV) tool. Two summary scores will be calculated: the physical health summary (PHS) and the mental health summary (MHS) scores.
2. HIV RNA viral load is a surrogate marker of whether drug treatment is working by suppressing the virus. It is commonly understood as a surrogate of being adherent to treatment and may indicate treatment failure. Viral load will be measured using standard HIV RNA measurement (threshold <400 copies ml).

Outcomes measured at baseline and two years later at end line.

Key secondary outcome(s)
1. Household food security: We will measure household access to sufficient nutrition using the Household Hunger Scale, which was developed by the Food and Nutrition Technical Assistance Project (FANTA) project by adapting the nine-item Household Food Insecurity Access Scale (HFIAS) for cross-cultural use.
2. Household income and expenditures: We will collect detailed income and expense information from the respondents every two weeks upon grant receipt, as well as 12 months after grant receipt.
3. Savings and asset accumulation: We will assess the rate savings and asset accumulation for each recipient according to amount saved at 12 months after receiving the grant. The tool we will use considers savings in terms of both cash savings and acquired household items, including animals.
4. Time allocation: Detailed time use data will be collected during the baseline, and every two weeks upon grant receipt, as well as 12 months after grant receipt.
5. Sexual Behaviour: We will assess sexual behavior using the Joint Clinical Research Centre (JCRC, Uganda) Sexual behaviour questionnaire, developed for use specifically with HIV+

patients. The questionnaire inquires of number and types of sexual partners, condom use with different partners and at the last sexual intercourse respectively in the previous 6 months, as well as disclosure of HIV status to sexual partners.
6. CD4 T-cell changes: We will assess CD4 T-cell changes, as a function of immune status using TASO clinic attendance and laboratory readings.
7. Healthcare interruption and retention: We will assess retention in the antioretroviral therapy (ART) program according to whether the patient has attended any TASO clinical appointment in the previous 4 months and survey questions on adherence to medication in the 3 days before the survey occurrence.
8. Attendance of household children in school: Attendance of eligible children (i.e. all children aged 5-17) in school programs will be based on a detailed household child roster that will include information on grade completed for each child, current school attendance, and the type of school (government or private) attended.

Completion date
01/08/2015

Eligibility

Key inclusion criteria
1. Men and women aged ≥ 18 years
2. Current clients at The AIDS Support Organization (TASO)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/08/2013

Date of final enrolment
01/08/2015

Locations

Countries of recruitment

Canada

Uganda

Study participating centre
25 University Private, Rm 212
Ottawa
Canada
K1N6N5

Sponsor information

Organisation
Canadian Institutes of Health Research (Canada)

ROR
https://ror.org/01gavpb45

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (Canada)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary