Efficacy of Social Self-Value Package to Improve Empowerment and Quality of Life among People Living With HIV under Antiretroviral Treatment in Nepal: A Randomized Controlled Trial

Dharma Nand Bhatta

A Thesis Submitted in Partial Fulfillment of the Requirements for the Degree of Doctor of Philosophy in Epidemiology (International Program)

Prince of Songkla University

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ABSTRACT

Background

Empowerment is a means of dealing with troubles of relatively incapable peoples and by mediating the role susceptibility plays in making and facilitating social anxieties. It is a cost effective response to enhance individuals in the societal system. It helps to achieve structural factors including political, environmental, economic and social obstacles. Social self-value package was the empowerment intervention, an education program that targeted on autonomy, self-esteem, self-care, social and family adjustment, and human and health right. The primary aim of this study was to assess the effectiveness of the intervention to improve empowerment and quality of life among people living with HIV. Secondary aim was to examine the reduction in stigma and improvement in social support.

Methodology

Open label, parallel, randomized controlled trial was conducted at the antiretroviral treatment (ART) center of Nepal from September 2014 to June 2015. HIV infected participants receiving ART from six to twenty four months, and was aged 18 years and above, were randomly assigned to receive either control or intervention group. Allocation concealment was done by using sequentially numbered opaque sealed envelopes. Six weeks intervention was led by two public health professionals. Face-to-face interview was carried out to collect data among 132 (intervention n = 66 and control n = 66) participants and was followed up at 3- and 6-months after the baseline. Feasibility and acceptability of the intervention was measured by using both qualitative and quantitative techniques. Significant

differences within the group by time were analyzed using appropriate tests included chi-square or Fisher exact test or Wilcoxon signed-rank test. Mean score within the group by time for empowerment, QoL, stigma and social support was measured. Effectiveness of the intervention package was analyzed using Difference in Difference (DiD) and mixed-effect non-linear regression.

Results

Among 1447 screened HIV infected people, 66 were taken for intervention and tested intervention acceptability between September and November 2014. For the acceptability, mean age of the participants was 36.4 years, 47% were female, and 30.3% had higher secondary and above level education. Significant change was found between pre- and post-test score of attitude towards HIV related issues in each session. Participants' acceptability and satisfaction reveals higher after the end of the all sessions. Qualitative approach detected similar findings from both participants and counselors.

At the baseline mean age of the participants was 36.1 (SD = 7.8) years, 47% were male, 43.9% were indigenous, and 71.2% had primary to higher level of education. More than half of participants diagnosed with HIV before their 33 birthdays and majority were infected through sexual contact. Baseline demographic and clinical characteristics were not significantly different in control and intervention group. The mean scores of empowerment, QoL and social support were increased and the stigma score was reduced in the intervention group compared to the control group at 3- and 6- months. An intervention effect was significantly increased in empowerment, QoL and social support and reduced in stigma scores by time in intervention group. No unfavorable events were detected during study period.

Conclusion

Social self-value intervention package was found to be acceptable and effective to improve empowerment, QoL, social support and reduce stigma.

Key words: *HIV; AIDS; ART; quality of life; intervention; randomized*

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LIST OF ABBREVIATIONS AND SYMBOLS

HIV	Human Immunodeficiency Virus
AIDS	Acquired Immune Deficiency Syndrome
PLH	People Living with HIV
QoL	Quality of LIFe
ART	Antiretroviral Therapy
HAART	Highly Active Antiretroviral Therapy
ARV	Antiretroviral
IDUs	Injecting Drug Users
WHO	World Health Organization
VDCs	Village Development Committees
MSM	Men Who Have Sex with Men
MTCs	Male Sex Worker Transgender and their Clients
FSW	Female Sex Worker
PWIDs	People Who Inject Drugs
TB	Tuberculosis
CHBC	Community and Home Based Care
PMTCT	Prevention of Mother to Child Transmission
NRTIs	Nucleoside Reverse Transcriptase Inhibitors
NNRTIs	Non-Nucleoside Reverse Transcriptase Inhibitors
PI	Protease Inhibitor
USA	United States of America
RCT	Randomized Controlled Trial
PRSP	Poverty Reduction Strategy Paper

CHAPTER I

INTRODUCTION

1. Background

1.1 Study background

HIV infection is a global public health concern. Although national and international strategies and actions have been integrated to prevent and control transmission worldwide, in 2012, total 35.3 million were HIV infected of which new HIV infection were 2.3 millions. In the same time South and South East Asia was estimated 3.9 (2.9-5.2) millions of HIV infected people. Antiretroviral therapy (ART) is well-known to be the best evidence-based intervention to prevent deaths attributed to HIV. In 2012, 10.6 million diagnosed with HIV received ART and total 92% were received in low and middle income countries.[1-3] People living with HIV (PLH) faces the problems of stigma, fear of death, loss of opportunities, disclosure, sexual behavior, treatment, social support, quality of life (QoL), and physical health, multiple behavioral and mental health.[4-11] In Nepal, there were an estimated 50,200 PLH by the end of 2011 and the national HIV prevalence in the general population was 0.3%.[12]

At present, the combination of ART, highly active antiretroviral therapy (HAART), that included three or more types of drugs are suggested worldwide for the viral load suppression. For adolescents and adults, first line regimes of the ART are d4T/3TC/NVP, ZDV/3TC/NVP, TDF/3TC/EFV, d4T/3TC/EFV, ZDV/3TC/EFV and TDF/3TC/NVP. When the first line treatment was failed the second line treatment includes ZDF + 3TC + LVP/r and TDF + 3TC + LVP/r were suggested.[13] Since 2004, HAART has been implemented to all HIV infected people in Nepal free-of-charge. Up to July 2013, a total of 22,994 HIV infections were reported and 8,544 patients received ART. Although ART coverage has been increased from 10% (2007) to 24% (2011), the coverage is still low.[12] The probability of survival has been increase with the access of ART. Study form South Africa revealed that the life expectancy from 49.2 years in 2003 to 60.5 years in 2011.[14] Other study reported that the probability of survival increased 0.84 at 2 years and 0.81 at 3 years. The median

time among death and enrollment was 9.1 months.[15] Death was recorded more within first three months and the risk factors for death were similar before and after three month. Increased in adherence has good result on survival, improved CD4 and viral load.[16-18] However, treatment resistance and drug toxicity of ART has been reported that might change the treatment choices.[15-17]

After ART era, the problem of death has been changed to problem of living with chronic status. As a result, the issues of HIV related health and QoL are becoming a life time problems with the new remedies and prevention strategies.[19-25] In addition, factors of age, marital status, occupation, female, ethnicity, IDUs, low education and income or economic status, family relation, low CD4 count, number of children, stigma, disclosure and ART were also associated with QoL among PLH.[26-37] Stigma, fear of death, loss of opportunities, disclosure, sexual behavior, treatment and social support were shown to be related to quality of life (QoL), physical health, multiple behavioral and mental health. In order to make the holistic care to PLH, not only ART but also improvement of QoL is important. However, these problems are interlinked thus the intervention implemented should be integrated. The empowerment is the crucial and cost-effective key concept to improve QoL, service access and psychological states.

Intervention could be beneficial for empowerment to increase prevention and treatment adherences.[38] Empowerment can play crucial role to change their role and knowledge to improve quality of life without enforce and dictate, but with increased responsibilities.[39, 40] Social and gender disparities, dependencies and poverties are key confronts to HIV prevention.[41] However, recent findings reveal that the HIV/AIDS is linked with social evolution and is called disease of disparity instead of disease of poverty.[41, 42] Empowerment is a main notion to improve good QoL, mental health, and well being of PLH through improved communication and social relations.[43-45] Ample education about HIV/AIDS is the practical instrument for empowerment of PLH where cultural and other barriers for prevention.[46] Study suggests that physical symptoms, ART, psychological well-being, social support, coping strategies, spiritual wellbeing are the important predictors of QoL and other

strongly associated factors with QoL was the different stages of the disease, and infections.[47]

To address these issues, justifiable objective of corrective behavior change and intervention for empowerment programs had significant development of QoL for risk population.[48, 49] Finding reveals that the PLH has inadequate social support and it has been associated with different factors including QoL, immune function, coping approaches, management of disease and enhanced mental health.[50, 51] There is numerous benefits of social support have been documented.[51-53] Stigma associated with HIV and AIDS has difficult concept with its epidemic and key obstacle in the prevention as well in treatment.[54] It was thought that the enhanced ART has the possible to reduce stigma but still there is dread to the determination of stigma.[55] Stigma is associated with different factors including gender, family and social relation, loss the family face, disclosure, self-efficacy, adherence, social support, QoL, health care satisfaction, and coping strategy.[56-59] Multidimensional approaches involving social learning theory and Buddhism philosophy to induce self-value is essential for empowerment development. This can enhance better quality of life, and positive aspects on stigma and social support.[60]

Empowerment is a way of dealing with problems of comparatively immobilized populations (PLH) and by arbitrating the role helplessness plays in making and enabling social anxieties and protects health and human rights. Center for disease control (CDC) defined as a QoL is an individual's wellbeing including all physical, psychological, social, spiritual and environmental aspects of the individual's life may be impacted over time by a disease, a disability, or a disorder. Stigma is an undesirable or discrediting characteristic that an individual possesses, thus reducing that individual's status in the eyes of society.

1.2 Study setting background

Nepal is located in the South Asia as a landlocked sovereign state and currently is a "Federal Democratic Republican". Total population is approximately 27 million and total area is 147,181 KM^2. It is landlocked by China in the north side Himalayan borderer and by India in the east, west and south border (Figure 1). Capital of the Nepal is Kathmandu, has largest population. An annual population growth rate

is 1.35%. Currently constitution has developed six autonomous provinces and before it has development regions (5), zones (14), and districts (75). In the district level there are metropolitan, municipality and village development committees (VDCs). VDCs are the first government administrative points and some district has municipalities. All the VDCs have nine wards or villages. The capital city of Nepal, Kathmandu has 1.5 million populations. Based on 2010 World Health Organization (WHO) data, Nepal ranked 139 in the life expectancy in 2010 with the average Nepalese living to 65.8 years.[61]

Figure 1 Maps of Nepal

The Nepal Ministry of Health and Population estimated that there were 50,200 people are HIV infected in Nepal in 2011 and national HIV prevalence was 0.3 for the people of 15-49 years).[62, 63] The distribution of infection were among the age 0-14 years was 3805 (7.6%), among the age from 15 years and above was 46,484 (92.4%) and age above 50 years was 3,246 (6.5%). Among the infected people, 66.5% were male and 33.5% were female. In addition, infection was accounted by men who have sex with men (MSMs), male labor migrants, transgender and client, injecting drug users (IDUs), clients of female sex workers (FSWs), and female sex workers (FSWs) with 27.0%, 14.0%, 7.2%, 4.4%, 2.2% and 1.5% respectively.[12] Those risk groups considered as a crucial connecting peoples for the transmission of HIV among general and vulnerable populations.[62]

Initiation of the treatment services for HIV infected people in Nepal was started from 2004 (February) with the aim of improving morbidity and mortality of HIV, develop the strategies or service delivery improvements and use. The ART,

clinical and medical checkup, regular TB-HIV screening, treatment and prevention services are available with the free of charge. Another trained community and home-based care (CHBC) workers provide home and community based services that focused good relation, reduced in discrimination and stigma, support hygiene and sanitation, and regular ART services. Additionally, nutritional, legal, psychological, medical support offered by CHBC, and monetary support is supplied to newly infected patients at ART centers.[64, 65] Although, the coverage of ART among HIV infected people is low and currently 24% are receiving the ART in the country.[66, 67]

Five out of 44 ART and six out of 62 prevention of maternal to child transmission (PMTCT) service sites are situated in Kathmandu. Another eighteen CD4 counts and caliber sites are established in different district in Nepal. Total 22,994 HIV infection was reported up to July 2013 and among them male is 14,560 female is 8408 and transgender is 26. Total 8,544 patients are taking ART among them male are 4546, female are 3972 and transgender is 26.[62, 66]

2. Literature Review

Review of the literature are based on the following: standard definitions; applied study designs and methods of individual studies; magnitude of the HIV in global and local; public health benefits, ART availability, positive and negative effects of the ART; QoL of PLH and the determinants and available interventions; empowerment in HIV issues and interventions; stigma in HIV and interventions; and social support in HIV issues and interventions.

2.1 Magnitude of HIV

Combat to HIV is a benchmark of millennium development goal (MDGs 6), which needs to be achieved in 2015. However, in 2012, around 75 million peoples have become infected with HIV from the beginning of the epidemic. An estimated 35.3 million globally (2.3 million new infection) and 3.9 million from Asia and Pacific were found infected with HIV (Figure 2).[1]

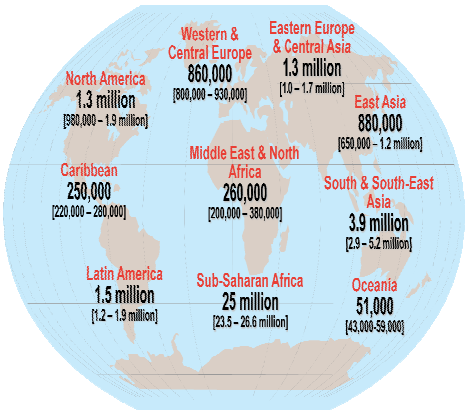


Figure 2 Global HIV estimation report 2013

Overwhelming target includes 50% reductions in both sexual and drug-related HIV and the transmission; elimination of new HIV infections among children; reaching 15 million people with HIV treatment, mobilizing US$ 22–24 billion for HIV programs; elimination of stigma and discrimination, gender inequalities and restrictions on entry, stay and residence; and integrating HIV with other health and development efforts.[3] Very hard to achieves by all the countries especially from developing countries without multiple efforts.

Global trend of total HIV infection, access of treatment and resources has been in increasing trend and new HIV infection and AIDS related death has been in decreasing trends (Table 1).[2]

Table 1 Global trends of HIV, treatment and resources

Year	PLH Total (million)	New HIV infection total (million)	New infection (adults) (million)	New infection (children)	AIDS related deaths (million)	People accessing treatment (ART) (million)	Resources US dollar (billion)
2001	30.0	3.4	2.8	550,000	1.9		
2002	31.0	3.3	2.7	560,000	2.1		3.8
2003	31.7	3.1	2.6	560,000	2.2		4.6
2004	32.2	3.0	2.4	550,000	2.3		5.7
2005	32.5	2.9	2.3	540,000	2.3	1.3	7.4
2006	32.8	2.8	2.3	520,000	2.3	2.0	8.8
2007	33.2	2.7	2.2	480,000	2.2	2.9	10.5
2008	33.5	2.6	2.2	450,000	2.1	4.1	14.6
2009	34.0	2.6	2.2	400,000	2.0	5.3	15.5
2010	34.4	2.5	2.2	360,000	1.9	6.6	15.6
2011	34.9	2.5	2.2	310,000	1.8	8.1	17.1
2012	35.3	2.3	2.0	260,000	1.6	9.7	18.9

There was an estimation of 350,000 (220 000–550 000) new HIV infections in Asia and the Pacific in 2012, a decline of 26% since 2001. The overall national prevalence of HIV in most countries in Asia and the Pacific remains low. The overall numbers of new infections have remained largely unchanged. However, into large size of the regional population there are a large numbers of people living with HIV. Emerging epidemics are becoming evident in a number of countries. For

example, between 2001 and 2012, new HIV infections increased 2.6 times in Indonesia; Pakistan has seen an eight-fold increase and new infections in the Philippines have more than doubled and Malaysia has also in increasing trend. Remaining eight countries shows in decreasing in HIV infection. The number of HIV infection has increased among various countries (Table 2).[68]

Table 2 Twelve countries with highest HIV burden and new HIV infection trends

	HIV Estimated 2012	
India	2,100,000	Estimated 2011
China	780,000	Estimated 2011
Indonesia	610,000	
Thailand	450,000	
Vietnam	260,000	
Myanmar	200,000	
Pakistan	87,000	
Malaysia	82,000	
Cambodia	76,000	
Nepal	49,000	
Papua New Guinea	25,000	
Philippines	15,000	
12 Countries total	**4,734,000**	

Figure 3 shows the HIV prevalence Nepal in 2012. The Nepal Ministry of Health and Population estimates that there were 50,200 people living with HIV (PLH) in Nepal by the end of 2011 and national HIV prevalence was 0.3 per).[62, 63] The distribution of infection were 3,805 among children in the 0-14 year's age group (7.6%), 46,484 among adults 15 years and above (92.4%) and 3,246 among people over the age of 50 years (6.5%).

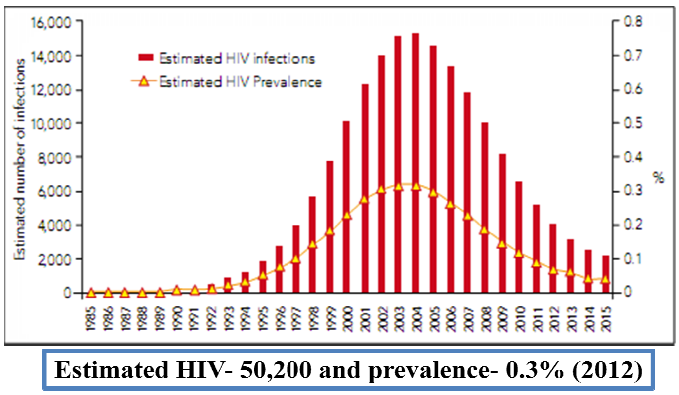


Figure 3 Estimated HIV prevalence Nepal, 2012

2.2 Antiretroviral therapy and its effect

PLH could be prevent from AIDS death through early starting of ART and reduce opportunistic infections such as tuberculosis. World Health Organization (WHO) has been formulated HIV treatment guidelines that recommend starting treatment immediately for all HIV infected people including pregnant women, HIV-positive partners in sero-discordant couples, children younger than five and people with HIV associated tuberculosis and Hepatitis B. However, there is still lack of ART supply and challenges to get it for all the PLH.[1-3] Standard regimen for ART has been developed by WHO for different stage and conditions. First-line ART should consist of two nucleoside reverse transcriptase inhibitors (NRTIs) plus a non-nucleoside reverse-transcriptase inhibitor (NNRTI). First line regimen for adult is recommended by WHO; TDF+3TC (or FTC) + EFV as a fixed dose combination is recommended as the preferred option to initiate ART (strong recommendation, moderate-quality evidence). If TDF+3TC (or FTC) + EFV is contraindicated or not available, one of the following options is recommended: AZT+3TC+EFV, AZT+3TC+NVP, TDF+3TC (or FTC) + NVP. First line regimens should discontinue d4T because of its well-recognized metabolic toxicities. Second-line ART for adults should consist of two nucleoside reverse-transcriptase inhibitors (NRTIs) + a ritonavir-boosted protease inhibitor (PI). Third-line regimens should include new drugs with minimal risk of cross-resistance to previously used regimens, such as integrate inhibitors and second-generation NNRTIs and PIs.[2, 3]

Around 9.7 million people in low and middle income countries were receiving antiretroviral therapy in 2012 (Table 1). This represents the 34% coverage of ART under the 2013 WHO guidelines and 28.6 million people are eligible for ART in 2013. Around 875,000 people from developed countries receiving antiretroviral therapy and total 10.6 million people were receiving antiretroviral therapy in 2012. It is clear that the estimated 35.3 million PLH need to treatment to combat new HIV.[1-3] There are numerous challenges to continuous adherence, available facilities, infrastructure with its advantages and disadvantages.

Government of Nepal has developed the HIV treatment guidelines based on the WHO guidelines. At present, three or more ARV drugs are recommended worldwide for the treatment of PLH. The first line ART regimens in adults and adolescent are ZDV/3TC/NVP, ZDV/3TC/EFV, d4T/3TC/NVP, d4T/3TC/EFV, TDF/3TC/NVP, and TDF/3TC/EFV. The second line regimens in adults and adolescent are TDF + 3TC + LVP/r and ZDF + 3TC + LVP/r, when the treatment failure, the second line is recommended.[13] There is hope for survival and longevity of the life but with the ARV drugs have multiple side effects. There are still various challenges to cope with ARV drugs including treatment monitoring, adherence and drug level monitoring which will affect the QoL among PLH.

Study has been revealed that the probability of survival has increased with the access of ART among PLH. Various studies had established increased probability or life expectancy. However, efficacy of the adherence is crucial to increase survival. Probability of the death has been recorded higher within the first three months and the risk factor for death remains same as late stage also. CD4 count, ART adherence, viral load and clinical stage have significant relationship. Most of result is in agreement with large scaled follow up study has revealed increased survival rate. Increase ART show the improvement of CD4 count and improved clinical stage. In the other hand, ARV drug has significant toxicity, resistance and adverse effect is vital problem to increase and continuity for adherence in PLH (Table 3).

Table 3 Benefits and effect of ART

Author/Year	**Method**	**Result**	**Critical appraisal**
Cohen MS et al. (2011)[18]	Quantitative study (countries: Botswana, Malawi, South Africa, Kenya, Zimbabwe, Brazil, India, Thailand, USA)	ART has established to reduce in transmission of HIV which has clinical benefit for both HIV infected and their uninfected sexual partners. It helps to increase on CD4 count and CD4 count will present the better health condition.	The article covers the different regions of the world and only covers serodiscordant.
Bor J et al. (2013)[14]	Qualitative study (South Africa)	Life expectancy was improved after ignition of ART. Adult life expectancy in 2003 was 49.2 years; by 2011, adult life expectancy had amplified to 60.5 years, and gained 11.3 years. Lower the risk of death.	This study examined the life expectancy after long time follow up (2000-2011).
Laurent C et al. (2005)[15]	Prospective observational cohort study (Senegalese, France)	Survival probability was found higher after ART. Efficacy of ART for viral load was found 22.5 to 23.0 $\log^{10}$ copies/ml and the median CD4 count rose with 225 cells/mm^3. The emergence of the drug resistance was relatively rare (12.5%).	Very small sample size and short duration follow up period.
Stringer JSA et al. (2006)[16]	Open cohort evaluation study (Zambia)	Death rate was higher within 90 days of starting ART (early mortality rate: 26 per 100 patient-years), and lower after 90	Follow up information taken with short time.

		days (post-90-day mortality rate: 5.0 per 100 patient-years). Mortality was high with low CD4 and greater clinical stage. Long time treatment has significant progress in CD4 count.	
Bhatta L et al. (2013)[17]	Retrospective cohort study (Nepal)	Mortality is higher before three month (21.9 per 100 person-years) and lower in later stage. Probability of survival is based on the duration of ART.	Information was analyzed with long time follow up.

The survey conducted in Thailand showed the evidence of benefit from ART among family. ART helped to improve expenses of family, reduce negative attitude of community reduce the worry of health, improve the family continue contribution and psychological support. However, uncertainty of cure of HIV remains psychological distress and help only postponed the epidemic.[69] However the study was based on convenient sampling and was not able to establish the spread of ART and consequence in relation with epidemic. A cross-sectional study from Thailand among PLH indentified benefit of ART. Adherence to ART and disclosure were significantly but modestly associated with each other.[31] This study used baseline data of randomized controlled trial, fail to establish the causal relationship, and adherence to ART measurement was weak.

A qualitative study from China highlighted the disclosure problem and consequences of HIV infection. Disclosure of HIV status has both positive and negative effects and is a complicated issue, as well as challenged for family members. Positive impact of disclosure includes strengthening family relations, help in medical care and counseling; and negative impact includes fear, isolation, avoidance and psychological burden.[70] This study has a small number of participants that conducted within specific groups of population. Systematic review from developing countries

including 15 sub-Saharan Africa and two from South-east Asia revealed that there was variation on HIV disclosure. Fear of being rejection, unfaithful, violence, partner's reaction, blame, unfaithfulness, frighten partner, family conflicts, discrimination, separation, confidentiality, social isolation, divorce, stigma were the most common barriers of disclosure of HIV. Educated women shared results with their partners more often than illiterate women; younger age was associated with higher disclosure rate.[71] These all the studies were failing to cover all the population and based on only female population. Mostly the disclosure information has been taken only with sexual partner.

A cohort study from United States of America (USA) highlighted the stress among PLH for their disclosure. Study revealed that how participants appraised disclosure, whether disclosure was experienced as stressful, and whether disclosure or nondisclosure functioned as a way of coping with an HIV diagnosis.[72] Sample was taken as newly infected and inexperienced participant could not mention on better way for their disclosure process. Most of the HIV patients disclose their status with HIV positive sex partners than negative and others. Disclosers feel more likely to think they had accountability to disclose and had more unprotected sexual activity than non-disclosers. Impact of disclosure is varying with the context to context and has developed positive and negative emotional consequences. Ironically, participatory action research from Ghana revealed non-disclosure attitude hamper the treatment and supports provided by family; and encouraging disclosure with trusted environment will help to reduce stigma.[73] This study focused only qualitative nature of the information and based on female population.

2.3 Quality of life of PLH and determinants

HIV might not only influence the physical well being of a human being but also the overall quality of life (QoL) of those PLH. The evaluation of QoL is vital to thoughtful how people's lives are exaggerated by HIV. It assists to assess the human and financial costs and benefits of new programs and interventions, and could be used to monitor and evaluate different programs. At the personal level, QoL evaluation can assist health care providers in planning of interventions in the area where QoL is a vital problem.

Among the various definition of QoL, center for disease control (CDC) defined as “how the individual’s wellbeing including all physical, psychological, social, spiritual and environmental aspects of the individual’s life may be impacted over time by a disease, a disability, or a disorder”. The World Health Organization (WHO) defined QoL “as an individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns”.[74, 75]

Some issues have been aroused nearby the dimension and evaluation of QoL of PLH and AIDS and need to discuss the assets of appropriate instruments. Various studies used different scales to measure QoL. Subjective measures has appraised of published articles. Very few scales were found theoretically complete in terms of the scope obtainable for evaluation among several scales those were developed to assess QoL of PLH. Most of the tools have been developed and tested primarily in a single culture and from developed countries. As a result, little is identified about the QoL of those living in developing countries where required for culture sensitive QoL tools is presently the utmost. It is also unclear as to how applicable the translations of such tools might be for the majority of PLH that live in developing countries with greatly dissimilar cultures and unparalleled health resources.[74, 76] In this background WHO group has been developed the WHOQOL-HIV instruments for assessing QoL of people under HIV infection. Recently WHOQOL-HIV instrument has been developed with methodological appropriateness with cross-cultural settings.[77] This tool could be valid on different settings and can translate on different language. In addition of WHOQoL-HIV, most of the scales were developed in USA (Table 4).

Table 4 Tools for measure of QoL of PLH

Author (Year)	**Tools**
Wu et al. (1997)	MOS-HIV
Lubeck et al. (1997)	AIDS-HAQ
Holmes et al. (1997)	HAT-QoL

Leplege et al. (1997)	HIV-QL31
Lenderking et al. (1997)	Self-assessment for general health
Smith et al. (1997)	MQoL-HIV- multi-dimensional QoL questionnaire for HIV/AIDS

Cross-section studies conducted in USA and Nepal revealed similar findings that age, sex, ethnicity, IDUs, low education and income, and CD4 count were found associated factors with lower QoL among PLH. However, ART was not associated with QoL of PLH.[32, 33] Other cross-sectional studies from India also in agreement with this finding that the education, income, occupation, family support and clinical status found to be significant factors for QoL and female gender had lower scores in role performance and psychosocial functioning domains.[34, 35, 78, 79] Similarly, cross section study from Croatia revealed the QOL was determined by education, income, sex, occupation, marital status, age, family support and clinical categories of the patients. There was no gender difference in CD4 counts or use of antiretroviral therapy.[80] Cross-section study from Bangladesh has similar findings that low QoL among PLH associated with education, CD4 count, urban residence, employment, and young age. Interestingly the QoL was found higher among women than men.[81] Other cross-section study from Brazil revealed the similar findings that income and employment was associated with QoL.[82] Contradictorily ART was not associated with QoL where CD4 count was associated with QoL among PLH. This might be happen due to adverse effect of the ART and toxicity of the drugs. Chronic nature and incurable worry might be the other related factor to reduce QoL. However, all the study findings are based on cross-sectional information and low sample size with week sampling techniques. It could not establish the causal relationship. However, the QoL among PLH has been reported low.

A study conducted in China revealed high level of QoL among parents living with HIV with their children. Number of children in the family was negatively associated with the overall QoL. Disclosure of HIV status to other people were more likely to report a higher level of QoL than those who did not disclose.[36] Study sample

has been recruited based on referral and advertisement. Result may not be generalizable because the sample size was small and the causal relation was not established with study design. Study subject was parents so the information might be influenced with their family perspective. Another descriptive study from India revealed the social relationship and environment domain were highly influenced by social support. ART had a significant independent positive influence on the physical domain. Younger age, female gender, rural background, shorter duration of HIV, non-intake of ART, non-disclosure, non-peer counseling, and greater HIV related stigma were the high risk factors of poor QOL and higher social support has higher QoL. Education, per capita income and marital status did not influence QOL.[37] Study was based on descriptive measures of QoL and could not establish the relationship with other variables.

Randomized controlled trial (RCT) form USA revealed the QoL is significantly better among the ART taking patient, when the adherence is sustained and QoL increased with 12 months follow-up. Antiviral adherence level is associated with QoL. If the adherence will reached up to 80%, statistical significant will be improved with QoL.[28] Study itself realizes that the self-reported adherence measurement was not good even though the association has been established between virological and immunological outcomes. This study did not highlight the impact of toxicity and adverse effect of drug in QoL. Study from Thailand analyze the baseline data of randomized controlled trial revealed the QoL was positively correlated with social support, education and income.[83] This study information was collected from care giver of PLH. Findings highlighted by the relationship path but could not establish the causal pathways. Different intervention was applied in different countries to improve QoL. Those interventions includes cognitive behavioral stress management (CBSB), psycho-education, mantram intervention, yoga intervention, transcendental meditation, mindfulness-based stress reduction (MBSR), self-care symptom management strategies, aerobic, exercise, and peer support. Most commonly followed theories were social-cognitive model of behavioral change, social action theory, diffusion model of innovation, Freire's pedagogy, Buddhism philosophy, and psychoneuroimmunology theory.

Study suggests that physical symptoms, ART, psychological well-being, social support, coping strategies, spiritual wellbeing and psychiatric conditions are the important predictors of QoL. Socio-demographic characteristics, such as age, gender, education, income employment status and disease related variables such as disease stage, opportunistic infection, CD4 count etc have been found to be strongly associated with the QoL of PLH.

2.4 Empowerment and HIV

World Health Organization's Alma Ata Declaration (1978) first expressed the goals of community contribution and equity, with following addition to empowerment in the Ottawa Charter and Jakarta health promotion declarations.[45] The carrying jointly of health with social and economic growth has been a comparatively current phenomenon, with the 2000 United Nations MDGs, which incorporated women's empowerment and health interventions, the World Bank's Strategic Framework and poverty reduction strategy (PRSP), which recognized empowerment of poor people as one of two priority strategies to improve development efficiency.[84] WHO health promotion strategies have explained community action and empowerment as requisites for health. Empowerment strategies therefore mean challenging control and social injustice, through political, social, and psychological processes that uncover the mechanisms of control, the institutional or structural barriers, the cultural norms and social biases, and therefore enable people to challenge internalized oppression and to develop new representations of reality. Empowerment can be seen as a dynamic interplay between gaining greater internal control or capacity (personal transformation/psychological empowerment) and overcoming external structural barriers to accessing resources (community or institutional transformations).[45]

Empowerment is a complex issue and broad term which defined with various ways. Several studies have been used the word empowerment but did not define how it used and merely give accurate definition and measurement. Kabeer highlighted important methodological points and defined as, "the ability to make strategic choices where that ability did not previously exist".[85] Further other highlights in empowerment is "the process which resources (not only financial and

creative property but also chances, abilities, community associations and other environmental factors) and organization, or the capability to perform in one's own attention". It is also believed as being multi dimensional, occurring in social, economic, legal and political dimensions.[86]

According to Zimmerman, empowerment may be viewed on different levels: individual, organizational or community. These levels are closely linked. In empowered communities, empowered organizations exist, and an empowered organization is reliant on the empowerment levels of its members. Empowerment definition has addressed three components; first, individual empowerment (upward individual awareness and assurance to tackle domination); second, relational empowerment (an enhanced capability to discuss and pressure relational resolution); third, group empowerment (act at the limited or advanced level to change domineering societal constructions),[87, 88] Through the process of empowerment, communities are able to assume power to act effectively to change their lives and environment. The community empowerment process promotes the participation of people, organizations and communities for increased individual and community control, political efficacy, improved QoL and social justice.[89]

So far there is not any appropriate tool to measure empowerment among HIV/AID people. However, we can consider it based on the empowerment theories and basic principle to measure it. There are few tools available to empowerment other than HIV/AIDS related. One of the scale developed by Roger et al is appropriate to measure with different dimension of empowerment.[90] It is a 28 item empowerment scale. An example of an item included in the scale is 'I am often able to overcome barriers'. Statements are responded to on a four-point agreement scale ranging from strongly agree = 1 to strongly disagree = 4. It has five subscales viz. self-efficacy/self-esteem (9-36 score), power–powerlessness (7-28 score), community activism and autonomy (5-24 score), righteous anger (3-12 score) and optimism and control over the future (4-16 score). Reliability or internal consistency of the scale was found good (Cronbach's alpha = .86) and construct validity was also satisfactory.[90] As part of the change of the empowerment instrument it will be checked and improved with pilot study focusing feasibility of the questionnaire and

the accurateness of the wording of statements. Construct validity will be checked and corrected after discussion with different experts. There will take a note on hard to understand and out of context or they feel strange and will be corrected. The analysis of these comments will not reveal any difficulties related to a cultural sensitivity of the statements included in the questionnaire.

WHO regional office for Europe's Health Evidence Network (HEN) had sketched the pathways of empowerment. Empowerment processes took place on the psychological, organizational and community levels, and most often function in combination with other intervention processes, outcomes also understood within several areas and levels. Once a community may be identified as empowered or as producing results, however, maintenance of these conditions cannot be assumed. Empowerment outcomes are not fixed, may not be moveable to all issues, or may transform over time as political or economic situation change; it might be success in one domain but unsuccessful in another domain. This supports the need to frequently evaluate alterations within the prospect arrangement, to evaluate the goals of change as well as modifies in how communities concern their society for different objectives (Table 5).

Table 5 Pathways of empowerment[45]

Empowerment Program Components/Strategies:	**Empowerment Outcomes:**		
	Psychological	**Organizational**	**Community/Political**
1. Personal skills: • planning/actions • access to information 2. Supportive environments: • supportive groups • dialogical approach • based on indigenous knowledge 3. Community action/participation:	1. Intrapersonal change • political efficacy • collective efficacy • belief in group action • motivation to act • perceived control 2. Sense of community • community identity • bonding social capital	1. Well-functioning services • publicly accountable • equitably distributed • efficient o integrated • culturally appropriate • maintained overtime 2. Organizational effectiveness and capacity • sustainability	1. Enhanced civil society • structures for participation • increased social capital 2. Good governance • decreased corruption • increased transparency • accountability

• meaningful • decision-making • use of lay leaders • leadership/advocacy • organization capacity 4. Healthy public policy: • collective actions • effective organization structures • transfer power • promote transparency 5. Reorienting health care: • involve constituents	• trust • reciprocity 3. Participation 4. Critical consciousness of society	• constituency building • produce outcomes • effective leadership • empowering to members • bridging social capital 3. Effective inter-organizational networks/ partnerships	3. Human rights • Increased civil liberties • Anti-discrimination policies 4. Pro-poor development • increased micro-enterprises • increased material assets • enabling economic policies 5. Transformed socio-economic, environmental conditions and policies

A descriptive study from United Kingdom (UK) revealed relationship between service provider and clients was crucial for better adherence which enhanced QoL. Clinician and patients' relationship might be valuable for treatment adherence. Patients' capacity could be increased with the conversation related to treatment, empowerment and trust. Patients' can be empowered through education and communication intervention which will help to construct trusted bond.[38] This study started to emphasize the empowerment among PLH with treatment adherence. However, this was the superficial and limited with descriptive and small scale. A view point from the Piot (2006) highlight the communication, activities, social relations, emotional equilibrium, attentiveness manners were the common vital factors which improved and addressed the QoL of HIV infected people. These factors were commonly introduced among empowerment intervention that expected to improve QoL. The authors suggest that the QoL for AIDS patients could be improved if others recognized and accepted their chosen management style. Social and gender

disparities, dependencies and poverties are key confronts to HIV prevention.[41] Author highlighted the HIV with social aspects, public health crisis and natural tragedy.

There are various empowerment programs targeting for people at high risk for HIV/AIDS including sex workers, injection drug users, MSMs and others. Previous findings from different research show that using original information and peer from the community, has been revealed to progress outreach and to generate community ownership of programs. Rifkin (2003) highlighted the theoretical framework that describes the relationship between community empowerment and health equity.[91] Different programs like Mpowerment project for gay and bisexual men have revealed that psychological empowerment and social connecting outcomes can power the social framework of gender associations.[92] It emphasized the small group activities among community that empower the people. For instance, a program from San Francisco prejudiced communication ease, changes in conventional gender positions and decision-making power and an HIV/AIDS empowerment project from Mexican-American gay men changed their risky sexual behavior.[93] The interventions that promoted women's empowerment in the larger circumstance of reproductive independence may be more efficient than approaches incomplete to provide female condoms.[94] However, these studies were specifically among risk and vulnerable group that empower to change their behavior for positive health.

Sonagachi intervention program is the successful program in India that empowers the sex worker to reduce infection and prevention of HIV. Sustainability was assessed in the 12 year-old Sonagachi intervention that has successfully reduced HIV infection and increased condom use among sex workers in Calcutta.[95] Its victory was recognized to developing empowerment model, counting the use of peer outreach workers, broad community alarms as the preliminary position of the project, leadership development of the women, support by health professionals; and the ultimate yielding of leadership to a new sex worker association. Reproduction of this study has revealed alike assessment outcomes.[96] In sum, HIV/AIDS prevention empowerment strategies that address access, self-esteem, inequities and awareness have enhanced health status. There are various success empowerment programs across the world but sparse to targeted for PLH.

Various places community empowerment intervention has been conducted among sex worker to reduce the vulnerability of HIV/AIDS and other J Sex Transm Dis. Albeit no one has perfect measurement of empowerment related constructs. Empowerment intervention among HIV/AIDS is also sparse and no one perfect measurement has been available and success in various low and middle income countries (Table 6).

Table 6 Community empowerment interventions among sex worker and measures

Author/Year/ Country	**Description of the empowerment intervention**	**Intervention components**	**Measurement of empowerment**
Basu I et al. (2004)[96] (India)	Activities organizing the community and advocacy with the aim of better self-esteem, independence, and self- determination among the sex workers. Concerning their overall health and well-being and that of their children; fostering group harmony; and increasing awareness about rights of sex workers.	Peer education for HIV/STI transmission and prevention, social marketing of condom, STI screening and treatment.	Specific measurement of the empowerment was not available.
Blankenship KM et al. (2008)[97] (India)	Community involvement and mobilization has been established as social change agents (SCA) among sex workers which provided peer education.	Peer education for HIV/STI transmission and prevention, distribution of Condom, STI screening and treatment.	United power including united identity, united efficacy and united agency, and control over work, and economic power.
Gangopadhyay DN et al. (2005)[98] (India)	Development of empowerment of sex workers to amplify their united power	Peer education for HIV/STI transmission	Specific measurement of the empowerment

	to progress their social, political, and economic conditions.	and prevention, Social marketing of condom, STI screening and treatment.	was not available.
Halli SS et al. (2006)[99] (India)	Encouragement a sense of community, harmony, and empowerment among sex workers in order to take united power over their lives.	HIV/STI peer education, condom distribution, encouragement of STI care seeking.	Collectivization index developed to measure the degree of united related to sex worker involvement.
Kerrigan D et al. (2006)[100] (Dominican Republic)	Reinforce wisdom of harmony and the united assurance toward STI/HIV prevention within and crossways sex institutions.	Peer education for HIV/STI transmission and prevention, social marketing of condom, STI screening and treatment.	Measurement of environmental structural support for HIV prevention among sex workers.
Kerrigan D et al (2008)[101] (Rio de Janeiro, Brazil)	Encouragement the treatment of sex workers, violence prevention, kits and materials, literacy classes, financial management activities and psychosocial support.	Peer education for HIV/STI transmission and prevention, Social marketing of condom, STI screening and treatment.	Sense of community, diminished powerlessness and insecurity, increased access to and management of personal material

			resources, and increased social participation and social acceptance.
Lippman SA et al. (2010)[102] (Corumba, Brazil)	Provide opportunity to engage in dialogue around sex work, human rights, discrimination, and violence	Peer education for HIV/STI transmission and prevention, Social marketing of condom, STI screening and treatment.	Measurement of social structure, participation in community, access to social and material assets.
Ramesh BM et al. (2010)[103] (India)	Recognize and address the concerning and complexities of sex workers, community mobilization, capacity building of local organizations to implement HIV prevention programs and services.	Peer education for HIV/STI transmission and prevention, social marketing of condom, STI screening and treatment	Specific measurement of the empowerment was not available.
Reza-Paul S et al. (2008)[104] (India)	Recognize and address the concerning and complexities of sex workers, community mobilization, capacity building of local organizations to implement HIV prevention programs and services.	Peer education for HIV/STI transmission and prevention, Social marketing of condom, STI screening and treatment	Specific measurement of the empowerment was not available.

A descriptive article based on the project developed by European commission highlighted unhealthy HIV infected people need to empower as they can perceive healthy members in society. They must image of self as healthy survivor and empowered and might be engaged to help and empower themselves to other HIV positive peoples. Sometime HIV positive individual may have a negative impact on HIV/AIDS progression.[105] Another commentary advocated gender relations, economics and migration need to address on prevention intervention strategies which empower the PLH which enable to raise voice in new epidemic condition. This effort can be useful to reduce transmission of HIV.[106] Descriptive paper highlighted HIV related organization, PLH and government might be aware that the effect of empowerment and QoL of PLH. It is necessary to give emphasis that the PLH can share and speak about QoL and empowered themselves.[48] This study put critique on QoL that purposes recognize health and self-empowerment. Descriptive study from Ghana revealed HIV/AIDS epidemic has greater pressure on the barriers to prevention and care. Ample education about HIV/AIDS is the practical instrument for empowerment among PLH, cultural and other barriers to HIV/AIDS prevention.[46] This study emphasized the prevention of HIV through education empowerment that will change the behavior, attitude and social relations. However, study did not analyze the structural approaches of education empowerments.

2.5 Stigma among PLH and determinants

Goffman defined “stigma as an undesirable or discrediting characteristic that an individual possesses, thus reducing that individual’s status in the eyes of society”.[107] Stigma can product from a particular attribute, such as a physical abnormality, or it can stem from pessimistic attitudes toward the behavior of a group, such as homosexuals or prostitutes. Further Goffman’s definition, stigmatization is the community tagging of an entity or group as unlike or unusual. Others have defined stigma as social practices that are associated to community supremacy construction.[108, 109] Several authors divide stigma into felt (refers to real or imagined fear of societal attitudes and potential discrimination arising from a particular undesirable attribute, disease, or association with a particular group) or perceived stigma (refers to the real experience of discrimination) and enacted stigma.[110] The

HIV/AIDS stigma includes 4 broad trends where first three give primacy to psychosocial factors (ignorance, unconscious anxieties, and unconscious processes to wider power relations), the fourth to socioeconomic factors.[9]

There is unavailability and ambiguity of clear concept and measure of HIV stigma at an individual level and it might be the barrier for HIV treatment adherence and prevention. Based on the different literature review it is communicative to clarifying concept and measure of HIV related stigma. This concept express how the stigma of HIV has been obtained that could be harmful for both infected and uninfected individuals. The emphasis has given to usefulness of HIV stigma research information that will give the clear information and address its different aspects. However, there are various tools have been available to measure HIV related stigma among PLH. Among the various available stigma scales most of the scale developed in United States and few are in African regions. There is one scale developed for developing countries (Table 7). In this study, information is collected to use stigma scale for HIV/AIDS related stigma developed by Genberg et al. (2008), which is appropriate for developing countries.[111] This scale has three dimension including shame/blame/social relation, perceive discrimination, equity, which can cover the perceived and enacted stigma among PLH.

Table 7 Stigma scales

Author/ Year	**Country**	**Scale title**
Pleck et al. (1988)	USA	Phobia (AIDS)
Shrum et al. (1989)	USA	Attitude scale – AIDS
Froman et al. (1992)	USA	Attitude scale - AIDS
Harrison et al. (1994)	USA	Scale for attitude and conservative views for AIDS
Preston et al. (1995)	USA	AIDS scale - attitudes of Nurses'
Mulford et al. (1996)	USA	Scale for AIDS sufferer blaming
Sowell et al. (1997)	USA	Stigma scale - HIV

Davis et al. (1999)	China	Questionnaire - AIDS
Fife et al. (2000)	USA	Stigma and social impact of disease
Berger et al. (2001)	USA	Stigma scale - HIV
O'Hea et al. (2001)	USA	Scale for attitudes toward women living with AIDS
Herek et al. (2002)	USA	Stigma index - AIDS
Herek et al. (2003)	USA	People living with AIDS feeling thermometer
Kalichman et al. (2005)	South Africa	Stigma scale – AIDS
Hamra et al. (2006)	Kenya	Stigma - HIV/AIDS
Holzemer et al. (2007)	Lesotho, Malawi, South Africa, Tanzania and Swaziland	Stigma instrument -HIV/AIDS
Genberg et al. (2008)	Zimbabwe and Thailand	Stigma scale - HIV/AIDS
Kalichman et al. (2008)	South Africa, Swaziland, USA	Stigma (internalized) scale - AIDS
Sayles et al. (2008)	USA	HIV (internalized) stigma scale
Stein et al. (2008)	China	Stigma scale - multidimensional
Van Rie et al. (2008)	Thailand	Stigma scale - HIV/AIDS
Visser et al. (2008)	South Africa	Attributed stigma scale and internalized stigma scale
Zelaya et al. (2008)	India	Stigma scale - HIV/AIDS

A quantitative study based on secondary analysis of baseline data from RCT in USA revealed the association among sex, physical health and social support with stigma.[57] Other determinant could not include in the structural equation model and was not establish the sequence and causal relationship. Qualitative study from China explored that stigma might be reduced by significant efforts on joining self-support programs, education, and helping each other.[56] Stigma itself not affects only on PLH but it affects the family and community as a whole. The study also emphasized for empowerment of family and PLH. Prospective study from USA revealed that factors like health care satisfaction and coping may minimize stigma's effect on medication adherence.[59] It was a prospective study but, due to the small sample size result might not be generalizable. It has been emphasis on treatment adherence and stigma and not with other variables. Qualitative study from Zimbabwe explored that the enhanced ART has the possible to reduce stigma but still there is dread to the determination of stigma.[55] Findings from cross-sectional study in USA had also similar agreement that poor access to care and ART adherence associated with stigma.[112] Study highlighted to increasing in ART access and other interaction with economic and psychological factors but did not make any relationship with ART adherence and stigma because of the constraints of study design. Availability of ART and good prevention of HIV might decrease transmission, but delaying to disclosure habit and low level of counseling raised the sustained fundamental wave of stigma.

Descriptive cross-sectional study form China suggested that self-efficacy is an important predictor for medication adherence and QoL, HIV stigma as a mediator should not be neglected. Health care providers should also evaluate HIV stigma conditions when seeking to improve self-efficacy through interventions.[58] This study gives emphasis to health care providers and those are vital actors for adherence and reduce stigma among PLH. However, study did not mention the effective way to establish good relations and how to improve psychological encouragement among PLH that will reduce the stigma.

Baseline data analysis of RCT from Thailand revealed significant association among stigma, social support, and income.[29] This study excluded who those have no children so it could not be generalized with other PLH. However,

sensitivity analysis give some evidence that stigma is associated with other variable. Cross-sectional study from USA suggested that stigma has a good correlation to social support. It held disclosure concerns of the study participants to be a great factor in stigma that has to be tackled.[113] Study covered only HIV positive young MSMs. Although study enforced to continue care of stigma is crucial in clinical or community settings. Other cross-sectional study from USA highlighted similar findings that stigma, social support, and QoL has significant association among PLH and lengthy time of diagnosis of HIV, support form friend and higher education also found associated with stigma.[114, 115] This study has given some insights that the peer support was the crucial for coping stigma. However, information was collected only from African-American ethnicity which was less generalizable with other population and could not make causal relationship.

2.6 Social support among PLH and determinants

Social support has appeared to acquire different magnitudes and is articulated in different forms and ways. The foundation of social support can move toward in the outline of emotional support from peers, friends and family. It can originate from social communications in the community including different persons and from dealings with the environment. Social support which social structures that help to people with their psychological sources to tackle with emotional problems (giving love or sympathy), information, helpful assists (money, skills, advices). It has numerous dimensions, namely emotional, informational, and instrumental support. Emotional support has been defined as “providing esteem and affiliation to others”.[116] Instrumental carry includes economic or shelter support,[117] and informational support has been accounted as giving suggestion and information on social, health, or employment issues.[118] Evidence from literature supported that social support has both positive and negative portions. For instance, someone can share their problem to get social support but it would rather produce some positive support or negative which becomes a new problem again.

Different tools have been developed to measure social support. The social support scale uses social support questionnaire (SSQS).[119] The SSQS has 12-item tools those dealings two features of apparent social support: six odd numbered

objects calculate social support network (support perceived by number of people), the total number of people in the individual's social support is additional separated into family network and non-family network support and six even-numbered objects dealings perceived satisfaction from social support network. The specific support is calculated on a six-point Likert type scale ranging from very satisfied to very dissatisfied, which measures overall satisfaction. The original scale was customized into a 14 point scale. The modified odds objects were to calculate ''whom they could really count on when they needed help for'' treatment and help from partner, for living arrangement, for food, for transportation and others, along with two even number for level of satisfaction from support. After the factor analysis of seven odd objects result found three factors that match up with different support function; tangible, informational, and emotional support.

Cross-sectional study from India revealed social support was mediated with adherence and self-efficacy.[120] Research finding shows that the social support has been associated with different outcomes together immune function, coping approaches, efficient management of disease. Studies conducted in USA among HIV positive women QoL, and enhanced mental health. Numerous benefits of social support and has various recognized barriers to obtain supports including not availability of family members, PLH friend death, none acceptance, feels stigmatized, feeling of family burden, limited to meet others, and non disclosure of the status.[51, 53, 117] Other qualitative study also from USA found social support would be less when the low level of social relations with family and friends. There is no any evidence to differ social support among ethnicity. HIV related distress, stigma and social support can be improved with the supportive interactions from health care providers. Social support, perceived HIV stigma are interrelated with PLH and their family.[121, 122] All the studies have been highlighted importance of social support and associated barriers and determinants. However, all the studies were cross-sectional and had small sample size. Few studies showed the strong analysis but could not establish the causal relation.

Study conducted in South-Africa revealed higher social support was perceived with the relationship of close friends and family members. QoL was

significantly improved after taking medication with long time and decreased with the presence of co-morbid health problems.[123] Study focused to determine the nature of relationship among social support and other variables. Even though, the study objective was to determine the relationship with social support and other variables. It could not establish the type of social supports and its weight on outcomes. Cross-sectional study from Nepal found that family support is less important than non-family support network. It has been recognized that the social support is fundamental concerns and significantly associated for QoL.[124] This study highlighted the socio-cultural context can alter the QoL and social support.

Social support facilitates emotional adjustment to chronic illness, including HIV infection. Access to social support among PLH depends on different factors including the degree to which an individual has disclosed his or her HIV status, adherence, cultural context, economic, sex and support can obtained from different people such as family members, friends, community and sex partners.

2.7 Intervention process and effects

Intervention study conducted in USA covered only Hispanic women in certain geographic areas and failed to generalize to other population. This study examined the biological risk, behavioral risk, social-cognitive/community prevention aspects. This study used social-cognitive model for behavioral change and did not provide the process of theory how it work. Study did not provide the detailed contents of intervention which areas have been covered. Dichotomized variables and self-reported information may violate the continuous variable analysis assumption. Sequence generation and blinding did not clearly followed.[125] Another intervention from USA conducted among mothers living with HIV with their children aged 6 to 20 years. Inclusion criteria were not clearly motioned as study said mother living with HIV but in the recruitment process it was mentioned that female care giver also eligible. Sequence generation concealment, allocation and blinding were not followed clearly. Intervention process and manual has been mentioned clearly. However, four session of intervention process for mother and child was together and remaining was separately. Intervention process did not mention any theoretical perspectives and methods. The subjects were mothers and adolescents and could not be generalized

with other PLH. Study included higher than 6 years child but mentioned only about adolescent and not details were available. Analysis did not show the effects on Adolescent intervention and did not mention ethical considerations for those subjects (Table 8).[126]

Systematic review of intervention for on HIV affected family from USA, Thailand and South Africa highlighted the effective approaches of interventions. Psycho-educational processes help the affected people and family cope their stress and chronic medical psychological illness that increase capacity to manage transition period of infection and enhance to solve the problems. Process, function and principle of across intervention likely to be similar but must be targeted to predicted problems. Series of activities and script might not be feasible for all the session and it will not guarantee that participants follow after intervention but intervention might be appropriate with the cultural and context (Table 8).[127]

Intervention study from China highlighted the empowerment of the PLH with their family. This study planned to implement among multiple level including PLH, community, seronegative members, and children. It was aimed that the empowerment process reduces the depression, stigma and improve social support and family functioning. This study included the family members who those knew the status of family member living with HIV. This inclusion criteria might persist the bias whether intervention effectively worked or not to increase social support when family member already had support and knowledge about PLH. Intervention followed the social-action theory and contents and process has been mentioned. This study did not cover who did not disclose their HIV status among the family. Outcome did not separate among the family member and PLH. Intervention could not address the distinct level of the problems where level of the problems are not similar among family member and PLH.[128] RCT based on behavioral intervention from Thailand could improvement in outcome variables only but not other variables like social support and stigma. Study did not mention about randomization, allocation concealment and subject inclusion criteria. Study superficially highlighted the intervention process and used Buddhism philosophy. Study subjects were recruited from different geographical locations that could maintain the contamination but did

not mentioned clearly about cluster variation. Study recommended that the behavioral intervention can useful to improve QoL (Table 8).[49]

RCT among PLH and their family member from Thailand revealed the significant improvement in QoL after intervention. Study had taken the family member and PLH from different geographical location. However, it did not mention how the family members and PLH was recruited for control and intervention. Random allocation of the subject and sequence concealment did not mention clearly. Study mentioned intervention methods and process clearly and used Buddhism philosophical theory. This study finding could not make generalization because who those did not disclose their status were not recruited. The study subjects were from different location but did not make comparison with those locations whether the background might be different for each location that persist bias on outcome.[129] RCT from Switzerland based on cognitive behavioral intervention effect revealed improvement in QoL after success of intervention. Intervention methods and contents were described. Random allocation and sequence generation concealment were mentioned. Risk of bias and blinding did not mentioned clearly in this study (Table 8).[130]

Table 8 Intervention and effects

Authors, Year Country	**Methods**	**Results**	**Measures**
Peragallo N et al. (2012)[125] (USA)	RCT, Health education and promotion and self care intervention.	Improved communication with partner, improved HIV-related knowledge, improved intentions to use condoms, decreased barriers to condom use, and increased community prevention attitudes.	Biological, behavioral, social cognitive and community prevention.
Rotheram-Borus et al. (2012)[126]	RCT, cognitive-behavioral	Intervention: significantly more likely to monitor their CD4 cell count; and alcohol and drug use	Parenting behavior, mental health,

(USA)	intervention.	habit were decreased among their children. It had been established to good family relationship.	sexual behavior, substance use, child behavior.
Rotheram-Borus et al. (2011)[127] (USA, Thailand, South Africa)	Systematic review of HIV affected family intervention.	Common health, mental health, transmission are more common and challenges among risk groups. Intervention may affect and need to agreement with different points in different situation such as local health priorities, delivery sites, and cultural context of intervention place. Intervention reliability robust these phenomena and quality of intervention.	Theoretical prospective of the behavioral and social intervention.
Li L. et al. (2011)[128]. (China)	RCT, Together for Empowerment Activities, education intervention.	Study findings reveals that the social support and family functioning were significantly improved among intervention group.	Depression, social support, family functioning.
Li L. et al (2010)[49] (Thailand)	RCT, Behavioral intervention.	No significant differences were found in gender, age, education, annual income, or years since HIV diagnosis, stigma, depression, HIV disclosure, social support.	Social support, disclosure, depression, internalized shame or stigma,

			mental health, physical health.
Li L et al. (2012)[129] (Thailand)	RCT, Education intervention.	QoL has significantly improved at 6 months (P = 0.0014).	QoL, depression, family function.
Berger S. et al. (2008)[130] (Switzerland)	RCT, Cognitive behavioral intervention	QoL was improved after intervention.	QoL, anxiety, depression.

3. Rationale

Epidemiological data highlighted that the HIV is shifted as pandemic disease where the new HIV infections and death related to HIV/AIDS are still alarming. The prevalence of HIV remained widespread and epidemic contained extremely heterogeneous. Expectancy of HIV have reported in decreasing trends but risky sexual behavior promoted HIV transmission among general people, re-infection and co-infection among infected people was uninterrupted. Disease burdens were reported more common among HIV infected populations compared to general populations that might alter the QoL. Life expectancy was improved after initiate the highly affective antiretroviral therapy (HAART).

However, different UN agencies reported the variation of HIV transmission and the existing discrimination and stigma among HIV infected people. Importantly, UNAIDS set the target of '90-90-90' for case notification, ART treatment and viral suppression by the year 2020. Treatment coverage of ART is limited which can contribute to either increase or decrease an anxiety, stigma, low social support and QoL (QoL). The conclusion on which dimensions of HIV affect the QoL of HIV infected people is still contradictory. Moreover, effects on treatment of HIV might be affected by several factors that can develop stigma, deterioration of QoL and social support and disempowerment. In addition, the psychological, social and cultural factors are crucial for HIV control and prevention but there is no any prescribed intervention is available to achieve these targets.

There are various types of interventions (behavioral or social) available to improve QoL of PLH but the outcome is inconclusive. Further, empowerment program found to improve QoL, drugs and psychological states. Improving empowerment is shown to be one strategy for vulnerable people but it was still not directly intervened in HIV infected people with ART. This empowerment concept would be the best cost effective approach for intervention. Empowerment and social support could be helpful assets among HIV infected people that enhance QoL, reduce in stigma and improve ART adherence in resource poor settings, including Nepal. However, HIV related empowerment based programs are sparse and it has been necessary to strengthen and implement with usual ART and other programs with political and social transforms. There is an urgent need to develop extensive socially and culturally accepted, cost-effective and dynamic intervention in resource poor settings. We reviewed the appropriate contents of available interventions and revised according to culture and context. We applied the appropriate theoretical frameworks for developed contents. Therefore to fulfill this gap, the intervention, a social self-value package developed, to improve the empowerment and QoL of HIV infected people.

4. Research questions

1. What is the effect of social-self value package on empowerment and QoL of people living with HIV under ART?

2. What is the relationship of empowerment with QoL, social support and stigma?

5. Research objectives

General objective

To evaluate the efficacy of social self-value package on improvement of empowerment and QoL at 6 month follow-up.

Specific objectives

1. To determine the improvement of empowerment and QoL among PLH receiving social-self value package.
2. To assess the relationship between QoL, empowerment, stigma, and social support among PLH.

CHAPTER II

RESEARCH METHOD

6. Conceptual framework

The effect of empowerment on the QoL is tested through the social self-value package as the intervention. However, empowerment, social support and stigma, risky sexual behaviour, disclosure and ART adherence are also associated and may affect to the QoL directly and indirectly. Demographic, clinical and behavioural characteristics can influence the empowerment, social support and stigma and QoL.

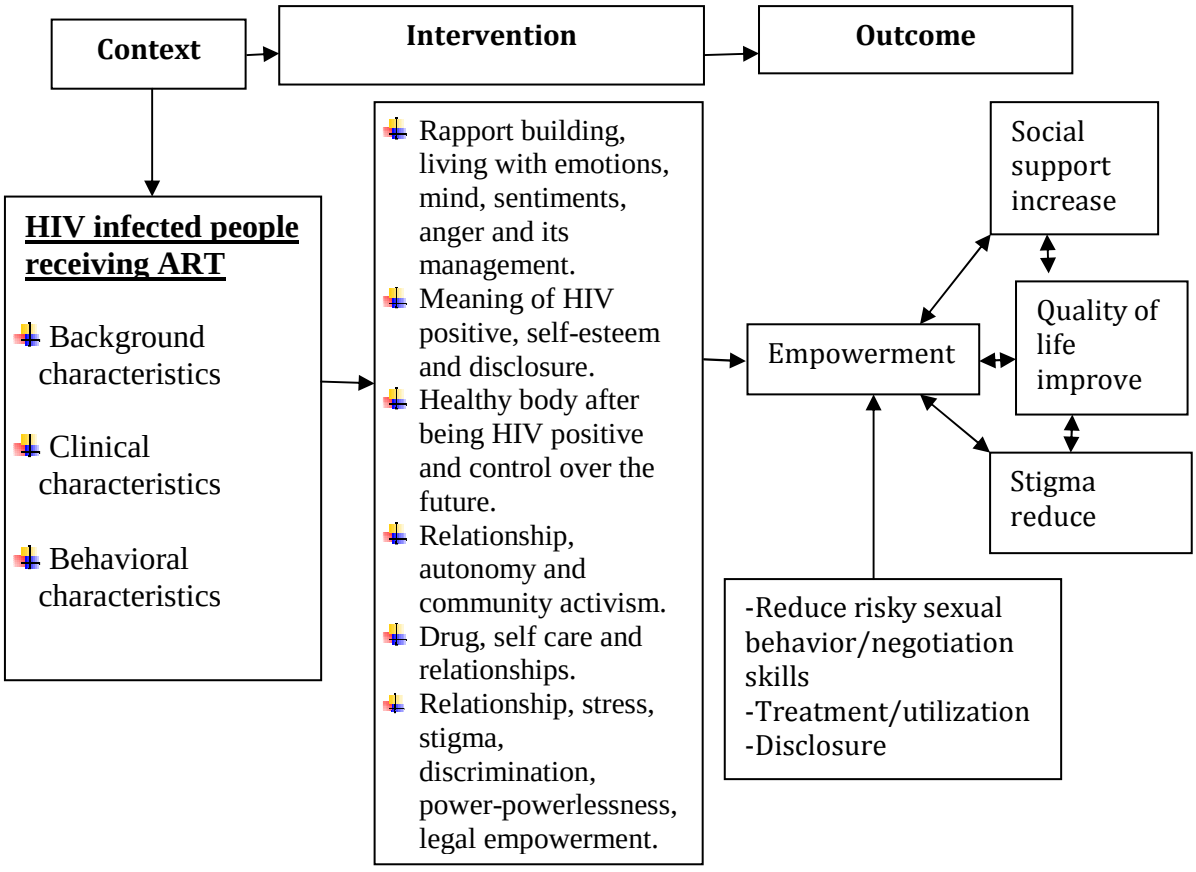


Figure 4 Conceptual framework

7. Methodology

7.1 Study design

An open-label, parallel, randomized control trial comparing intervention with a conventional control group was conducted.

7.2 Study settings

The study site was one of the largest (more than 1500 HIV patients received regular services) public ART center at Sukraraj Tropical and Infectious Disease Hospital (STIDH), Teku, Kathmandu, Nepal, run by the government of Nepal and was a part of the National Center for AIDS and STD Control (NCASC). It was purposively selected. The study was conducted from September 2014 to June 2015. There are 5 ART centers in Kathmandu district of Nepal, where HIV infected patients attend for receiving ART, namely Teku hospital, Bir hospital, Katni children's hospital, teaching hospital Maharajgunj and Maiti Nepal. The first four centers are situated in the metropolitan areas and are national level government referral hospitals. The last center is run by NGOs (Figure 5).

In addition the ART voluntary counseling and testing (VCT) services, counseling and services are provided in the center. Medical and clinical services provide and manage general HIV related co-infections, other opportunistic infections, and STD/STIs. General physical examination and laboratory facilities also provided. Further, routine lab examinations, CD4+ lymphocyte cell count and viral load assessment are also provided with the cooperation of public health national laboratory center. Along with ART other general drugs are provided to treat opportunistic or co-infection and other associated diseases especially TB-HIV treatment.

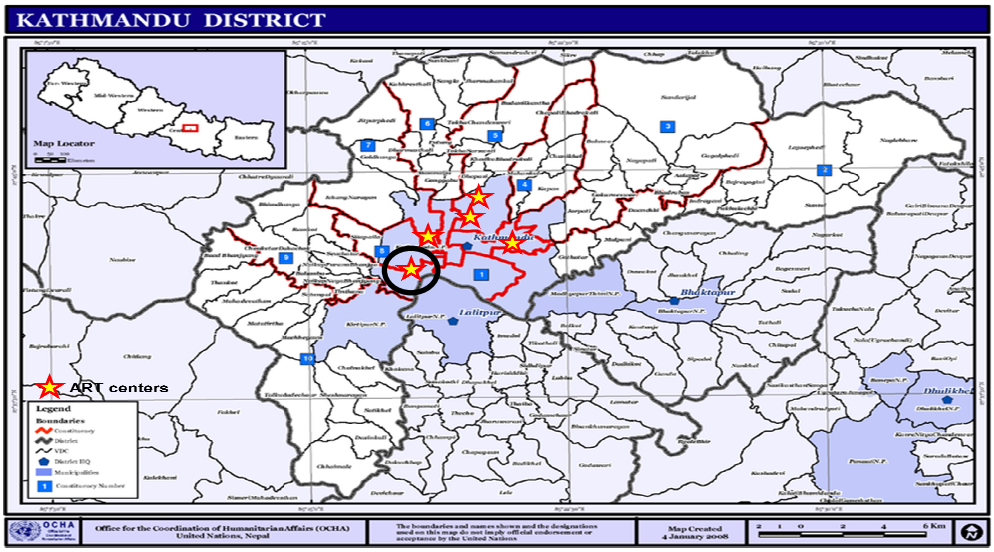


Figure 5 ART centers in Kathmandu, Nepal

7.3 Study sample

7.3.1 Inclusion criteria:

1. People with HIV infections aged equal or above 18 years attended at ART center

2. Enrolled in ART and currently using ARV drugs between six months and two years.

3. Agreed to participate in the trial for 6 months from recruitment until the completion of follow up.

7.3.2 Exclusion criteria:

1. Those having psychotic disorders, visual or hearing retardation which is unable to communicate

2. Those participating in any other education programs.

7.4 Sample Size

The primary outcome of the change of QoL was considered for sample size calculation using the difference of percentage of mean change between two groups. The sample sizes in the two groups were equal. Since there was no previous study for the mean change of intervention ($\mu_1 - \mu_2$), the 20% difference was applied, which was equal to 0.52 of one standard deviation (σ). Comparison of two

independent means or testing the difference between two means (two-sample t-test) formula was used.[131]

$N = 2\sigma^2 (z_{\alpha/2} + z_{\beta})^2 / (\mu_1 - \mu_2)^2$

$N = 2\sigma^2 (z_{\alpha/2} + z_{\beta})^2 / (0.52\sigma)^2$

$N = 2(1.96+0.84)^2/0.52^2 = 58$ in each group → a total of 116 subjects

To compensate the incomplete follow up about 10%, 132 were recruited (66 for each group).

7.5 Randomization and allocation concealment

Randomization by a block of six was performed by an independent person using computer generated random number. Individual assignment codes were properly concealed seal-opaque sequentially numbered envelopes and opened in the presence of study participants. Intervention facilitator and research staff were assigned the participants for either intervention or control.

7.6 Blinding

Our intervention was not blinded to the participants or researchers. However, we blinded the outcome assessors. The outcome assessors did not know the participants' assigned group or information at baseline, 3-month and 6-month follow up.

7.7 Intervention methods

HIV related intervention was based on health education, promotion, counseling and self care for PLH. This intervention was based on the theoretical framework of social learning theories for behavioral change with social-cognitive model,[132, 133] and pedagogy of oppressed theory.[134] The social learning model included the activities that support self-efficacy (e.g., prevention, condom use, negotiation, communication). Pedagogy theory had the importance of contribution to the skills and knowledge which was encouraged the participant in activities based on the real ground.

Empowerment related intervention was developed with the Ewart's social action theory for public health psychology to enhance the self behavior change

and social inter-dependence.[135] Other important factors like stigma, social support, family support, ART adherence, and other supports were also appropriate under the social action theory. It was ample the intervention outcome of empowerment for QoL and social support. The empowerment model developed by Gutierrez was followed for empowerment process. It had five step course of empowerment viz. accepting the client's definition of a problem; identifying and building upon strengths; engaging in a power analysis of a client's situation; teaching specific skills; and mobilizing resources for clients and advocating for clients.[136] Another realistic aspect of Buddhism has been used in various studies.[49] Buddhist philosophy supported self awareness, responsibilities, support, help to others and impermanence and useful for intervention activities.

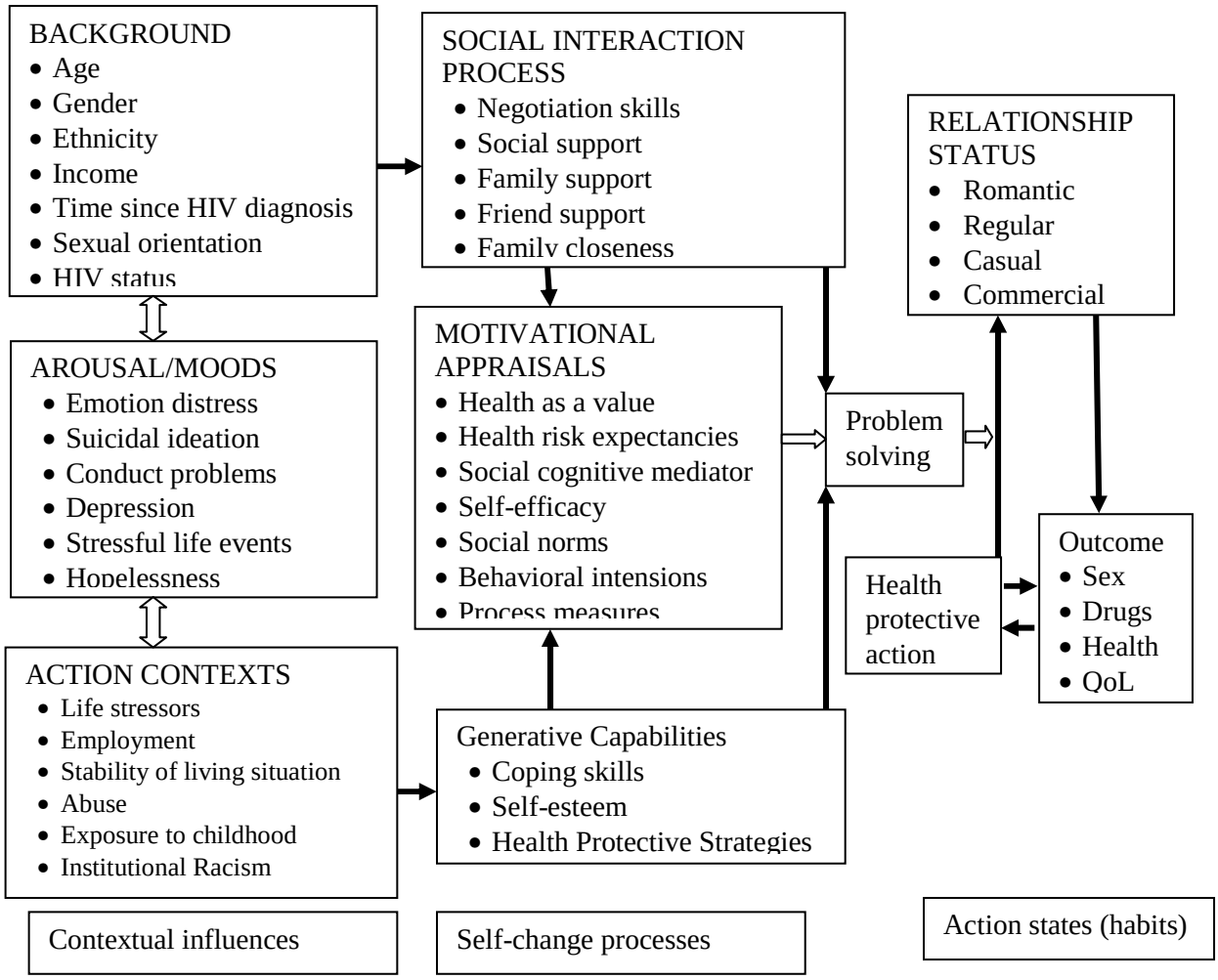


Figure 6 Social action theory developed by Ewart

7.7.1 Contents of intervention

The goal of this intervention was to improve empowerment and QoL, along with an increase in ART adherence and social support, and a decreased stigma and risky sexual behavior.

Intervention prospectus was outlined based on the broad qualitative and quantitative literature review of obtainable primary or secondary HIV interventions. Intervention contents in this intervention were modified from different intervention modules. Ten different common principles were developed by different researchers. These contained inappropriate belief and myth of HIV, prevention, treatment, self care, negotiation, freedom, and help others for protection.[127] Another widespread empowerment intervention based on gender and powers that empowered by increasing abilities and knowledge relating to sentimental, social, sexual and physical factors which increase vulnerability.[137] Similar contents and structure were developed for HIV positive behavioral intervention.[138] Empowerment intervention focused on sentiments, behaviors, cognitions, and wisdom of control, serious physical and social surroundings, and act to implement control.[87, 139, 140]

Intervention manual was corrected based on the opinions and comments provided by experts. Intervention was friendly and practical rather than expertise and given by local public health officers. Intervention was maintained by local culture and context which had respect local term and tongue. A pilot study was conducted to check the appropriateness of the contents in the intervention manual. Discussion, Role-play, participatory learning activities (PRA/PLA), videos and lecture methods were utilized during the intervention. For the contents of the discussion, role-play, PRA/PLA and lecturer are available in the intervention manual. Different motivational videos and power-point were developed (quotation and contents found form different Buddhism books and websites: http://www.anger-management-techniques.org/dealing-with-anger.htm/, http://www.dealingwithfear.org/fear-of-death.htm/#video). We used motivation videos that freely available (https://www.youtube.com/watch?v=4FfamcxsrC,https://www.youtube.com/watch?v=gKFSVs-mA6c, https://www.youtube.com/watch?v=kqhKxFAmRYY). These efforts had given through public health graduate expert trainers. Monitoring and investigation

were done by local health officers that ensured the fidelity, quality and reliability of the intervention. Facilitator or trainer was not involved in the assessment process, which eliminated the potential bias.

The intervention was delivered in Nepali language once in a week lasted 1.5 hours over six weeks (n = 6 sessions). Each session lead by two trained (public health graduated national level trainer) intervention facilitators, and designed as a group session (approximate 8-10 participants per session). The group (total 7 groups) had both male and female participants. Intervention manual explained the method of role playing by husband and wife and it had empowered them with gender equality. All the facilitator and supportive staffs got the three days training. Each session was participatory and participants friendly based on problems and challenges faced by PLH. Details of contents and each session's goal were presented in the following (Table 9).

7.7.2 Overview of Intervention

Table 9 Intervention contents

Session	Goals	Related theory	Expected target of outcome
Session 1: Rapport building, living with emotions, mind, sentiments, anger and its management	✚ Identify comfortable and uncomfortable situations ✚ Discuss part events and pity for healing to participants' history ✚ Discuss feelings and experiences within the group ✚ Produce knowledge and build up abilities in emotions and sentiments ✚ Identify all the tension and	Buddhism philosophy Empowerment theory	• Expression of emotions, mind, sentiment, anger, fears of death. • Manage negative thinking and thoughts, righteous anger.

	produce an idea to cope with tension reveals the unnecessary thinking and circumstances and fight with negative thoughts. Good thinking and things living with HIV, irritations and its types, and learn alternatives to irritations.		
Session 2: Meaning of HIV positive, self-esteem and disclosure	Discuss the meaning of self-respect/confidence/self-esteem Perform the self-respect actions that discover the aspects of one's personality. Strategies, barriers and facilitate to safe disclosure Develop knowledge in stigma, study the character of stigma in one's life and discuss how to defeat with it.	Social learning theory Empowerment theory Social action theory Social learning theory	• Self-efficacy/self-esteem. • Self-respect, empower to disclosure. • Defeat stigma. • Disclosure with communication
Session 3: Healthy body after being HIV positive and control over the future	Produce knowledge in sexual, sentimental, emotional and physical areas. Optimism and control over the future. Explore what it means to be HIV positive or	Empowerment theory	• Client's situation being after positive & optimism and control over the future.

	negative to be a man or women - Discuss about treatment, care after positive, sexuality and barriers. - Discuss transmission and prevention for being a healthy sexual person	Social action & learning theory Buddhism	• Behavior change being healthy sexual person. • Self awareness for treatment or prevention.
Session 4: Relationship, autonomy and community activism	- Produce knowledge and build up abilities in the social/community/family areas, autonomy and community activism. - Find out the distinction among harmful and healthy relationships. - Discuss the way to identify and cope with harmful relationship. - Develop strategies to establish effective communications with the wishes, sentiments and desires. - Planning the social and family role maintain.	Social action theory Empowerment theory Buddhism	• Relationship (family/society) . • Autonomy and community activism & teaching specific skill for harmful .relationship. • Family & social responsibilities and supports.
Session 5: Drug, self care and relationships	- Produce knowledge and build up abilities in the sexual, social areas - Perform excellent communication and	Social learning theory	• Risky sexual behavior, negotiation and communication with partner.

	listening abilities - Aware of opportunistic infections, other diseases and partners sexual behaviors - Discuss the impacts of drug, alcohol, and smoking to one's life. - Eating habits, diets, and exercise effects on one's life	Social action theory	• Adherence to ART, drugs, self behavior change (smoking, alcohol, diet, exercise.
Session 6: Relationship, stress, stigma, discrimination, power-powerlessness, legal empowerment	- Discuss workplace difficulties, discrimination, legal protection, health and human right. - Formulate the objectives for the future - Discuss to join the social and community activities, strategies to raise voice - Find out the situation that you got tension and practice methods to reduce stress and worries. - Conclude and sum up the intervention program	Empowerment theory Social action theory	• Discrimination, health and human rights, legal protection, power-powerlessness. • Social and community activities and inter-dependences.

7.7.3 Conventional control

The conventional control group was PLH those receiving ART from ART center and did not take any education program. Those treated as standard care of ART patients in ART centers.

7.8 Quality and fidelity assurance

Different time monitoring and measures were applied to ensure the faith of intervention implementation. Local health officers from the department of health service supervised each session and monitor intervention facilitators to make sure the assurance of the time and contents allotted for each activity. In addition, all sessions were recorded after getting consent from participants. End of the every session debriefing was performed by intervention facilitator and research assistants appraise the issues with implementation and their degree of faith to activities as written in the intervention manual. All the intervention facilitators promised a high degree of assurance, and there were no significant variations among facilitators in relation to the number of sessions completed.

7.9 Data collection

7.9.1 Preparatory phase

1. Permission was taken from the ART center before start the study activities.

2. Approved English version of the training manual and questionnaires were translated into Nepali and the expert checked for similar meaning.

3. The accuracy of the contents of intervention manual and the questionnaires in Nepali was checked and evaluated.

3.1 Draft of contents of intervention manual was assessed by professionals at the ART center for checking the accuracy and feasibility descriptively.

3.2 The discussion among the trainers at the ART center was conducted.

3.3 Three national training experts related to HIV/AIDS evaluated the validity of the questionnaire.

3.4 The contents of intervention manual and the questionnaires modified based on the comments and validity findings (face and content validity).

4. Reliability of the procedures of intervention and questionnaires conducted with PLH similar to the process conducted in the trial.

4.1 Prototype of discussion with intervention modules or session with 3 PLH each session was conducted. Again ambiguous and unclear contents were identified among PLH discussion and were corrected after discussion.

4.2 Evaluation form for each session (5-point Likert type 5 items) was tested.

4.3 The reliability of intervention and evaluation form was analyzed. Pilot study focused feasibility and acceptability of the intervention as well as reliability of the questionnaires. Accuracy and validity was checked with the translated and revised questionnaires. In addition, acceptability at local cultural and context was assessed.

4.4 The training activities and performances as well as questionnaires were modified.

5. Training was conducted for the research team that comprised two intervention facilitators and three research assistants.

7.9.2 Data collection phase

1. All PLH who visited ART was screened by 3 research assistants using inclusion and exclusion checklist (Annex I). All the participants were screened consecutively at the ART center in the office hour of the ART service center. If the participants meet the inclusion criteria and agreed to participate in the study, then further informed consent and randomization process were followed.

2. All recruited PLH were invited to participate in the study and they were informed and signed for consent (Annex II).

3. They were randomized as randomization guideline. The seal-opaque consecutive number envelop was opened in front of the participants in order to assign the participants into the intervention or control. For the intervention group we made the appointment for the group formation and time and date allocation for intervention sessions.

4. All recruited PLH were interviewed using the constructed questionnaire measured all variables (Annex III).

5. For the intervention group, eight to ten participants per group was arranged for intervention using module (Annex IV) and all procedures as in the protocol by weekly session for six weeks. All the participants in the intervention group were compensated for each of their six sessions with an amount equivalent to US $ 20 in the local currency. The control group did not receive any compensation.

6. The acceptability of social self-value package in intervention group was assessed through mixed methods (quantitative and qualitative) Attitudes, content understanding and satisfaction were measured by constructed questionnaire in Annex III. The attitude was performed in accordance with the objectives of each session before and after the session using the pre- and post-test (Annex V).

7. Content understanding and satisfaction were measured by Client Satisfaction Questionnaire (CSQ-8) and Session Evaluation Forms (SEF), respectively which were performed at the end of six sessions.

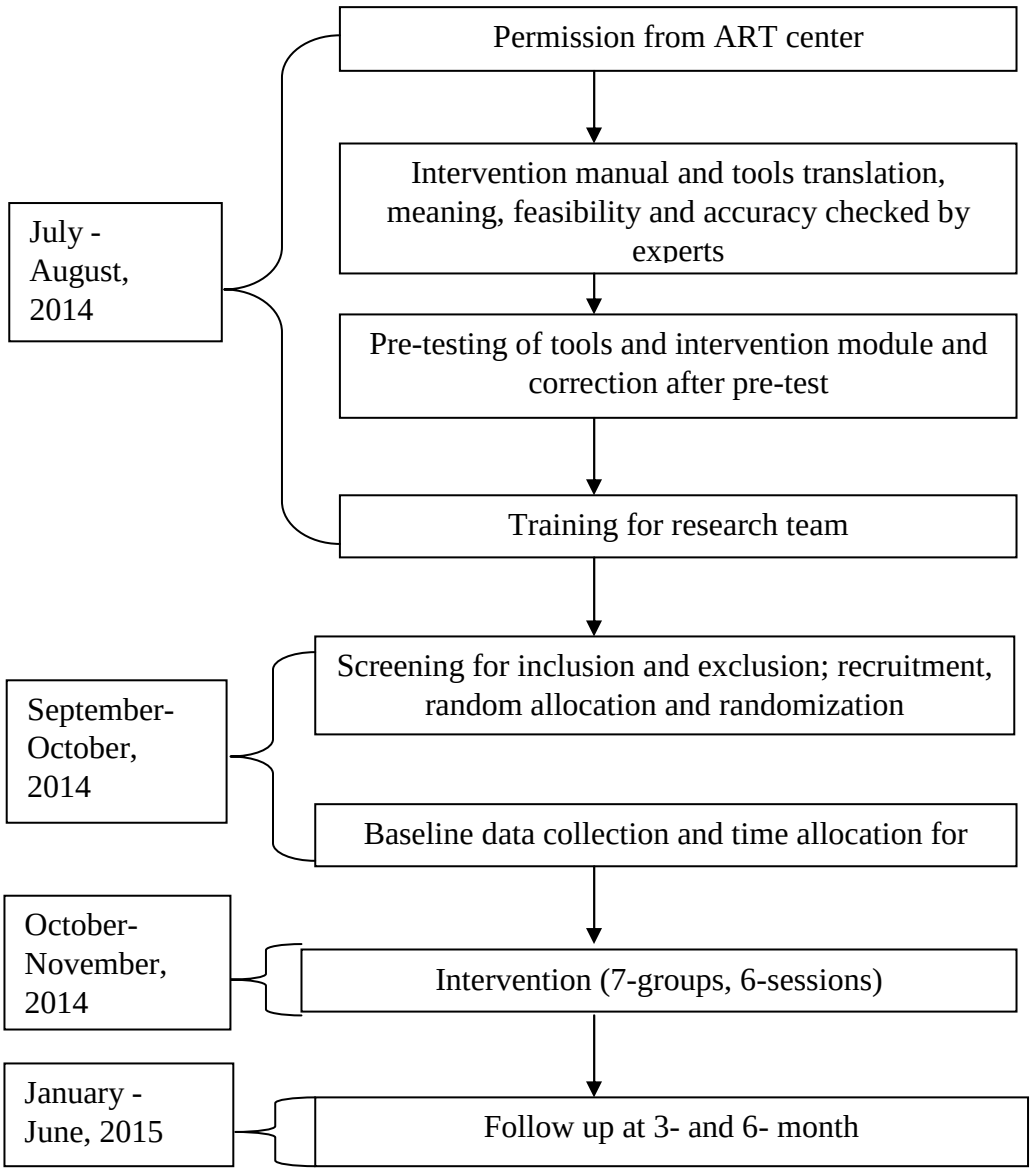
8. Qualitative session was conducted after end of the six intervention sessions using in-depth interview. In depth interview was obtained from both participants and instructors. Seven participants were purposively selected from all the seven groups and two instructors. Participants assigned into the intervention group were discussed about the appointment for attending the sessions. All (nine in depth interviews) information was recorded by tape recording and notes then it was transcribed verbatim. After transcription thematic analysis was done by two researchers.

9. Participants assigned into control group were approached as conventional process.

10. Apart from intervention, all participants in both intervention and control groups were treated the same.

11. All participants were followed up at 3 and 6 months after the randomization using the same questionnaire in Annex III.

Follow chart of activities



7.10 Variables

7.10.1. Dependent variable

1. Empowerment

Empowerment was measured by using an empowerment scale developed by Roger et al.[90], containing a total of 28 items each measured on a four-point agreement scale ranging from strongly disagree to strongly agree. Total empowerment score ranged from 28 to 112. There are five subscales, namely self-efficacy/self-esteem included 9 items (9-36 score), power–powerlessness included 7

items (7-28 score), community activism and autonomy included 5 items (5-20 score), optimism and control over the future included 4 items (4-16 score) and righteous anger included 3 items (3-12 score) (Annex III).

2. Quality of life (QoL)

QoL was measured using WHOQOL-HIV[76] containing a total of 29 items each measured on a five-point Likert scale ranging from negative perceptions to high or positive perceptions. Total and each domain score ranged from 4 to 20. There are six domains including physical, psychological, level of independence, social, environmental and spiritual. Along with those domains one general item score was included that measured overall QoL and general health (Annex III).

7.10.2. Independent variables

1. Socio-demographic, clinical and behavioral characteristics

Demographic, clinical and behavioral characteristics included age in years, gender, race/ethnicity, marital status, education, employment status, Occupation, number of children, number of family members, per capita income, years since HIV diagnosis, years since ART start, clinical stages, mode of transmission, morbidities, sex partner, risky sexual behavior (coded as yes or no), adherence to ART (coded as yes or no) and disclosure of HIV status (coded as yes or no, if response was yes then the number of persons disclosed was recorded and dichotomized as ≤3 persons or >3 persons) (Annex III).

2. Stigma

Stigma was measured by using a stigma scales developed by Genberg et al.[111], containing 23 items each measured on a four point response scale ranging from strongly disagree to strongly agree. Total stigma score ranged from 23 to 92. There are three subscales, namely shame/blame/social isolation included 10 items (10-40 score), perceived discrimination included 8 items (8-32 score), Equity included 5 items (5-20 score) (Annex III).

3. Social support

The social support was measured using social support questionnaire number (SSQN) and social support questionnaire satisfaction (SSQS) scales.[119, 141] Both parts had included six questions. The SSQN collected the number of supportive persons that counts for different types of social supports. The SSQS recorded with six points Likert scale including 1= very dissatisfied, 2= fairly dissatisfied, 3= a little dissatisfied, 4= a little satisfied, 5= fairly satisfied and 6= very satisfied that assessed satisfaction level from available support.[119] Total score of the SSQS was ranged from 6 to 36. Higher SSQN indicate perceived higher level of supportive persons and SSQS indicate higher level of satisfaction from available support (Annex III).

4. Acceptability of the social self-value package

Attitude on content of the session was measured using 5-point rating scale. High score indicated positive attitudes. The CSQ-8 was used to appraise the participant's satisfaction with the empowerment intervention, including intervention procedures, intervention quality and quantity, intervention outcomes, and other general satisfactions.[142] The SEF questionnaire that was used ten items on a 4-point Likert scale aimed at obtaining information about the participant's understanding with the intervention sessions (i.e., what they learn, intervention was informative or not, session was interesting or not, topic was relevant to their life or not).[143] Information about intervention related relevancy, time, content areas, and level of understanding was also collected qualitatively (Annex III).

7.11 Data management and analyses

In order to simplify the data entry and analysis the collected data were coded in standard form. Then the data entered onto a computer using Epi Data 3.1. Range and skip check was done automatically during data entry. Analysis was done in R software. All the entered records were checked by the researcher at the beginning of the analysis and obvious disparities were cleaned.

The internal consistency of attitude scores of each session was calculated by Cronbach's alpha. Median and inter quartile rage (IQR) of summed attitude scores of each session were compared before and after the package using

Wilcoxon's Signed Rank test. A p-value less than 0.05 was considered as significant. The percentages of satisfaction of each item for CSQ-8 were calculated descriptively. Mean and standard deviation of each item of SEF were presented. Retention rate of session attendance was presented descriptively.

Qualitative information was analyzed using thematic analysis by two independent researchers and then final themes and subthemes were developed. All the analysis process was conducted with the agreement between researchers and checked by an expert.

Demographic and clinical characteristics were compared between the intervention and the control group at baseline. Baseline differences between the intervention and standard care were measured using appropriate tests included Chi-square or Fisher exact or t-test or Wilcoxon signed-rank tests.

Effect of the intervention on empowerment, QoL, stigma, social support risky sexual behavioral, adherence to ART and disclosure of HIV status was analyzed using the difference of mean scores or proportions at baseline, 3- and 6- months follow up between intervention and control group depending on either continuous or categorical data.

Further the impact of the intervention was estimated using Difference in Difference to determine the changes in the empowerment score between baselines and post-intervention. In addition, we emphasized the differences in empowerment score between control and intervention group at baseline (pre difference) and at 3 and 6 months follow up (post difference).

Difference in Differences (DiD)

Uses of the DiD methods became very extensive and used to determine the causal effects. It employs recognizing precise the intervention and evaluates the differences in results before and after the interventions for treated and untreated groups. We analyzed the DiD to evaluate results between control and intervention groups at baseline and post-intervention. Ordinary Least Squares produced the estimates and standard error with repeated data set on empowerment among control and intervention group for baseline and post-intervention periods.

This can be shown as following equation:

$$y = \beta_o + \beta_1 D^{post} + \beta_2 D^{Tr} + \beta_3 D^{post} D^{Tr}[+\beta_4 x] + e$$

Where y is outcome of interest (empowerment), Dpost is the time dummy, DTr is the intervention group dummy, Dpost DTr is the time and intervention interaction, β3 is the estimate of DiD, x is the vector of control variables and e is the error term.

Further we analyzed the effect of intervention on primary and secondary outcome using mixed-effects non-linear regression model. Individuals were used as a random intercept and slopes from baseline to post-intervention between the intervention and control group. A mixed-effects non-linear regression model was used to assess the intervention effect on the improvement of empowerment, QoL, social support and reduced stigma. Covariates included age, gender, HIV status, group (standard control vs. intervention), time (baseline, 3-, and 6-months follow-up), and group-by-time interaction were analyzed. The relationship between empowerment, QoL, social support and reduced stigma were measured. We compared the differences between the different model and selected final best fitted model.

Mixed effects non-linear regression models were used to analyze the relative intervention effects on social support, stigma and QoL with the stratification by higher empowerment vs. low empowerment. Intervention effects with 95% confidence interval with stratification among both intervention and control group at baseline, 3- and 6- months follow up were plotted. All the analysis was done in R software and P-value <0.05 was considered as a significant.

7.12 Interim analyses and stopping rules

Government health official team visited ART center from the beginning of the intervention to assess and monitor the trial. They appraised the compliance with the protocol, quality of data and completeness, recruitment process, sample and sample size and ethical kindness. We did not anticipate any unfavorable effects of education process, so we did not apply interim analysis or stopping rules in this intervention.

8. Ethical consideration

All participants were informed and signed the written informed consent before recruitment in the trial by the counselor and research team leader. Participants were assured that they could withdraw from the study at any time and for any reason. If any participant withdraws from the study, all their information was removed in final analysis. The project design did not assume any probable risk to the participants. All the information and identity of the participants were strictly protected. All the collected information was coded and kept in a locked cabinet. Strict group rule was developed by participants themselves during the intervention period which mainly concerned confidentiality and respect. None of the laboratory and other tests was executed.

Participation in the intervention might be difficult for the participants. In this project, we minimized this risk by informing them about the study process; withdrawal of the participants, confidentiality and anonymity during the recruitment clearly. Counselors supervised and observed each participant during intervention for their comfort. Payment vouchers were provided to cover participants travel costs and to compensate their time during the intervention session and assessment after the intervention. All six sessions of the intervention activities were designed with a standard protocol. The researchers and research team had no conflict of interest. The main researcher and research team had no any financial or direct benefit or loss from the outcome of this study. We believe that the outcome from this study would improve the empowerment, QoL, adherence, social support and reduce the stigma among HIV infected people.

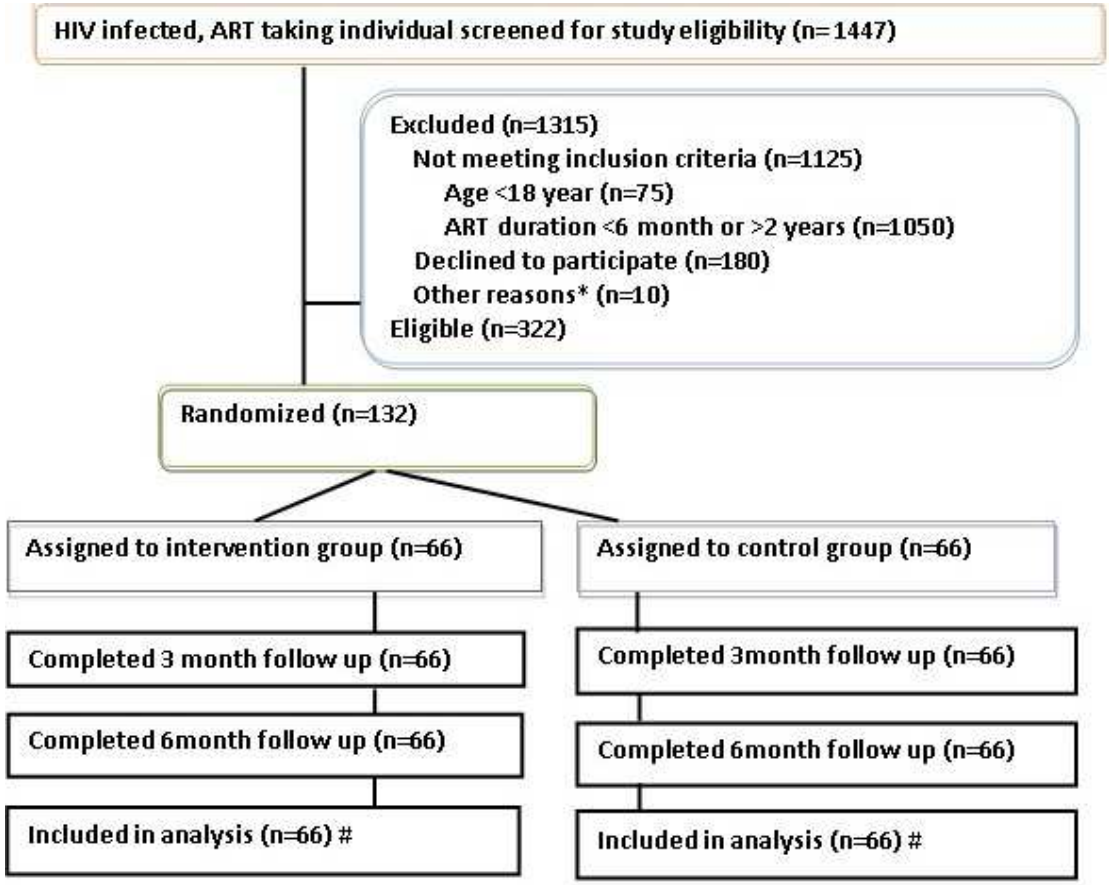
To maintain confidentiality and data safety, a standard protocol was followed.[144] National ethical guidelines and the principles of the declarations of Helsinki were followed. This project design was approved by Ethics Committee of the Faculty of Medicine, Prince of Songkla University, Thailand, under reference number 57-0146-18-5 and granted by the Institutional Ethical Review Board of Sukraraj Tropical and Infectious Disease Hospital (STIDH), Nepal, under reference number 063/071/72 (Annex VI). This project has been registered under trial registration number TCTR20140814002 (Thai Clinical Trial Registry, www.clinicaltrials.in.th).

CHAPTER III

RESULTS

1. Trial profile of the study

Recruitment process was conducted from September to November 2014. Based on the inclusion criteria, 1447 HIV infected people who were receiving ART were screened. Of these, 1315 were excluded because of 1125 were not met the inclusion criteria, 180 were refused to participate without any cause and 10 were not available at the time of recruitment or transferred out from the ART center to other ART center. Enrollment and randomization were carried out between September and October, 2014. After the enrollment was finished, intervention sessions were conducted between October and November, 2014. First follow up assessments were performed after three months of baseline (January-February, 2015) and six months follow-up assessments were done after three months of first follow up (May-June, 2015). Finally 132 HIV infected ART receiving participants were assigned to receive either the intervention (n=66) or standard care (n=66) group. Based on the demographic characteristics, there was no significant difference among the participants who those were included and excluded from the study. After the baseline three and six months follow up information were taken among both intervention and control group. All the participants were included for the final analysis and no loss to follow up was detected (Figure 7).



*Patients transferred out or missing between consent and randomization
Intention-to-treat analysis

Figure 7 Trial details

2. Acceptability of the social self-value package

2.1 Quantitative findings

We recruited 66 participants for the acceptability study. The mean (SD) age of the participant was 36.4 (6.8) years, 53% were male, and 40.9% were from indigenous ethnicity. Two third (69.7%) had a less than higher secondary level of education. About half (48.49%) of the participants were living with HIV for a period of more than one year (Table 10). Attitude of the participants towards HIV contents had been significantly changed after each session. Cronbach's alpha was recorded and ranged from 0.85 to 0.93 for each session (Table 11).

Table 10 Background characteristics (n=66)

Characteristics	**n (%)**
Age in years (Mean:36.35, SD:6.77)	
24 to 35	33 (50.0)
36 to 56	33 (50.0)
Sex	
Male	35 (53.0)
Female	31 (47.0)
Ethnicity	
Non-indigenous	39 (59.1)
Indigenous	27 (40.9)
Education	
Less than higher secondary	46 (69.7)
Higher secondary and above	20 (30.3)
Religion	
Hindu	44 (66.7)
Other	22 (33.3)
Marital status	
Married	49 (74.2)
Widowed	16 (24.2)
Divorced	1 (1.5)

Duration of ART received	
6 months to < 1 years	24 (36.36)
1 to 2 years	42 (63.64)
Duration living with HIV	
≤ 1 years	34 (51.51)
> 1years	32 (48.49)

Table 11 Comparison of attitude scores before and after each session

Session	**Participants = 66 Cronbach's alpha**	**Before (IQR)**	**After (IQR)**	**P-value**
1	0.92	10 (8,12)	21 (20,22)	<0.001
2	0.91	12 (11, 13)	19 (18, 20)	<0.001
3	0.85	14 (13, 15)	20 (19, 21)	<0.001
4	0.93	10 (8, 11.8)	21 (20, 22)	<0.001
5	0.91	18 (15, 20)	23 (22, 24)	<0.001
6	0.91	10 (10, 11)	21 (20, 22)	<0.001

Various aspects of the participant's satisfaction were measured where more than 93% wanted to join again, come back again and recommend others. Majority (>90%) of the participants reported that the quality of the program was highly satisfactory, good and helpful (Table 12). Acceptability of the session was reported higher with the mean score ranged from 3.68 to 3.82 with the 0.40 to 0.49 standard deviation (Table 13).

Table 12 Participants' satisfaction on the package

Item	n (%)
Quality of program	
Excellent	60 (90.9)
Good	6 (9.1)
Fair	0
Poor	0
Wanted for program	
Yes, definitely	63 (95.5)
Yes, generally	3 (4.5)
No, not really	0
No, definitely	0
Program met need	
Almost all of my needs have been met	59 (89.4)
Most of my needs have been met	7 (10.6)
Only a few of my needs have been met	0
None of my needs have been met	0
Like to recommend the program to friends	
Yes, definitely	62 (93.9)
Yes, I think so	4 (6.1)
No, I don't think so	0
No, definitely	0
Satisfaction with the amount of help	
Very satisfied	61 (92.4)
Mostly satisfied	5 (7.6)
Mostly dissatisfied	0
Very dissatisfied	0
Program helped to deal with problems	
Yes, they helped a great deal	60 (90.9)
Yes, they helped	6 (9.1)
No, they didn't really help	0
No, they seemed to make things worse	0

Overall satisfaction with program	
Very satisfied	60 (90.9)
Mostly satisfied	6 (9.1)
Mostly dissatisfied	0
Very dissatisfied	0
If you were to seek help again, would you come back to our program	
Yes, definitely	63 (95.5)
Yes, probably	3 (4.5)
No, probably not	0
No, definitely not	0

Table 13 Acceptability of all sessions

Items	**Participants = 66 Mean (SD)**
Learned a lot of skills	3.76 (0.43)
Able to apply the knowledge	3.68 (0.47)
Given an opportunity to participate	3.74 (0.44)
Well organized program	3.80 (0.40)
Interesting sessions	3.82 (0.39)
Presenter stimulated my interest during the sessions	3.77 (0.42)
Relevant with the context	3.82 (0.39)
Enjoyable learning experience	3.77 (0.42)
Would recommend to others	3.73 (0.45)
Comfortable participation	3.71 (0.46)

Frequency of the retention in each session was recorded with individual attendance. The overall retention was 96.6% in the intervention. Male participants had less retention compared to female participants. Fifth session had recorded low retention (n= 61, 91.8%) (Figure 8).

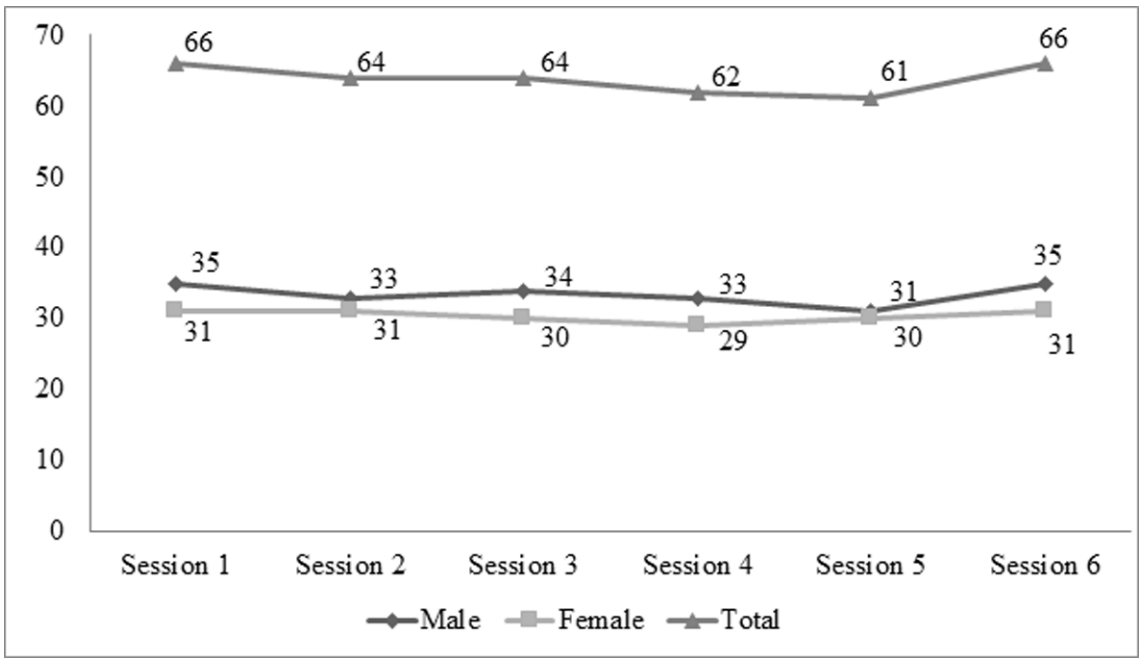


Figure 8 Frequency of retention attendance by session and gender

2.2 Qualitative findings

Three main themes include acceptability, usefulness of the contents and weakness of the package's acceptability were developed. Different sub themes were identified under main themes.

I. Acceptability of the package

Comprehensive topics with details

All of the participants and counselors agreed that the package provided necessary information for HIV infected people which addressed the principal issues for empowerment comprehensively. One participant said "*It really helped me to understand different problems and ways to solve them and I would like to recommend this program to other colleagues facing the same problems.*"

Group sessions and settings

All the participants agreed to participate in group sessions and were excited to share their feelings with others. Counselors also liked the ideas of group settings for action plan and group session. One participant said "*I never had this type*

of opportunity to share my feelings with others with similar problems, I feel hopeful to live."

Goal settings and grounded rules

Both counselors and participants prized the activities of goal settings of life and grounded rules of sessions which made the participants feel safe and respected one. One participant stated "*this step aware me to set goals in my life and make my life easier*".

Active participation and interactions

Participants appreciated the useful interactions among other friends. Counselors agreed that they enjoyed interacting with friends in topics involving sexual, physical, emotional, and psychological issues. One participant said "*I talked with my friends freely and this helped me to understand my problems in a way that I never had before.*"

Personal feelings and care

All the participants expressed that how they experienced with their emotion, society, and sexual life and counselors said that this discussion made them able to balance their feelings and take care of bad feelings. One participant said "I*t provide me the technique to control my bad feelings and aware for treatment in right time.*" One counselor stated "*All the participants know the way to manage their negative feelings.*"

Appropriate allocation of activities

Participants and counselors were happy with the amount of time allocated to activities and tasks and need to be continuing with government programs. However, few participants wanted more time for some activities. One participant said "*Activities and time allocation was nicely managed and after each task the refreshment gave us energy.*"

II. Usefulness of the package's contents

Healthy and self-health care

All the participants agreed on their own values for healthy life and it made them responsible towards their own health. One counselor stated "*This session made clear to all the participants that the value of self-care and responsiveness for being a healthy and health care.*"

Positive relationship with society and family

It was really effective to maintain healthy, pleasant and peace relations among society and family. One participant stated "*I could able to make happy myself and family too and even closely work with my society also*."

Stigma and coping

All the participants received the different techniques that could help to coping with stigma with positive thinking. One participant stated "*I am confident with my ability to cope with stigma and I can help others too*."One counselor said "*Participants enjoyed the activities that encouraged and enabled them to cope with any type of stigma*."

Stress and anger management

Participants were happy to receive the session that enabled them to manage negative thinking, emotions, and stresses. One participant said "*I found better ways to control my emotion and make myself less stressed*."

Protective sexual behavior

Most of the participants learned a lot from this session which was related to risky sexual behavior and different ways to negotiate for protective sexual activities. One participant said "*I will never have sex without a condom even with my husband.*" One counselor stated "*even though they were previously diagnosed with HIV; they learned negotiate skills with innovative ways for protective sexual activities*."

HIV disclosure among family and others

All the participants benefited, enjoyed and actively participated in the discussion about HIV disclosure. One participant expressed "*I did not talk even with other HIV positive persons, now I can tell to others also and I hope it gives me relief on my stresses*." One counselor said "*disclosure activities and ways of disclosure were very well received by most of the participants, where the session pointed out the value and relevancy of disclosure.*"

Laws and empowerment

All the participants understand human rights, health rights and existing laws related to discrimination of HIV infected people that helped to empower them and make them strong. One participant stated "*I did not know my rights before, but now I am clear on this and I can fight against stigma and discrimination of people infected with HIV*."

Self-esteem and self-confidence

All the participants realized the human values and respect which were the assets for empowering HIV infected peoples. One participant said "*This package helped me to feel up and I can work much more without any fear*." One counselor stated "*This session enabled and encouraged them for self-esteem and self-confidence which was barrier for their well-being*."

Sustainability of the program

Participants and counselors were likely to anticipate continuity of this package at ART centers. One participant said "*If this program will not continue through the ART centers, I may not have a chance to share the things I learnt and there will be no motivation for life*." One counselor said "*most of the participants wanted to see their friends share the things again and this is necessary to provide in clinical settings*."

III. Weakness of package's acceptability

Limited time for practice

All the participants and counselors suggested that better to increase sessions with same contents otherwise limited time schedule with various contents

and time allocation for the session was perfect. One participant suggested "*Even I could not manage my time for all the session, if it will be continued by government program need to increase session with same contents*."

Home assignments

All the participants and counselors said that goal settings during session times among the group were very interesting. However, the task assigned to do at home was not appropriate and no one was interested to do this. One participant suggested "*I enjoyed discussing with friends and I learned but the writing work in home I do not like, even it was knowledgeable*."

Table 14 List of themes and subthemes

Themes	**Subthemes**
Acceptability of the package	Comprehensive topics with details
	Group sessions and settings
	Goal settings and grounded rules
	Active participation and interactions
	Personal feelings and link with care
	Appropriate time for allocation of activities
Usefulness of the package's contents	Healthy and self-health care
	Positive relationship with society and family
	Stigma and coping
	Stress and anger management
	Protective sexual behavior
	HIV disclosure among family and others
	Laws and empowerment
	Self-esteem and self-confidence
	Sustainability of the program
Weaknesses of package's acceptability	Limited time for practice
	Home assignments

3. Demographic, clinical and behavioral characteristics of the study participants

The mean ages of participants in the intervention and control groups were 36.3 (SD = 8.8) and 35.8 (SD = 6.8) years, respectively. Majority (59.1%) of the female participants was in the control group and 47% were in the intervention group. Nearly half of the indigenous participants were in the control group and 40.9% were in the intervention group. Nearly one third of the participants were unemployed in the both control and intervention group. Three fifth (56.1%) of the participants were not educated in the control group and 28.8% were in the intervention group. Four in one (25.8%) participants were not married in the both control and intervention group. Median family per capita income level of the participants were 50 (IQR 30-67) USD per month in both control and intervention group. There were no significant differences in the demographic characteristics at baseline between the control and intervention groups (Table 15).

Table 15 Baseline demographic characteristics

	Control group (n=66)	**Intervention group (n=66)**	**p-value**
Age (years)			
Mean(SD)	35.8 (8.8)	36.3 (6.8)	0.71
≤36	36 (54.5)	41 (62.1)	0.48
>36	30 (45.5)	25 (37.9)	
Gender			0.22
Female	39 (59.1)	31 (47)	
Male	27 (40.9)	35 (53)	
Ethnicity			0.60
Indigenous	31 (47.0)	27 (40.9)	
Non-indigenous	35 (53.0)	39 (59.1)	
Religion			0.44
Hindu	49 (74.2)	44 (66.7)	
Others	17 (25.8)	22 (33.3)	

Occupation			0.85
Unemployed	22 (33.3)	21 (31.8)	
Informal employee	25 (37.9)	23 (34.8)	
Formal employee	19 (28.8)	22 (33.3)	
Education level			0.10
Illiterate informal	29 (43.9)	19 (28.8)	
Primary and above	37 (56.1)	47 (71.2)	
Marital status			0.10
Single	17 (25.8)	17 (25.8)	
Married	49 (74.2)	49 (74.2)	
Children			0.09
No	14 (21.2)	6 (9.1)	
Yes	52 (78.8)	60 (90.9)	
Number of children			0.08
≤2	39 (59.1)	50 (75.8)	
>2	13 (19.7)	10 (15.2)	
Family per-capita income (USD*)			
Median (IQR)	50 (30-67)	50 (30-67)	0.81
≤50	41 (62.1)	44 (66.7)	0.72
>50	25 (37.9)	22 (33.3)	

* 1 USD = 100 NPR, IQR = inter quartile range, SD = standard deviation

Nearly half (51.5%) of the participants from both control and intervention group were diagnosed with HIV before their 33rd birthday. The median age at ART initiation was 35 years for both control and intervention group. Majority (72.4%) of the participant's spouse was HIV infected in the control group and 58.1% were in the intervention group. Nearly half (48.5%) of the participants in the control group 62.1% in the intervention group were infected through sexual contact. Half of the participants were with clinical stage I & II in the control and intervention group. Morbidity of the tuberculosis was found 15.2% in the control group and 12.1% in the

intervention group. There were no significant differences among behavioral and clinical characteristics between control and intervention group (Table 16).

Table 16 Clinical and behavioral characteristics

	Control group (n=66)	**Intervention group (n=66)**	**P-value**
Age at HIV diagnosis			
Median (IQR)	33 (26.5, 41)	33(30, 40)	0.56
≤33 years	34 (51.5)	34 (51.5)	0.10
>33 years	32 (48.5)	32 (48.8)	
Age at ART initiation			
Median (IQR)	35 (28, 42.8)	35 (30.2, 40.8)	0.55
≤35 years	36 (54.5)	38 (57.6)	0.86
>35 years	30 (45.5)	28 (42.4)	
Duration of ART			0.60
<1 year	38 (57.6)	34 (51.5)	
≥1 years	28 (42.4)	32 (48.5)	
Spouse HIV status			0.15
Negative	16 (27.6)	26 (41.9)	
Positive	42 (72.4)	36 (58.1)	
Mode of HIV transmission			0.16
Others	34 (51.5)	25 (37.9)	
Sex-worker	32 (48.5)	41 (62.1)	
Sexual intercourse in last 3 months			1.00
Yes	50 (75.8)	50 (75.8)	
No	16 (24.2)	16 (24.2)	
Sexual intercourse with non-spouse			0.78
Yes	7 (14)	9 (18)	
No	43 (86)	41 (82)	

Clinical stage			1.00
I & II	34 (51.5)	35 (53)	
III & IV	32 (48.5)	31 (47)	
Known morbidities			0.80
Tuberculosis	10 (15.2)	8 (12.1)	
Other	56 (84.8)	58 (87.9)	

4. Effectiveness of social self-value package on social characteristics

4.1 Clinical and behavioral

Risky sexual behavior, adherence and disclosure

Proportion of the unprotected sexual intercourse with any partner was significantly decreased among the intervention group and was increased among the control group at three months and six months follow up. The proportion of the adherence to ART was significantly decreased among the control group at six months follow up. The proportion of the disclosure of HIV status was significantly increased at three and six months follow up in the intervention group compared to the control group (Table 17).

Table 17 Pre- and post-intervention differences on behavioral and clinical characteristics

	Baseline			Three month follow up			Six month follow up		
	Control (n=66)	**Intervention (n=66)**	**P-value**	**Control (n=66)**	**Intervention (n=66)**	**P-value**	**Control (n=66)**	**Intervention (n=66)**	**P-value**
Unprotected sexual intercourse with any partner in last 3 months*			0.82			0.001			0.001
No	38 (76.0)	36 (72.0)		19 (35.8)	47 (100.0)		19 (36.5)	45 (95.7)	
Yes	12 (24.0)	14 (28.0)		34 (64.2)	0 (0)		33 (63.5)	2 (4.3)	
Ever forgot to take ART			0.16			0.38			0.007
Yes	23 (34.8)	32 (48.5)		26 (39.4)	32 (48.5)		48 (72.7)	32 (48.5)	
No	43 (65.2)	34 (51.5)		40 (60.6)	34 (51.5)		18 (27.3)	34 51.5)	
Forgot to take ART last week			0.78			0.001			0.001
Yes	6 (9.1)	8 (12.1)		56 (84.8)	0 (0)		20 (30.3)	0 (0)	
No	60 (90.9)	58 (87.9)		10 (15.2)	66 (100.0)		46 (69.7)	66 (100.0)	
Disclosure of HIV status with*			0.93			0.001			0.001
≤3 persons	46 (80.7)	45 (77.6)		46 (76.7)	18 (27.3)		44 (73.3)	2 (3.0)	
>3 persons	11 (19.3)	13 (22.4)		14 (23.3)	48 (72.7)		16 (26.7)	64 (97.0)	

*Missing data, p-value=Fisher's exact test

4.2 Stigma

The mean scores of the stigma domains were rapidly decreased after the intervention at 3- months follow up and slightly decreased at 6-months follow up among the intervention group. All the domains score were constant among the control group from baseline to 6- month follow up (Figure 9).

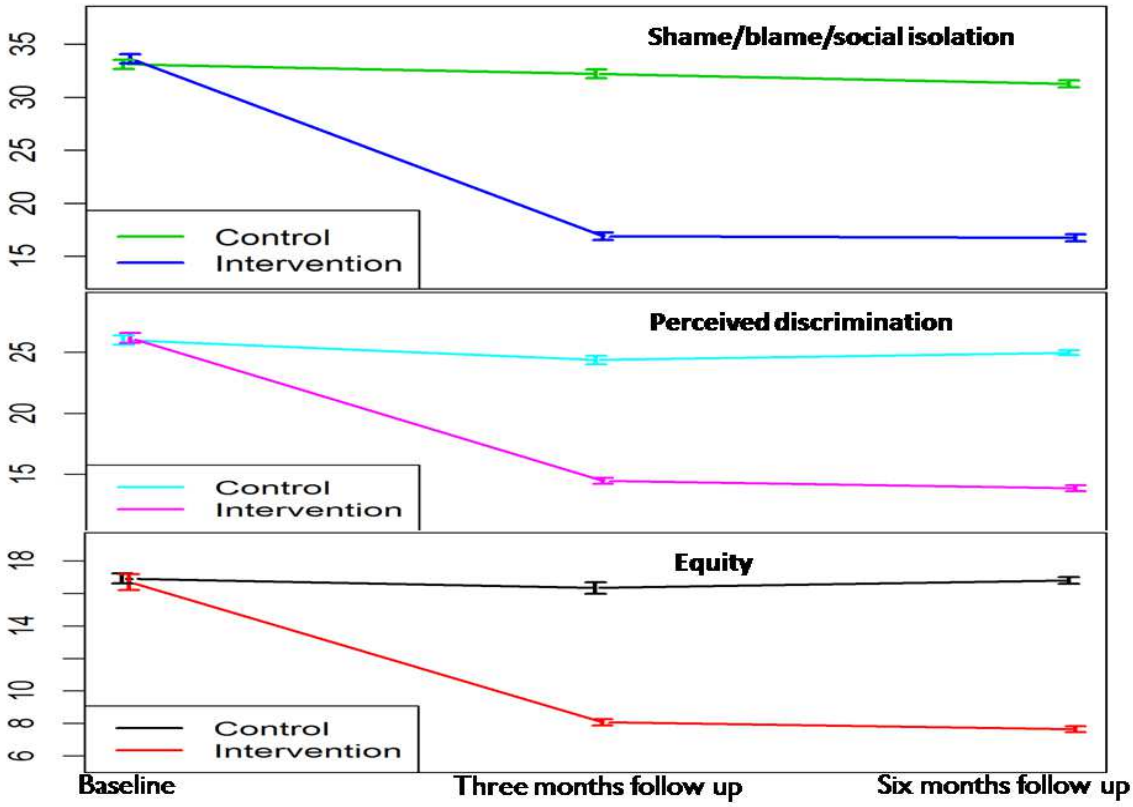


Figure 9 Average stigma domain score with 95% CI

The mean overall score of the stigma was rapidly decreased after the intervention at 3 months and slightly increased at 6 months follow up among the intervention group and score among the control group were constant (Figure 10).

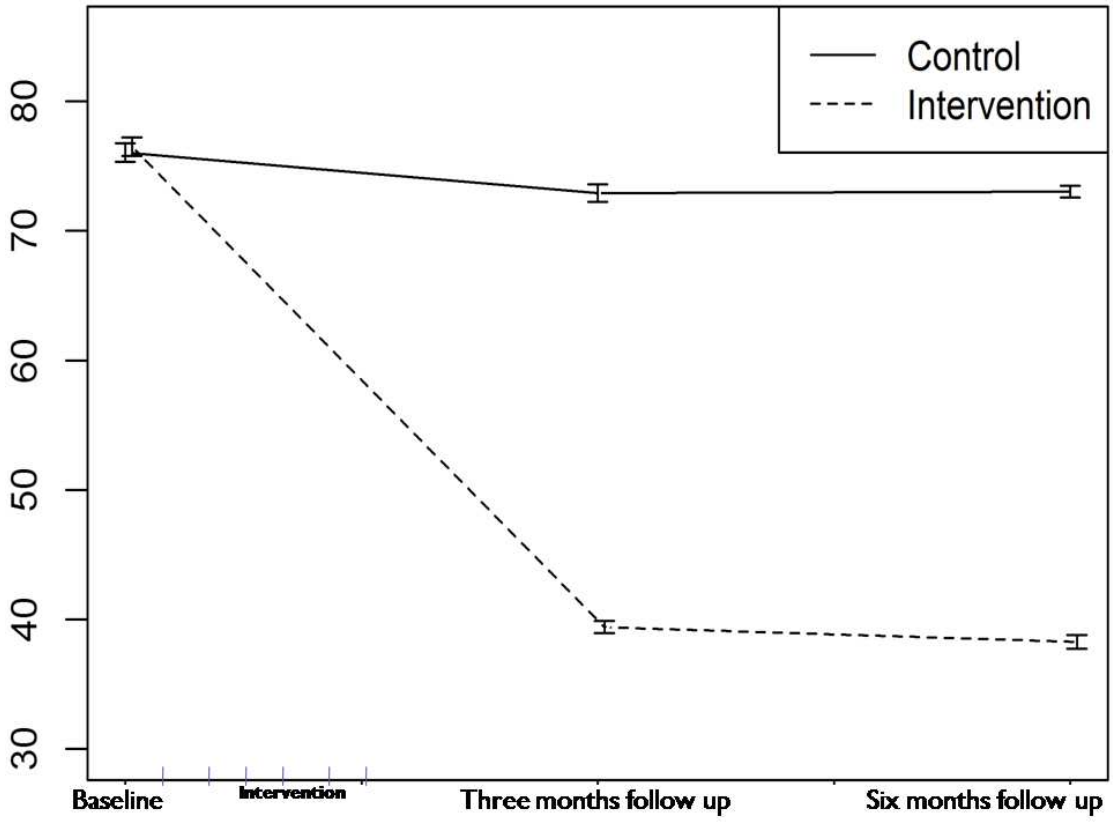


Figure 10 Average stigma total score with 95% CI

4.3 Social support

The mean score of the social support number rapidly increased after the intervention at 3 months and steadily increased at 6 months follow up among the intervention group and score among the control group were slightly increased up to 6 months follow up (Figure 11).

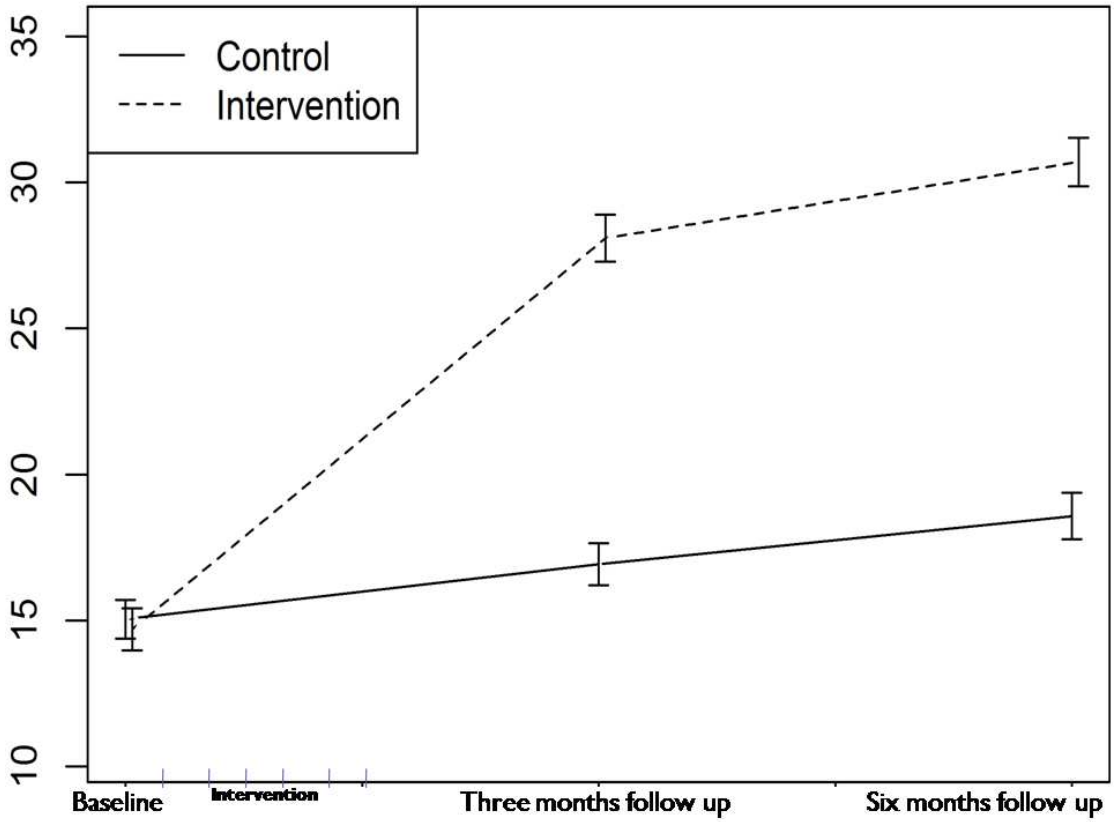


Figure 11 Social support questionnaire number (SSQN) with 95% CI

The mean score of the social support satisfaction rapidly increased after the intervention at 3 months and steadily increased at 6 months follow up among the intervention group and score among the control group were slightly increased up to 6 months follow up (Figure 12).

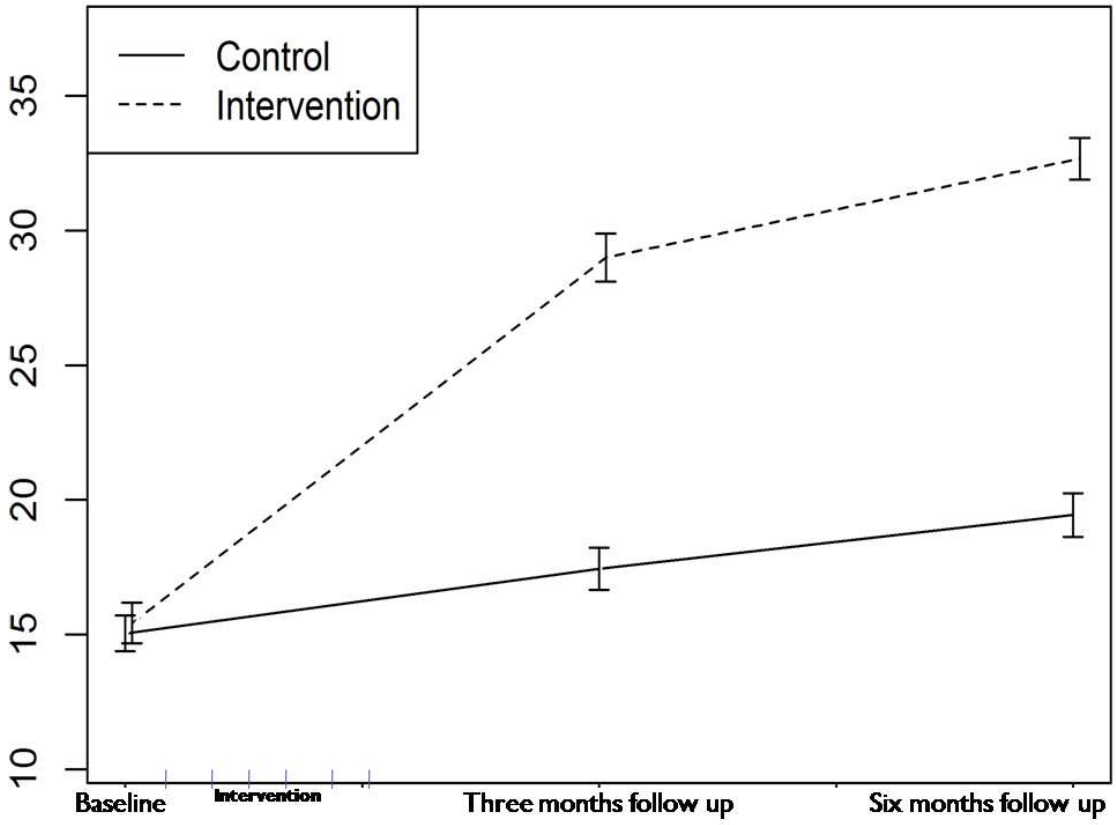


Figure 12 Social support questionnaire satisfaction (SSQS) with 95% CI

5. Efficacy of social self-value package on empowerment

The mean score of the empowerment domains were rapidly increased after the intervention at 3- months follow up and slightly increased at 6-months follow up among the intervention group. All the domains score were constant among the control group from baseline to 6- month follow up (Figure 13).

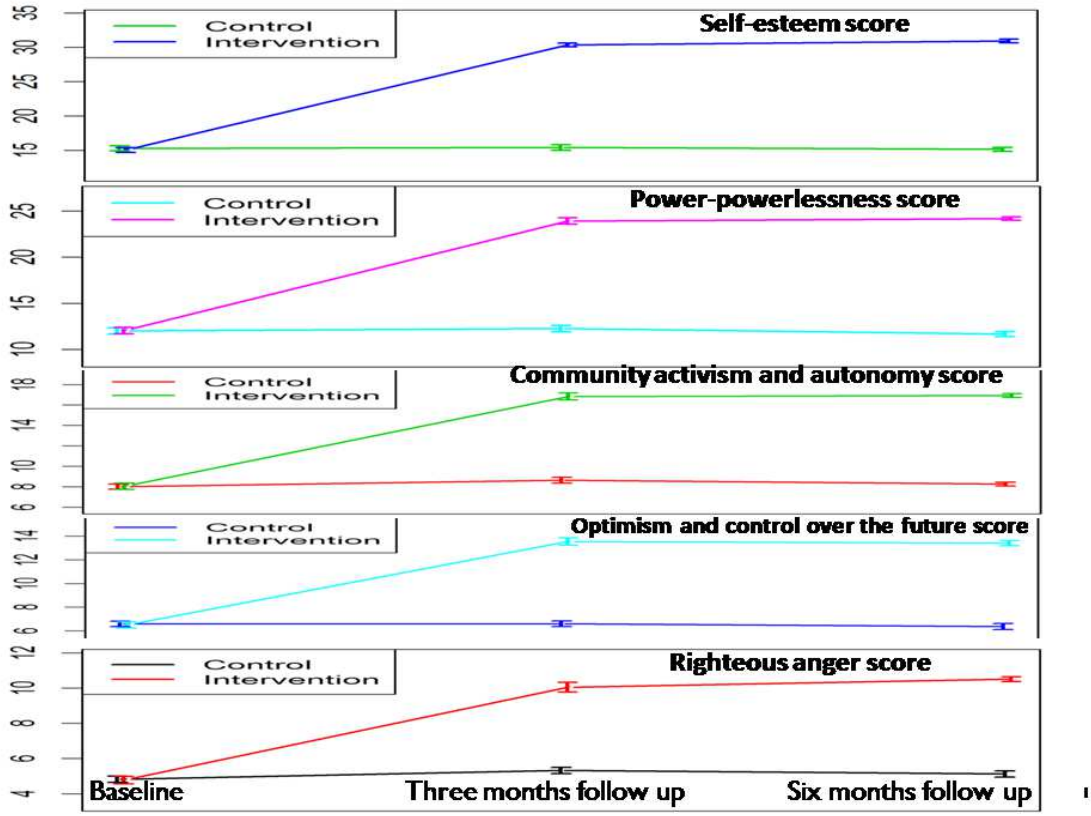


Figure 13 Average empowerment domain score with 95% CI

The mean score of the empowerment rapidly increased after the intervention at 3 months and slightly increased at 6 months follow up among the intervention group and score among the control group were constant (Figure 14).

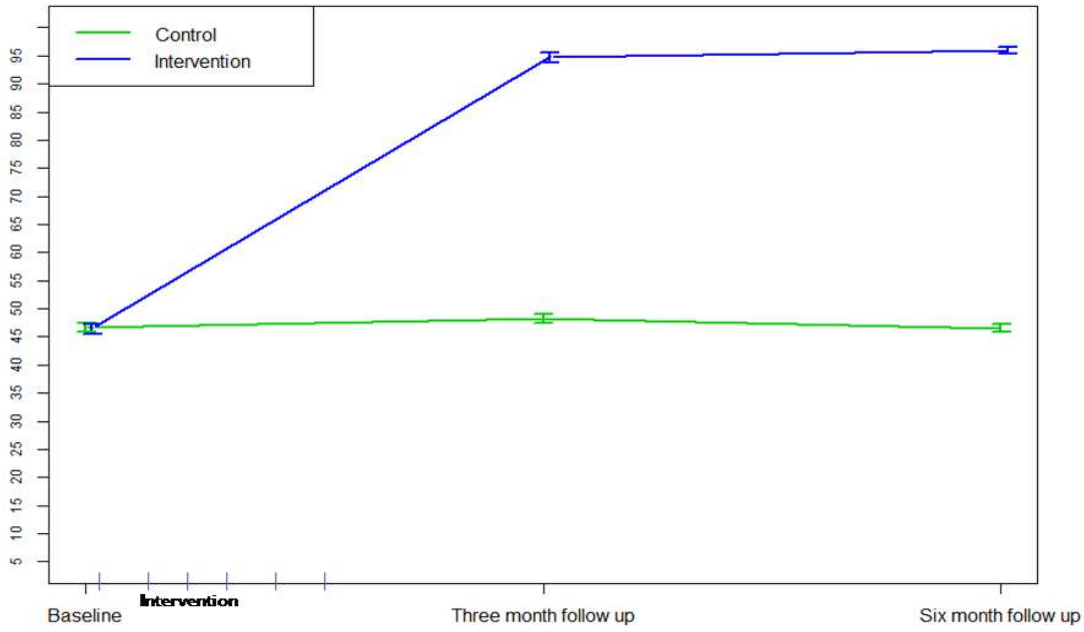


Figure 14 Average empowerment total score with 95% CI

There was no significant differences at baseline empowerment mean score among control and intervention group. Similarly, scores of the domains of the empowerment mean score was not significantly different between control and intervention group at baseline. Impact of the intervention (Difference-in-Difference) at 3-(46.77, $p < 0.001$) and 6- months (49.71, $p < 0.001$) was significantly higher for the intervention group in all domains of empowerment. The impact of the intervention for all the domains of empowerment at 6 months was slightly higher compared to 3 months (Table 18).

Table 18 Impact of social self-value package on empowerment at 3- and 6-months follow up

	Baseline		3 month follow up		Pre-Diff	Post-Diff$_{3mo}$	DiD$_{3mo*}$ (Impact)	6 month follow up		Post-Diff$_{6mo}$	DiD$_{6mo*}$ (Impact)
	Control	Intervention	Control	Intervention				Control	Intervention		
Empowerment (total score)	46.70	46.38	48.23	94.68	-0.32	46.45	46.77	46.53	95.92	49.39	49.71
Self-efficacy/self-esteem	15.27	15.03	15.39	30.33	-0.24	14.94	15.18	15.12	30.91	14.79	16.03
Power-powerlessness	12.00	12.03	12.26	23.92	0.03	11.67	11.64	11.67	24.18	12.51	12.48
Community activism and autonomy	8.01	8.04	8.65	16.83	0.03	8.18	8.15	8.26	16.92	8.67	8.64
Optimism and control over the future	6.59	6.50	6.61	13.54	-0.09	6.94	7.03	6.36	13.41	7.04	7.14
Righteous anger	4.82	4.77	5.32	10.04	-0.04	4.73	4.77	5.12	10.50	5.38	5.42

*=p <0.001; Pre-diff: difference at baseline; Post-diff$_{3mo}$: difference at 3 month follow up; Post-diff$_{6mo:}$ difference at 6 month follow up; DiD$_{3mo}$: difference at baseline and 3 month follow up; DiD$_{6mo}$: difference at baseline and 6 month follow up

6. Effectiveness of social self-value package on quality of life

The mean score of the QoL domains were rapidly increased after the intervention at 3- months follow up and slightly increased at 6-months follow up among the intervention group. All the domains score were constant among the control group from baseline to 6- month follow up (Figure 15).

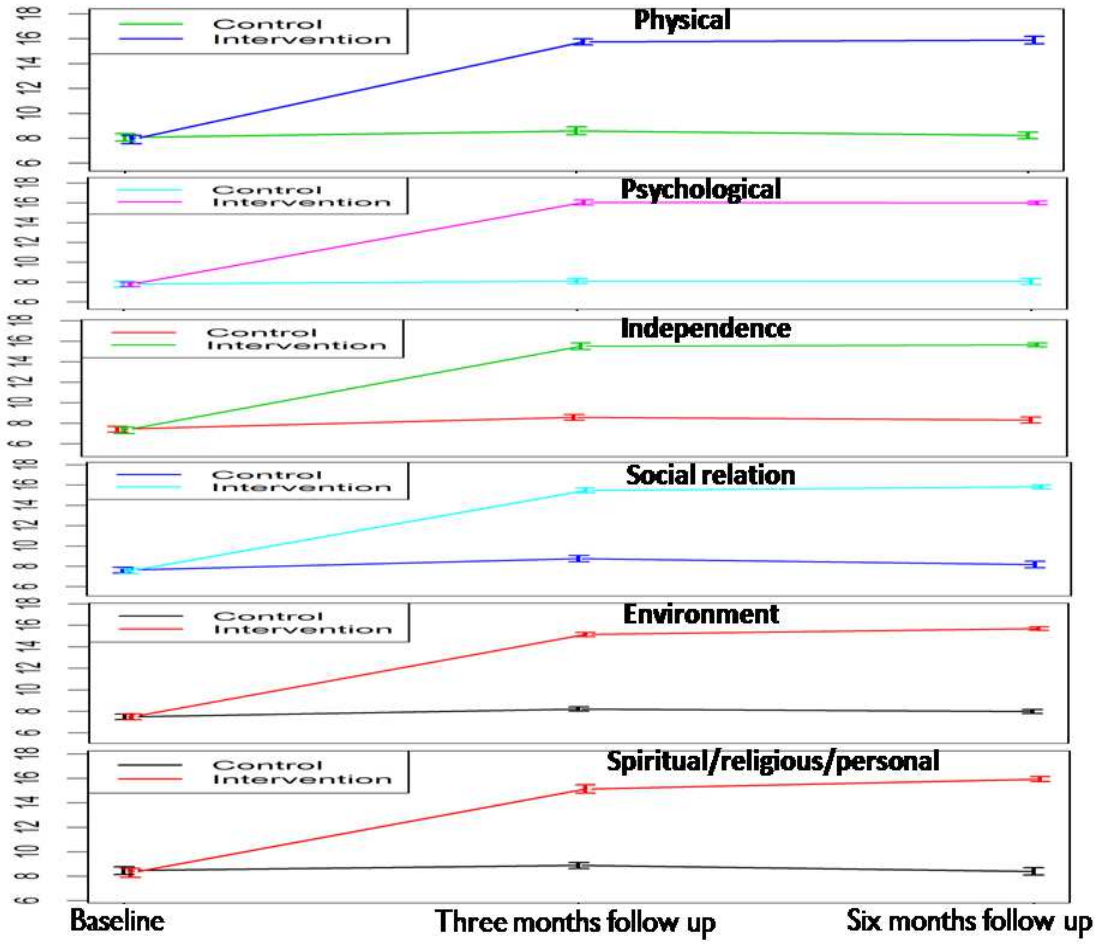


Figure 15 Average QoL domain score with 95% CI

The mean score of the QoL rapidly increased after the intervention at 3 months and slightly increased at 6 months follow up among the intervention group and score among the control group were slightly increased at 3 month and slightly decreased at 6 months follow up (Figure 16).

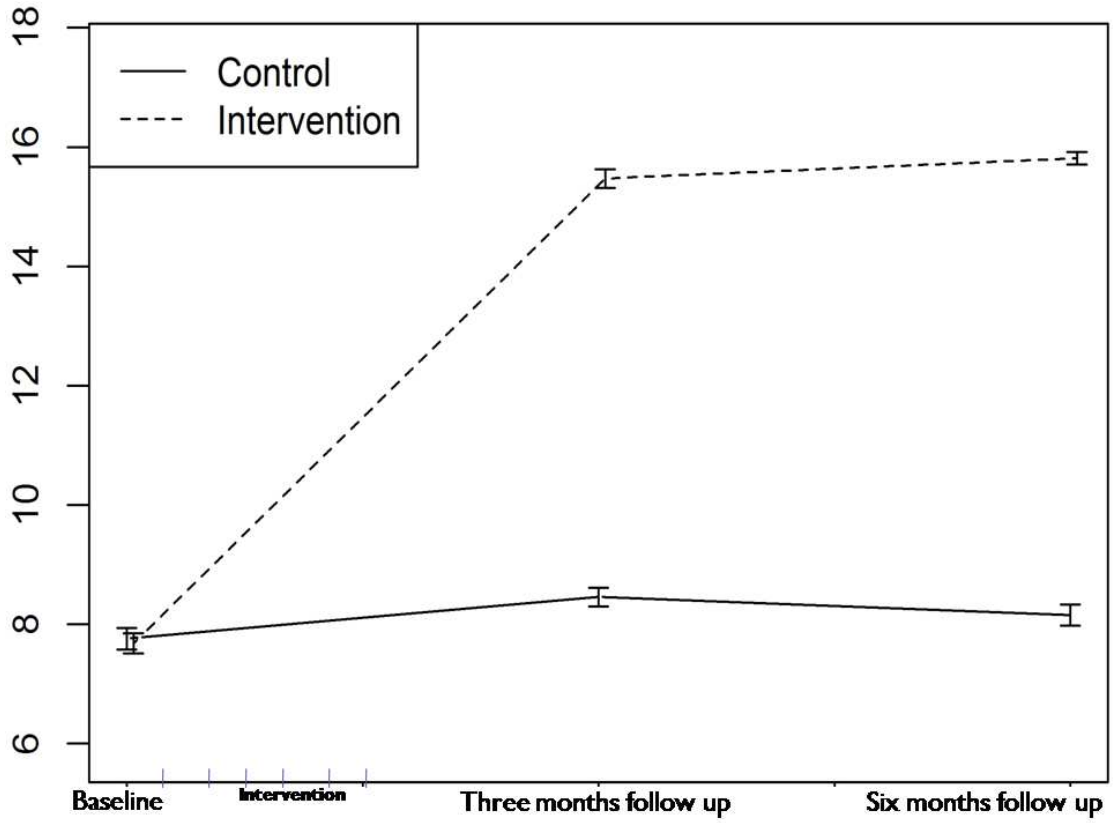


Figure 16 Average QoL total score with 95% CI

7 Relationship of empowerment with social support, stigma and QoL

After adjusting the covariates including age, gender, adherence to ART, group and time, improved empowerment was significantly associated with reduce in stigma ($p<0.001$) and positively associated with QoL ($p<0.001$). There were no significant effects on intervention group at baseline in any outcome variables (SSQN, SSQS, stigma and QoL). Improving on ART adherence was significantly associated with reduce in stigma ($p<0.001$). There was no significant association between any of the outcome variables with age. Significant effects were observed with all the outcome variables by time and interaction with time and intervention ($p <0.001$). After interaction with time (baseline to follow up) and group (intervention and control), significant improvement on social support, stigma and QoL at three and six months follow up among intervention group compared to control group (all p-values <0.001) (Table 19).

Table 19 Effect of social self-value package to social support, stigma and QoL using nonlinear mixed-effects regression model

Parameter	SSQN			SSQS			Stigma			Quality of life		
	Estimate	**SE**	**p-value**	**Estimate**	**SE**	**p-value**	**Estimate**	**SE**	**p-value**	**Estimate**	**SE**	**p-value**
Empowerment	-0.010	0.038	0.795	-0.024	0.040	0.544	-0.127	0.038	<0.001	0.057	0.009	<0.001
Age	-0.001	0.028	0.997	-0.038	0.029	0.196	0.005	0.016	0.744	0.005	0.005	0.289
Male vs. female	1.196	0.449	0.008	1.215	0.464	0.009	0.315	0.250	0.208	-0.009	0.074	0.896
ART adherence	-0.681	0.393	0.083	-0.424	0.409	0.300	-1.300	0.402	<0.001	0.145	0.105	0.151
Intervention vs. control at baseline	-0.496	0.532	0.351	0.243	0.550	0.659	0.388	0.425	0.360	-0.060	0.109	0.579
Intervention vs. control compare to baseline												
Three months follow up	11.983	1.868	<0.001	12.304	1.936	<0.001	-28.028	1.890	<0.001	4.430	0.474	<0.001
Six months follow up	12.967	1.977	<0.001	14.041	2.049	<0.001	-28.927	1.998	<0.001	4.904	0.501	<0.001

SE: standard error; SSQN: social support question number; SSQS: social support question satisfaction

After adjusting for covariates QoL, SSQN, SSQS, stigma; improved total QoL score was significantly associated with improved score of empowerment ($p < 0.001$). Increased in stigma level had a significantly lower level of empowerment ($p = 0.002$). Significant effect was not found between social support and empowerment. Improvement in empowerment was statistically significant at 3- and 6- months follow up among intervention group compared to control group ($p < 0.001$) (Table 20).

Table 20 Prediction of empowerment by QoL, stigma, social support, and intervention group using nonlinear mixed-effects regression model

Parameter	Empowerment		
	Estimate	SE	p value
QoL	1.431	0.237	<0.001
SSQN	-0.040	0.057	0.479
SSQS	0.029	0.055	0.590
Stigma	-0.196	0.062	0.002
Intervention vs. control at baseline	-0.141	0.527	0.027
Intervention vs. control compare to baseline			
Three months follow up	30.102	2.848	<0.001
Six months follow up	31.863	3.015	<0.001

After adjusting for covariates empowerment, SSQN, SSQS, stigma; increased level of empowerment score was significantly associated with QoL ($p < 0.001$). Significant effect was not found between social support, stigma and empowerment. Increased level of QoL was statistically significant at 3- and 6- months follow up among intervention group compared to control group ($p < 0.001$) (Table 21).

Table 21 Prediction of QoL by empowerment, stigma, social support, and intervention group using nonlinear mixed-effects regression model

Parameter	Quality of life		
	Estimate	SE	p value
Empowerment	0.057	0.009	<0.001
SSQN	0.007	0.012	0.574
SSQS	-0.009	0.011	0.410
Stigma	-0.004	0.012	0.771
Intervention vs. control at baseline	-0.051	0.108	0.371
Intervention vs. control compare to baseline			
Three months follow up	4.310	0.610	<0.001
Six months follow up	4.788	0.642	<0.001

Relative intervention effects among intervention group in social support, stigma and QoL was found higher than the control group with the level of empowerment (higher empowerment vs. low empowerment) (Figure 17).

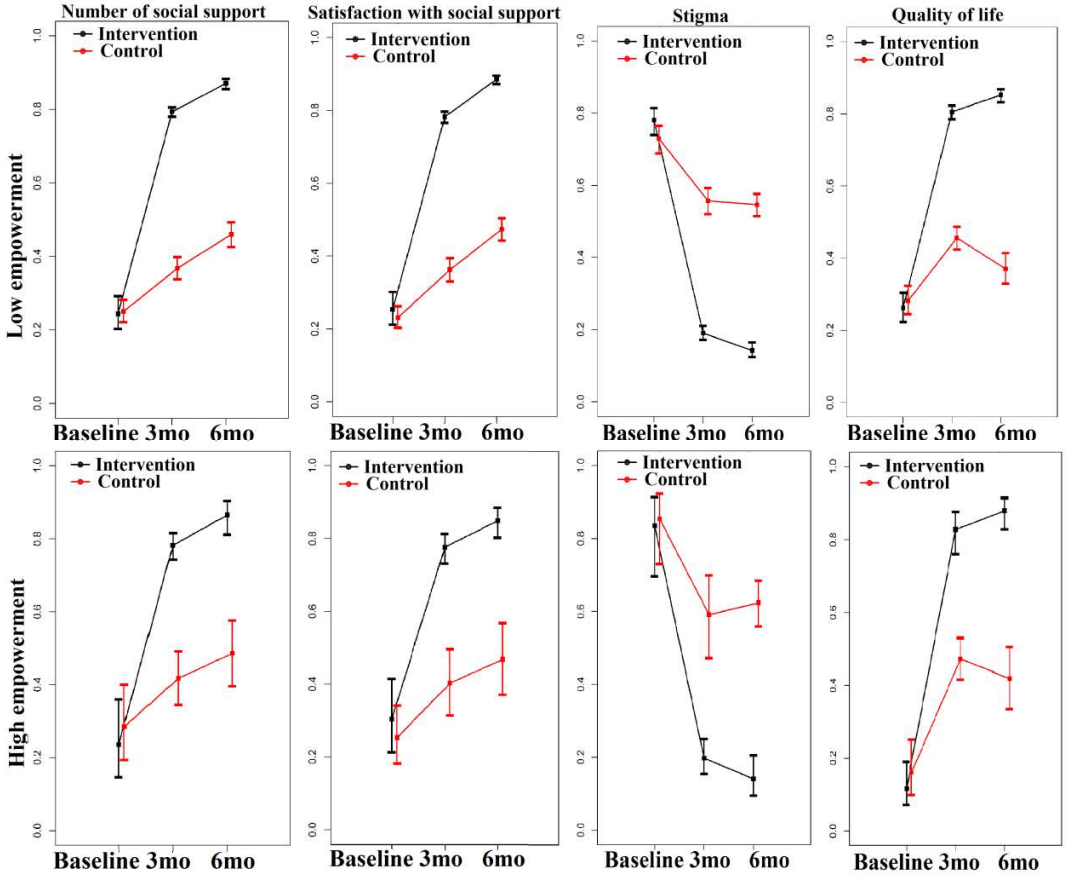


Figure 17 Relative intervention effects on social support, stigma and QoL stratified by empowerment using nonparametric mixed effect model

All p-values for time trend between intervention and control on each outcome were significantly different with $p<0.001$, 3mo = Three months follow up, 6mo = Six months follow up

CHAPTER IV

DISCUSSION AND CONCLUSIONS

1. Discussion of main findings

1.1 Acceptability of the social self-value package

Feasibility of a social-self value intervention package was measured among HIV infected people. Both qualitative and quantitative methods have found the package was feasible and acceptable. Demographic characteristics were not different among the intervention participants. Majority participants belonged to adult age group and lower number of the participants had more than higher secondary and above level of education. Previous study conducted in Malawi had found similar characteristics of participants.[145] Studies from United States of America and Africa revealed changes on the attitude related to HIV among intervention participants which have similar with our study findings.[146-148] Extended technology model found that the social influence would make changes on one's attitude and behavior.[149]

Higher level of compliance or adherence has been linked with the level of satisfaction.[150] Our study findings revealed the higher level of satisfaction with the different features of intervention package. There was no gold standard tools and methods to measure satisfaction and variation among the satisfaction tools for HIV services.[151] We used the CSQ-8 tools for satisfaction measurement and determine the higher level of satisfaction. Studies conducted in United States of America revealed similar findings using similar tools for HIV infected people.[152, 153] Similarly, findings included group session, interactions, comprehensive topics, activities and time settings from qualitative methods found to be similar with previous studies.[145, 152, 154]

Several studies highlighted either one or more contents including coping stress or stigma, positive relationship, benefit on self-health care, disclosure, laws and empowerment, and self-esteem as similar in our intervention.[45, 127, 139, 140, 143, 152, 155-157]

We used SEF tools to measure acceptability of intervention package and found to be higher as similar with previous studies.[152, 158] Qualitative findings made the remarks for the improvement in the intervention package which was similar with previous studies findings.[152, 154]

Our study finding revealed the higher retention in the intervention sessions. However, feasibility and retention is always hard to study in HIV that might be the because of stigmatization and disclosure problems.[159] To maintain the retention in the intervention need to development of incorporated group, group dynamics be well planned, compliments their values without developing conflict, giving the chances to articulate their behavior and skills and emotional or motivational relationship building.[152] Although, previous study conducted in Malawi emphasized that the high retention rate might be due to the condition of incentives.[145]

Independently developed structures and contents of the intervention package were extensively corrected and reviewed by the experts. All the contents and structure of the intervention was pilot tested among real world settings that might increase reliability of the contents and structure of the intervention package. Different aspects like satisfaction, acceptability and attitude were measured for the acceptability of the intervention using combined qualitative and quantitative methods. All the combination of the measurement with higher attendance and retention revealed the excellent acceptability of the intervention package.

1.2 Effectiveness of the social self-value package

Baseline characteristics

Our findings revealed the intervention effects on behavior and clinical characteristics (risky sexual behavior, adherence to ART and disclosure HIV status) of HIV infected population. Changes on the behavioral and clinical characteristics would be possible to change in this intervention because these issues are incorporated in the intervention package. Positive impacts of the intervention to reduce risky sexual behaviors was revealed by a systematic review based on interventions.[160] Our findings

revealed the significant reduction in risky sexual behavior after the intervention among intervention groups. Improvement in condom use and decreased in risky sexual behavior was revealed by a systematic review based on community empowerment interventions among sex workers.[161]. Similar findings were highlighted by previous study that focused on the empowerment of HIV infected population.[162] Our intervention found that the adherence to ART was significantly increased after the intervention. Similar findings were revealed by previous studies that the adherence to ART were improved after the empowerment interventions.[163, 164] Our trial found that the significant improvement in disclosure of HIV status. This process could empower the victim, reduce the transmission of disease, increased the self-esteem, support and emotions from society or community networks.[165]

This empowerment intervention has imagined in a multiple ways that help to HIV infected people for social adjustment and increase relationships, autonomy, self-esteem, behavior change through the development of advocacy, strength, skills, cognition and independence. This result could be the course of impact which was related with the theory of empowerment. Empowerment intervention targeted to HIV infected population are not presented in this context and region. However, the extensively developed intervention package, fidelity of the intervention and qualified interventionist might be the motives for the improved outcomes. Even though the significant results revealed on secondary outcomes with small sample size, it could be suggested for further research with wide areas covered samples to determine the long term intervention effects. Empowerment could be measured with the dimension of community and self direction to empowerment. Community direction focused that the HIV infected population would have the power in the society and aspiration to promote community action in the unsociable world. Self direction emphasized that the HIV infected population could believe themselves to be self-efficacious, self-esteemed, and positive to their future.

Empowerment tools could be used with pre-tested and validated with experts. First, we discussed the contents of the questionnaire with two experts who

amended the language for suitability with HIV patients. Further contents were revised to be applicable to the Nepalese culture and contexts. We then discussed the content with three HIV infected people for clarity and acceptance, and amended it accordingly. After development of the revised version with experts and HIV infected people, we pre-tested the final version among HIV infected people. During the pre-test, we did not detect any comments and difficulties from participants. Internal consistency, as measured by Cronbach's alpha was high (0.97).

Empowerment, social support, stigma and QoL of HIV infected people at baseline were low among both groups. Social support, stigma and QoL was found to be greatly improved at 3 months follow up among the intervention group and continued for next 3 months. Positive effectiveness of empowerment intervention was found with social support, stigma and QoL among higher and low level of empowerment. Empowerment was significantly associated with social support, stigma and QoL; however, the empowerment significantly predicted to QoL. Variation at each time point of the data collection was small in each group. This small variation could be due to shared similar information by all the participants. Participants had represented similar demographic and clinical characteristics at the same ART center.

This study finding revealed the significant improvement in the empowerment score after intervention among the intervention groups compared to the control groups. Similar findings were highlighted by a previous study conducted in Canada.[163] However, the existing literatures are sparse to compare empowerment intervention outcome among HIV infected people.[128, 163]

Self-esteem could help to manage negative physical, social and emotional effects among HIV infected individual. This intervention was assumed to enhance self esteem to manage those issues. Our findings established the high correlation between empowerment and its domains. It was estimated that the correlation between different domains from higher (self-efficacy) to lower (righteous anger). Self-efficacy score found to be significantly improved after intervention among intervention group, which was

similar with previous different interventions findings among HIV patients.[162, 163, 166] Similar findings revealed from a systematic review based on community interventions that highlighted positive effects on self-esteem.[167]

Empowerment intervention could help to reduce and maintain anger where HIV infected people could not develop the feelings for revenge with their past. This was detected in our intervention that righteous anger (reactive feeling of fury over abuse) negatively correlated with the other empowerment domains. Highly increased righteous anger had an optimistic power on community and social adaption of HIV population. Our study revealed the significant improvement in community activism and autonomy, power-powerlessness (dependent and totally hopeless) and optimism & control over the future (wish and guarantee about the hope or flourishing outcome of something). This might be the effect of empowerment that developed capacities to restore and reorganized their daily lives.[168] Deficiency of the self-control and autonomy infected person would develop harassment on their life's goals. Lack of control over the future and powerlessness could be unlike a risk factor of the disease. Our findings of the DiD were further crosschecked by an ATE (average treatment effect) model with PSM (propensity score matching). This could help to reduce variable selection bias however the randomization process could eliminate the bias and we got the similar results.

1.3 Relationship of empowerment, social support, stigma and QoL

Our trial revealed the number of social supports and satisfaction with available social support. Increased empowerment in the intervention group showed increased in social support after the intervention. Literatures related to empowerment interventions based on HIV infected samples was difficult to find and difficult to compare this trial outcome with existing outcomes. Our study highlighted the increased social support after intervention which was similar with the results from existing randomized controlled trial based on psychological group support to HIV infected population.[166] In addition to this progress, control group has recorded slightly improvement social support after intervention. It might be due to the repetitive use of

same questionnaires for the data collection which could influence the participants behavior and might be the effect of contamination.[169] Empowerment process could promise to reduce discrimination, stigmatization, and cognitive state through improved social support.

Our empowerment intervention was found effective to reduce stigma at the post-intervention period. Similar findings was highlighted by systematic reviews that based on different interventions focused stigma reduction.[170, 171] In addition, report suggested that the limited literates of interventions available to reduce discrimination and stigma among HIV infected population.[171] Based on the available literature we developed the extensive empowerment intervention that can be suitable for local culture and context to reduce stigma and discrimination among HIV infected population. Empowerment theory could enhance the disenfranchised group that can help to defeat discrimination and stigma and our intervention work with this theoretical path. Increased adherence to ART significantly reduce stigma. A systematic review and meta-synthesis revealed similar outcome that the increased adherence was associated with reduced stigma.[172]

This empowerment intervention outcome revealed the significant effect in improving QoL among the intervention group. Systematic reviews based on diverse interventional and observational studies highlighted the uncertain results on QoL of HIV infected people.[173-176] This dissimilarity on the results might be due to the uses of diverse measurement tools, sampling and sample size, study settings context and culture in diverse studies. Thus, we developed different analytical strategies and approaches with pretested intervention manual and tools that fit for the local cultural and context which could increase the reliability of this trial and outcomes.

Social support could be the asset to improve stigma and QoL among HIV infected populations and previous studies revealed the association between social support, stigma and QoL.[177, 178] In addition a systematic review highlighted the QoL among HIV infected population were correlated with social support.[179] Nonetheless, in this intervention, stigma, social support, and adherence to ART were not significantly

associated with QoL. Statistically significant results were not detected with those variables and it might be due to the small sample size effect.

Further we collected background characteristics (age, sex, ethnicity, marital status, date ART started) for all the screened participants. There was no difference in these background characteristics between those who agreed to participate in the study and those who refused thus minimizing biological, environmental and socioeconomic bias. The given reasons for refusal to participate were lack of interest, time and perceived need for the intervention. The strong recruitment process enhanced a higher retention rate in the intervention group and lower loss to follow up at 3- and 6-months. The intervention sessions took place in the same center where the controls received ART. This could have increased the chance of contamination among the control group. To reduce this risk, we conducted the intervention after services had finished for the day in each center and participants were counseled not to disclose any activities during the study period. The fact that the findings did not show any changes among the control group after the intervention provides evidence of no or minimal contamination. On the other hand, provided incentives to the intervention group could lead to confirmation bias. Incentivized group might be more biased in their information than who did not get incentives.

Community-based interventions based on empowerment theory were found to improve empowerment for reduce in HIV transmission.[96-104] Intervention based on empowerment theory included family members with HIV infected people improved the social support and family functioning.[128] Further empowerment theory based program improve the service access, QoL, psychological states and drugs. Individual and group level behavioral and social interventions included social theories, pedagogy theory and Buddhism philosophy revealed inconclusive results to improve QoL among HIV infected people.[49, 125-130] Interventions based on the social or behavioral theories more focused on cognitive state and addressed the mental health which may improvements in participants' perceived mental health and general health which eventually translate to better perceived

physical health. However, the community interventions are sparse to improve QoL among HIV infected people. A controlled trial of an educational program found the improvement of adherence to antiretroviral therapy but no change in QOL was demonstrated. Possible reasons could be the biochemical characterization of HIV; ART had indirect effect on QoL; interventions started late with the course of treatment which could reduce deterioration of the psychological and medical condition; intervention contents not modified and not acceptable for culture and context; not pay attention to issues pertaining to internal and external validity; used “one-size-fits-all” packaged intervention in all the context. It was suggested that the interventions are more likely to succeed if they address family and community factors. Revised contents with cultural and context acceptable and appropriate theories used according to contents could be the best reasons for its effectiveness.

2. Strengths and limitations

A number of strengths of this trial should be noted. Our randomized trial was conducted in a real world study setting, participants assigned randomly and analysis assessor was blinded thus assuring a good external and internal validity. Pre-tested empowerment intervention package and other tools in various stages improved the reliability. Acceptability of the empowerment intervention package was reported to be higher among the participants. Participants’ attendance in the intervention sessions recorded higher and high retention maintained in the intervention and follow up period. Our trial is the first in its kind of multidimensional outcome study in Nepal conducted in the usual health service setting. This trial participant’s socio-demographic and clinical characteristics were similar with HIV infected people in Nepal which results could be generalizable to other infected populations. Rigorous analysis process and strong fidelity was maintained over the study period which guaranteed the high effect of the trial. Recall and reporting biases were cross checked in the ART center with reported adherence to ART.

Our trial has several limitations. Open level design and single setting might have a chance of contamination, although, the coding process could maintain and ensured anonymity and confidentiality. Further, our outcome revealed higher differences among intervention and control group. Outcome includes risky sexual behavior, adherence to ART and HIV status disclosure was found higher which could be the Hawthorne effect, that can reduce the power to identify a realistic variation from a trial.[180] Adherence to ART might be confounded with its side effects, toxicity, attitude and accessibility which could develop the social desirability bias. Although, familiar with the study setting the participants building and maintaining good rapport with the participants in the study process were presumed to reduce bias. Randomized controlled trial is a vibrant design which could reduce the different bias due to confounders, although, the trials based on behavioral intervention might have inherent biases. Same measurement tools used with same participants, reimbursement practice and consent process in several times might help to change the behavior of the participants among control and intervention group. Biomarker and economic aspects were not considered in this study. We could not test the psychometric properties for the validity of the tools because of the sample size but internal consistency of the tools was reported high. Measurement tools can be used in the different settings with checking its validity and reliability before using it. Highly skilled manpower was delivered the intervention in this trial that could be limited its accessibility and sustainability. It needs to be rechecked with limited resource settings with available manpower. Long-term effect and impact of the intervention were not assessed in this trial. Further small sample size could limit the validity of our secondary outcomes.

3. Conclusions and recommendation

The social self-value empowerment intervention program among HIV infected people was found acceptable and feasible. The intervention effectiveness was analyzed with the data collected at baseline, 3- and 6- months follow up. The effectiveness on empowerment of HIV infected people under ART was shown among

intervention group at 3- and 6- months follow up. Furthermore, risky sexual behaviors, adherence to ART and disclosure of HIV status were improved. The empowerment intervention significantly improved the QoL among the intervention group at 3- and 6-month follow up. Further, it significantly reduced the stigma and improved the social support among intervention group. Findings could be utilized at regular service settings for its sustainability and long-term effect. Although the intervention effects on secondary outcome were detected, we recommend evaluating in future multicenter studies with large sample sizes for monitoring the long-term effects. Empowerment intervention framework and measurement can be used in different settings after validating its cultural and contextual acceptability and applicability.

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ANNEX-I: Inclusion and exclusion checklist

Items	Yes	No
1. Age 18 or above		
2. Clinically diagnosed and enrolled for ART (between 6 month to 2 years)		
3. Able to communicate		
4. Have plan to stay at least six month in study settings		
5. Willing to give consent for baseline, follow up		
6. Willing to participate in either intervention or control group		
7. Psychotic disorder		
8. Antisocial personality		
9. Visual retardation		
10. Hearing retardation		
11. Not received any other education program last three months		
12. Not willing to disclosure among group		

If all the yes from no. 1 to 6 inclusion and then no. 7 to 12 any one yes exclusion

[ ] Included

[ ] Excluded reasons: _____

Signature_____Date_____

ANNEX-II: Informed consent form and certificate

Project title: Efficacy of social-self value package to improve empowerment and quality of life among people living with HIV under antiretroviral treatment in Nepal: a randomized controlled trial.

I am....., an interviewer, on behalf of Dharma N Bhatta, Pokhara University, Nobel College, Nepal to conduct an intervention study.

Purpose of the research: People living with HIV are vulnerable group and suffering from different physical, mental, economical and social problems. Due to the lack of knowledge about transmission, prevention and self care during illness has increase the stress and decrease the quality of life. The intervention aim is to evaluate the efficacy of social-self value package on improve of QoL and empowerment at 6 month follow-up. It will help to people improve the QoL, empowerment, social support and reduce the stress or stigma. PLH will increase the coping mechanism of stigma and self care awareness.

Procedures: You are requested to attain either intervention group or control group. You will give the answer of the questions three times (baseline, three month and 6 month) either controls group or intervention group. You need to spend around 40 minutes to answer the question by face to face interview from trained research assistant. If you will be assigned to intervention group, it will be conducted once in a week for eight week. Intervention session will be around 90 minutes. If you will be assigned to control group, you will be requested to give information based on the research question at baseline, 3-, 6- month follow up.

Risks and benefits: This is the community intervention, no drug and any regime will be used during study period. Intervention method will be conducted through education, discussion and participatory approach. We will not anticipate any risk from these processes and we will correct and minimize any possible risks. The intervention will help

during the illness difficulties and helpful to manage medical and social related problems to all the HIV infected peoples.

Confidentiality: All the information will be kept anonymously. All the intervention class will be conducted in secret places and venue will be fixed after discussion with participants. No identification contents will be used and unique number will be used for intervention and data collection process. A written certificate of consent will be signed by both the researcher and you.

Right to refuse and withdraw: You have the right to either agree or disagree to take part in this study. You can withdraw from study any point of time during study. Where you agreed on the participation of study and then you have right to refuse any question to answer or terminate the study. All the participation will volunteer and no incentive will be given for study.

Contact person: For any question before making a decision to join in the study, you can contact Dharma N Bhatta, Pokhara University, Nobel College, Sinamangal, Kathmandu, Nepal contact via mobile number: 9841485128, e-mail: dnbhatta@yahoo.com

I am fully understood the above information concerning to intervention study.

I have read or been informed of the above information. Any question concerning to this research has been answered to my satisfaction. I consent voluntarily to be a participant in this study and understand that I have the right to withdraw from the study at any time.

Signature of respondent…….

Signature of researcher……

Data: / /

ANNEX-III: Questionnaires/Instruments

Preliminaries

ID			
Data entry period	Baseline	3 month follow up	6 month follow up
	0	1	2
Interviewer code			

Part 1a: Socio-economic and demographic

Interview date : yyyy-mm-dd	**[2[0[1][ ][ ][ ][ ][ ]**
Characteristics	**Code**
1.1 Age [ ][ ][ ] years	1age [ ]
1.2 Sex [ ] 0.Female [ ] 1. Male [ ] 2. Transgender	2sex [ ]
1.3 Ethnicity [ ] 0. Indigenous [ ] 1. Non-indigenous	3eth [ ]
1.4. Religion [ ] 0. Islam [ ] 1. Christianity [ ] 2. Buddhism [ ] 3. Hindu	4rel [ ]
1.5. Occupation [ ] 0. Unemployment [ ] 1. Informal employment [ ] 2. Formal employment [ ] 3. Business	5occ [ ]
1.6. Education [ ] 0. Illiterate [ ] 1. Literate [ ] 2. Primary [ ] 3. Secondary [ ] 4. Higher secondary [ ] 5. Bachelor and above	6edu [ ]
1.7 Marital status [ ] 0. Single [ ] 1. Married [ ] 2. Widow [ ] 3. Divorced	7mrt [ ]
1.8 Children [ ] 0. No [ ] 1. Yes	8chd [ ]
1.9 No. of Children [ ]	9ncd [ ]
1.10 No. of family members [ ]	10nfm [ ]

1.11 Monthly personal income [ ][ ][ ][ ][ ][ ] NPR	11pin [ ]
1.12 Monthly family income [ ][ ][ ][ ][ ][ ] NPR	12fin [ ]
1.13 Smoking last 3 month [ ] 0. No [ ] 1. Yes	13smk [ ]
1.14 Alcohol last 3 month [ ] 0. No [ ] 1. Yes	14alc [ ]
1.15 Drugs last 3 month [ ] 0. No [ ] 1. Yes	15drg [ ]
1.16 Age at HIV diagnosis [ ] [ ]	16adg [ ]
1.17 Place at HIV diagnosis [ ] write name	17pdg [ ]
1.18 Age at ART started [ ] [ ]	18att [ ]
1.19 Transmitted from [ ] 0. Husband [ ] 1. Wife [ ] 2. Female sex worker [ ] 3. Male sex worker [ ] 4. Blood donation [ ] 5. Injection sharing	19trs [ ]
1.20 HIV status of spouse [ ] 0. Negative [ ] 1. Positive	20sts [ ]

Part 1b: Clinical aspects

1.21 Have you had sexual contact last 3 month? [ ] 0. No [ ] 1. Yes	21trs [ ]
1.22 sexual contacts with whom? [ ] 0. Wife [ ] 1. Husband [ ] 2. Sex worker [ ] 3. Friend	22trs [ ]
1.23 Have you used condom at last sex? [ ] 0. No [ ] 1. Yes	23cdm [ ]
1.24 Clinical stage [ ] 0. Stage I [ ] 1. Stage II [ ] 2. Stage III [ ] 3. Stage IV	24cst [ ]
1.25 Known morbidities [ ] 0. None [ ] 1. T.B. [ ] 2.	25cmo [ ]

[ ] 3.	
1.26 CD4 count [ ]	26cdc [ ]
1.27 Viral load [ ]	27vld [ ]
1.28 Have you ever forgotten to take ARV medicine? [ ] 0. No [ ] 1. Yes	28fmd [ ]
1.29 Have you forgotten to take ARV last 7 days? [ ] 0. No [ ] 1. Yes	29fmd [ ]
1.30 Have you ever disclosed your HIV serostatus? [ ] 0. No [ ] 1. Yes	30dis [ ]
1.31 Whom to you disclosed your serostatus [ ] 0. Wife [ ] 1. Husband [ ] 2. Mother [ ] 3. Father [ ] 4. Friends [ ] 5. All family member know	31dsp [ ]

Part 2: WHOQOL-HIV, Circle the number on the scale that gives the best answer for you for each question. (1- Not at all; 2- A little; 3- A moderate amount; 4- Very much; and 5- An extreme amount, + reverse)

S.N	Items						Code
Domain 1 Physical							
1.	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5	2ph1 [……]
2.	Do you have enough energy for everyday life?	1	2	3	4	5	2ph2 [……]
3.	How satisfied are you with your sleep? (+)	1	2	3	4	5	2ph3 [……]
4.	How much are you bothered by any physical	1	2	3	4	5	2ph4 [……]
Domain II – Psychological							
5.	How much do you enjoy life? (+)	1	2	3	4	5	2ps1 [……]
6..	How well are you able to concentrate?	1	2	3	4	5	2ps2 [……]
7.	Are you able to accept your bodily appearance?	1	2	3	4	5	2ps3 [……]
8.	How satisfied are you with yourself? (+)	1	2	3	4	5	2ps4 [……]
9.	How often do you have negative feelings, such as blue mood, despair, anxiety, depression? (+)	1	2	3	4	5	2ps5 [……]

Domain III-Level of independence							
10.	How much do you need any medical treatment to function in your daily life? (+)	1	2	3	4	5	2li1 [……]
11.	How well are you able to get around?	1	2	3	4	5	2li2 [……]
12.	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5	2li3 [……]
13.	How satisfied are you with your capacity for work?	1	2	3	4	5	2li4 [……]
Domain IV-Social relation							
14.	To what extent do you feel accepted by the people you know?						2sr1 [……]
15.	How satisfied are you with your personal relationships?	1	2	3	4	5	2sr2 [……]
16.	How satisfied are you with your sex life?	1	2	3	4	5	2sr3 [……]
17.	How satisfied are you with the support you get from your friends?	1	2	3	4	5	2sr4 [……]
Domain V-Environment							
18.	How safe do you feel in your daily life?	1	2	3	4	5	2en1 [……]
19.	How healthy is your physical environment?	1	2	3	4	5	2en2 [……]
20.	Have you enough money to meet your needs?	1	2	3	4	5	2en3 [……]
21.	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5	2en4 [……]
22.	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5	2en5 [……]
23.	How satisfied are you with the conditions of your living place?	1	2	3	4	5	2en6 [……]
24.	How satisfied are you with your access to health services?	1	2	3	4	5	2en7 [……]
25.	How satisfied are you with your mode of transportation?	1	2	3	4	5	2en8 [……]
Domain VI-Spiritual/Religion/Personal Beliefs							
26.	To what extent do you feel your life to be meaningful?	1	2	3	4	5	2sp1 [……]
27.	To what extent are you bothered by people blaming you for your HIV status?	1	2	3	4	5	2sp2 [……]
28.	How much do you fear the future?	1	2	3	4	5	2sp3 [……]
29.	How much do you worry about death?	1	2	3	4	5	2sp4 [……]
Overall QoL & general health perception							
30.	How would you rate your quality of life?	1	2	3	4	5	2gh1 [……]
31	How satisfied are you with your health? (+)	1	2	3	4	5	2gh2 [……]

Part 3: Empowerment scale (Roger ES et al. 1997). Circle the number on the scale that gives the best answer for you for each question (**S**trongly agree = 1, agree = 2, disagree = 3, and strongly disagree = 4).

S.N.	Items					Code
Domain I: Self-esteem/self-efficacy						
1.	I generally accomplish what I set out to do	1	2	3	4	3se1 [……]
2.	I have a positive attitude about myself	1	2	3	4	3se2 [……]
3.	When I make plans, I am almost certain to make them work	1	2	3	4	3se3 [……]
4.	I am usually confident about the decisions I make	1	2	3	4	3se4 [……]
5.	I am often able to overcome barriers	1	2	3	4	3se5 [……]
6.	I feel I am a person of worth, at least on an equal basis with others	1	2	3	4	3se6 [……]
7.	I see myself as a capable person	1	2	3	4	3se7 [……]
8.	I am able to do things as well as most other people	1	2	3	4	3se8 [……]
9	I feel I have a number of good qualities	1	2	3	4	3se9 [……]
Domain II: Power-powerlessness						
10	I feel powerless most of the time	1	2	3	4	3pw1 [……]
11	Making waves never gets you anywhere	1	2	3	4	3pw2 [……]
12	You can't fight city hall	1	2	3	4	3pw3 [……]
13	When I am unsure about something, I usually go along with the group	1	2	3	4	3pw4 [……]
14	Experts are in the best position to decide what people should do or learn	1	2	3	4	3pw5 [……]
15	Most of the misfortunes in my life were due to bad luck	1	2	3	4	3pw6 [……]
16	Usually, I feel alone	1	2	3	4	3pw7 [……]
Domain III: Community activism and autonomy						
17	People have a right to make their own decision, even if they are bad ones	1	2	3	4	3ca1 [……]
18	People should try to live their lives the way they want to	1	2	3	4	3ca2 [……]
19	People working together can have an effect on their community	1	2	3	4	3ca3 [……]
20	People have more power if they join together as a group	1	2	3	4	3ca4 [……]
21	Working with others in my community can help to change things for the better	1	2	3	4	3ca5 [……]
Domain 4: Optimism and control over the future						
22	People are limited only by what they think possible	1	2	3	4	3oc1 [……]
23	I can pretty much determine what will happen in my life	1	2	3	4	3oc2 [……]
24	I am generally optimistic about the future	1	2	3	4	3oc3 [……]
25	Very often a problem can be solved by taking action	1	2	3	4	3oc4 [……]
Domain 5: Righteous anger						
26	Getting angry about something is often the first step toward changing it	1	2	3	4	3ra1 [……]
27	People have no right to get angry just because they don't like something	1	2	3	4	3ra2 [……]
28	Getting angry about something never helps	1	2	3	4	3ra3 [……]

Part 4 HIV related stigma scale for developing countries (Genberg BL et al. 2008). Circle the number on the scale that gives the best answer for you for each question ((+ Questions with positively framed statements were reverse coded, Strongly disagree=SD, Disagree =D, Agree = A, Strongly Agree = SA, **Subscale 1: Shame/Blame/Social isolation** = 10 item (10-40 score), **Subscale 2: Perceived discrimination** = 8 items (8-32), **Subscale 3: Equity=** 5 items (5-20 score**),** Total score range 23-92).

S.N	**Items**					Code
Domain 1: Shame/Blame/Social isolation						
1	People living with HIV/AIDS should be ashamed	1	2	3	4	4sb1 [……]
2	People with AIDS should be isolated from other people	1	2	3	4	4sb2 [……]
3	People who have HIV/AIDS are cursed	1	2	3	4	4sb3 [……]
4	People living with HIV/AIDS deserve to be punished	1	2	3	4	4sb4 [……]
5	A person with HIV/AIDS should be allowed to work with other people **(+)**	1	2	3	4	4sb5 [……]
6	Families of people living with HIV/AIDS should be ashamed	1	2	3	4	4sb6 [……]
7	It is reasonable for an employer to fire people who have HIV/AIDS	1	2	3	4	4sb7 [……]
8	People with HIV/AIDS are disgusting	1	2	3	4	4sb8 [……]
9	People who have HIV/AIDS deserve compassion **(+)**	1	2	3	4	4sb9 [……]
10	People with HIV should be allowed to participate fully in the social events in this community **(+)**	1	2	3	4	4sb10 […..]
Domain 2: Perceived discrimination						
11	People living with HIV/AIDS face neglect from their family	1	2	3	4	4pd1 [……]
12	People living with HIV/AIDS face physical abuse	1	2	3	4	4pd2 [……]
13	People want to be friends with someone who has HIV/AIDS **(+)**	1	2	3	4	4pd3 [……]
14	People living with HIV/AIDS face ejection from their homes by their families	1	2	3	4	4pd4 [……]
15	Most people would not buy vegetables from a shopkeeper or food seller that they knew had AIDS	1	2	3	4	4pd5 [……]
16	People who have HIV/AIDS face verbal abuse	1	2	3	4	4pd6 [……]
17	People living with HIV/AIDS face rejection from their peers	1	2	3	4	4pd7 [……]
18	People who are suspected of having HIV/AIDS lose respect in the community	1	2	3	4	4pd8 [……]
Domain 3: Equity						
19	People with HIV should be allowed to participate fully in the social events in this community **(+)**	1	2	3	4	4eq1 [……]
20	People living with HIV/AIDS should be treated similarly by health care professionals as people with other illnesses **(+)**	1	2	3	4	4eq2 [……]
21	People who have HIV/AIDS should be treated the same as everyone else **(+)**	1	2	3	4	4eq3 [……]
22	People with HIV/AIDS do not deserve any support	1	2	3	4	4eq4 [……]

23	People with HIV/AIDS should not have the same freedoms as other people	1	2	3	4	4eq5 [……]

Part 5: Social support (Sarason IG et al. 1987). The following questions ask about people in your environment who provide you with help or support. Each question has two parts. For the first part, list all the people you know, excluding yourself, whom you can count on for help or support in the manner described. Give the persons' initials, their relationship to you. Do not list more than one person next to each of the numbers beneath the question.

For the second part circle how satisfied you are with the overall support you have. If you have had no support for a question, check the words "No one," but still rate your level of satisfaction. Do no list more than nine persons per question.

Please answer all the questions as best you can. Circle One Number on Each Line [Very dissatisfied (1), fairly dissatisfied (2), a little dissatisfied (3), a little satisfied (4), fairly satisfied (5), and very satisfied (6).]

S.N.	Items							Code
1.	Whom can you really count on to be dependable when you need help (list the persons e.g. father, mother, friends)	No one 1. 2. 3. 4. 5. 6. 7. 8. 9.						5ssn1 [……]
2.	How satisfied?	**1**	**2**	**3**	**4**	**5**	**6**	5ssq1 [……]
3.	Whom can you really count on to help you feel more relaxed when you are under pressure or tense?	No one 1. 2. 3. 4. 5. 6. 7. 8. 9.						5ssn2 [……]
4.	How satisfied?	**1**	**2**	**3**	**4**	**5**	**6**	5ssq2 [……]
5.	Who accepts you totally, including both your worst and your best points?	No one 1. 2. 3. 4. 5. 6. 7. 8. 9.						5ssn3 [……]
6.	How satisfied?	**1**	**2**	**3**	**4**	**5**	**6**	5ssq3 [……]
7.	Whom can you really count on to care about you regardless of what is happening to you?	No one 1. 2. 3. 4. 5. 6. 7. 8. 9.						5ssn4 [……]
8.	How satisfied?	**1**	**2**	**3**	**4**	**5**	**6**	5ssq4 [……]
9.	Whom can you really count on to help you feel better when you are feeling generally down-in-the dumps?	No one 1. 2. 3. 4. 5. 6. 7. 8. 9.						5ssn5 [……]
10	How satisfied?	**1**	**2**	**3**	**4**	**5**	**6**	5ssq5 [……]
11	Whom can you count on to console you when you are very upset?	No one 1. 2. 3. 4. 5. 6. 7. 8. 9.						5ssn6 [……]
12	How satisfied?	**1**	**2**	**3**	**4**	**5**	**6**	5ssq6 [……]

Intervention quality and satisfaction from participants

Client satisfaction questionnaire (CSQ-8, Larsen DL et al. 1979**).** Please help us improve our program by answering some questions about the services you have received. We are interested in your honest opinions, whether they are positive or negative. *Please answer all of the questions.* We also welcome your comments and suggestions. Thank you very much; we really appreciate your help (Score range 8-32). Circle your answer:

S.N.	**Question**					**Code**
1.	How would you rate the quality of service you have received?	Excellent (4)	Good (3)	Fair (2)	Poor (1)	csq1 [……]
2.	Did you get the kind of service you wanted?	No, definitely (1)	No, not really (2)	Yes, generally (3)	Yes, definitely (4)	csq2 [……]
3.	To what extent has our program met your needs?	Almost all of my needs have been met (4)	Most of my needs have been met (3)	Only a few of my needs have been met (2)	None of my needs have been met (1)	csq3 [……]
4.	If a friend were in need of similar help, would you recommend our program to him or her?	No, definitely not (1)	No, I don't think so (2)	Yes, I think so (3)	Yes, definitely (4)	csq4 [……]
5.	How satisfied are you with the amount of help you have received?	Quite dissatisfied (1)	Indifferent or mildly Dissatisfied (2)	Mostly satisfied (3)	Very satisfied (4)	csq5 [……]
6.	Have the services you received helped you to deal more effectively with your problems?	Yes, they helped a great deal (4)	Yes, they helped (3)	No, they really didn't Help (2)	No, they seemed to make things worse (1)	csq6 [……]
7.	In an overall, general sense, how satisfied are you with the service you have received?	Very satisfied (4)	Mostly satisfied (3)	Indifferent or mildly Dissatisfied (2)	Quite dissatisfied (1)	csq7 [……]
8.	If you were to seek help again, would you come back to our program?	No, definitely not (1)	No, I don't think so (2)	Yes, I think so (3)	Yes, definitely (4)	csq8 [……]

Session Evaluation Forms (SEF) questionnaires (Harper G et al. 2003)

S.N.	Question	Strongly agree	Agree	Disagree	Strongly disagree	Code
1.	Learned a lot	1	2	3	4	sef1 [……]
2.	Able to apply	1	2	3	4	sef2 [……]
3.	Given an opportunity to participate	1	2	3	4	sef3 [……]
4.	Well organized	1	2	3	4	sef4 [……]
5.	Interesting	1	2	3	4	sef5 [……]
6.	Presenter stimulated my interest	1	2	3	4	sef6 [……]
7.	Relevant	1	2	3	4	sef7 [……]
8.	Enjoyable	1	2	3	4	sef8 [……]
9.	Would recommend to others	1	2	3	4	sef9 [……]
10.	Comfortable participating	1	2	3	4	sef10 […..]

In-depth interview guideline for facilitator and participant:

Feedback could be anticipated into intervention from three areas are as follow:

Intervention **structure and format**: (a) group setting, (b) ground rules, (c) participant contract, (d) personal reflection and goal setting, (e) action plan calendar, and (f) linkage-to-care {The specific content included in the intervention (a) self-condense and self-esteem, (b) emotional regulation, (c) stress and coping, (d) anger, stigma management, (e) healthy relationships, (f) sexual risk reduction, (g) sexual networks, and (h) HIV disclosure, legal empowerment}.

Intervention **useful**: (a) the comprehensive nature of the intervention and the relevant topics, (b) the provision of individual and group sessions, (c) group setting, and (d) schedule

Need to **improvemen**t: (a) group dynamics, (b) session length, and (c) written assignments.

Thank you

ANNEX-IV: Overview of intervention manual

Session 1-Rapport building, living with emotions, mind, sentiments and its management

Outcome Participants can manage their sentiments, mind, and emotions or stress and negative thinking when they informed others and others know their status and cope with those things. **Skill** -Indentify comfortable and uncomfortable situations -Discuss past events and pity for healing to participants' history -Discuss feelings and experiences within group -Produce knowledge and build up abilities in emotions and sentiments -Identify all the tension and produce idea to cope with tension reveal unnecessary thinking and circumstances and fight with negative thoughts. -Good thinking and things living with HIV, irritations and its types, and learn alternatives to irritations. -Practice on positive thinking, manage anger with Buddhist philosophy	
Time total (90 minutes)	**Materials**
Activity **Check in (10 minutes)** -Ice breaker/welcome/explain objectives -Pair share introductions -Introduce: tokens, group rules **Pair Share (sharing feelings) (50 min)** -Identify comfortable and uncomfortable situations. -How did you feel when you were informed of the HIV infection? (Divide participants: talk about their feelings when they found out about their HIV status, change experiences in group)	-Tokens -Flipcharts -Pen Post goals on the wall before start the activity Write on flipchart ahead of time

-In any situation that you feel guilty, blaming, despairing or tired/what do you think and do? How do you manage? (Identify one difficult situation: what is a situation that happened this week that you made you feel guilty, blame other person, or depressed? where did you feel in your body? What did you talk to yourself? And what happened after that situation? (In a week, what was a situation that someone (kid, sister, friend, neighbor, etc) behaved badly to you? What did you talk to yourself? Is there any good thing you got from this situation? How do you think positively with the situation?) (What are good things about living with HIV?) -Ask for volunteers to give report **Let's talk (10 min)** -Way to manage with different feelings **Lessons Learned (5 min)** -Ask participants what they learned and write on a flipchart **Relaxation Exercise (5 min)** -Relaxation activity, make comfortable **Goal setting (5 min)** -Review guidelines for good goals on a flipchart -Ask participants for personal goal for the week **Wrap-up (5 min)** -Talk about good feeling or thing that they like from group activities, include and advice. -Preview next session and encourage attendance	-Today's topic and goals -Goals of the group

Session 2 – Meaning of HIV positive and disclosure

Outcome Participants will increase decision making skills regarding disclosure and understand self-esteem **Skill** -Participants discuss the meaning and importance of self-respect. -Participant identifies the self-esteem activities that explore the dimensions of one's life. -Practice the disclosure, identify barriers, strategies and advantages of disclosure -Develop knowledge in stigma, role of stigma in one's life and how to overcome it.	
Time total (90 minutes)	**Materials**
Check-In (10 minutes) -Introductions/Ice Breaking -Introduce tokens -Group rules -Review goal last week -Start talking about disclosing your HIV status (preview of this session) **Role play (25 minutes)** -Role play (Demonstrate by the facilitator and the assistant: Importance of self-esteem Disclosing with sister/mother/husband/wife Cope of stigma -Divide participants: Husband disclosing with his wife -How did they fee -Stigma developed	-Tokens -Flipcharts -Pens Write on Flipchart ahead of time: Today's Topic/Goals for the session

Pair share (25 minutes) -To whom you feel most comfortable to disclose you HIV status: rank 3-5 order -Divide participant in pairs and role play: Disclosure with the one you feel most comfortable. -Cope with the present stigma **Lessons learned (10 minutes)** -Ask participants what they learned and write on flipchart -Plan for disclosure and practice an effective communication **Relaxation exercise (10 minutes)** -Relaxation activity **Goal setting (5 minutes)** -Who you want to disclosure within next week. -How to develop self-esteem -How to cope with stigma. **Wrap-up (5 minutes)** Ask each participant to name one positive thing they gained from the group. -Preview next session and encourage attendance	

Session 3 - Healthy body after being HIV positive

Outcome	
Participants will develop the knowledge on healthy body, care access, prevention, emotions and sexual and sexuality. **Skill** -Participants will able to access to source of accurate on HIV/AIDS treatment, care, prevention and transmission. -Participants will understand what it mean to be HIV positive or negative to be a men or women -Participants will be able to effectively communicate with doctors and health personnel. -Participants will able to correctly describe common illness in HIV positive.	
Time total (90 minutes)	**Materials**
Check-In (10 minutes) -Introductions/Ice Breaking -Introduce tokens -Group rules -Review goal last week **Pair share (20 minutes)** -Share knowledge or experiences about illness after having HIV positive, and what are treatment and care -Difficulties in following the medical care and self care -Ask for volunteers to give report - How is HIV transmitted? (And ask participants what they want to know about HIV) -Prevention of HIV transmission : safer sex **Learning Spot (10 minutes)** -Use a flipchart to help teach about care after HIV positive, antiretroviral drug,	-Tokens -Flipcharts -Pens -Penis model -Condoms Write on Flipchart ahead of time: Today's Topic/Goals for the session

and opportunistic infections -How to access to other sources of information about the illness and access to adequate treatment -Risk of HIV infection : Between spouse (including issues of different risk level of husband and wife), Mother to child -Effect of re-infection **Pair share and Role play (20 minutes)** -Act out : Telling your doctor when you missed some medications -Bring them together and ask volunteers for a pair to have a role play for the group -Pair share: How to communicate with a doctor or a nurse in difficult situations? -Asking your partner to be tested for HIV -Husband ask his partner to have sex without condom -Husband and wife discuss on deciding to have children **Lessons learned (10 minutes)** -Ask participants what they learned and write on flipchart -Demonstration using a condom **Relaxation exercise (10 minutes)** -Relaxation activity **Goal setting (5 minutes)** - Review Guidelines for Good Goals on Flipchart -Ask participant for personal goal for the week **Wrap-up (5 minutes)** Ask each participant to name one positive thing they gained from the group. -Preview next session and encourage attendance	

Session 4 - Relationship

<table>
<tr><td colspan="2">Outcome

Participants will develop the knowledge for positive relationship with family, children and society.

Skill

-Participants can plan to manage role and function in the family and society

-Participants can deal with conflict or unhealthy or harmful or misunderstanding in the family and society.

-Participants will learn to have effective communications with sentiments, wishes and desires

-Participants will learn social and family role and activities in good atmosphere</td></tr>
<tr><td>Time total (90 minutes)</td><td>Materials</td></tr>
<tr><td>Check-In (10 minutes)

-Introductions/Ice Breaking

-Introduce “Tanjai Card”

-Group rules

-Review goal last week

-Inform about activities of today

Pair share (15 minutes)

-What changes happened in your family after one has the HIV infection?

-Mother : How to explain and relieve the worry when they feel worried about their health and problems with discrimination.

Discussion (20 minutes)</td><td>-Flipcharts

-Pens

-Tanjai card

Write on Flipchart ahead of time:

Today’s Topic/Goals for the session

Target group</td></tr>
</table>

-Discussion on changes of roles in a family or community when there is an HIV+ person. -Planning about society/family member's roles management -How is the current relationship between you and your child? Or in family, society -Planning to improve relationship with your child and improve child's discipline as well as in family, society **Pair Share-Role play (20 minutes)** -Divide participants and act out : Ask for more help in the family from your husband who has no job. -Bring them together and ask for volunteers to repeat their role play for the group. - How to talk to your child when he/she has aggressive behavior? Even with society and family. **Lessons learned (5 minutes)** -Ask participants what they learned and write on flipchart **Relaxation exercise (10 minutes)** -Relaxation activity **Goal setting (5 minutes)** - Review Guidelines for Good Goals on Flipchart -Ask participant for personal goal for the week **Wrap-up (5 minutes)** Ask each participant to name one positive thing they gained from the group. Preview next session and encourage attendance	

Session 5 - Drug, self care and relationships

<table>
<tr><td colspan="2">Outcome

Participants develop the knowledge for sexual and social health and appropriate self-health care after being positive.

Skill

-Participants will able to explain an importance of self care post HIV.

-Perform excellent communication and listening abilities

-Aware of opportunistic infections, other diseases and partners sexual behaviors

-Discuss the impacts of drug, alcohol, and smoking to one’s life.

-Eating habits, diets, and exercise effects on one’s life</td></tr>
<tr><td>Time total (90 minutes)</td><td>Materials</td></tr>
<tr><td>Check-In (10 minutes)

-Introductions/Ice Breaking

-Introduce tokens

-Group rules

-Review goal last week

-Review of this session

Pair share (15 minutes)

-How to take care one self

-Difficulties in self care practice

-Differences between healthy and unhealthy relationships

Learning spot (20 minutes)

-Health promotion activities, e.g. exercise, eating, diet,</td><td>-Token

-Flipcharts

-Pens

Write on Flipchart ahead of time:

Today’s Topic/Goals for the session</td></tr>
</table>

meditation, avoiding drug, alcohol, smoking -Aware on opportunistic infection -Dealing with unhealthy relationship -Good communication and listening skill **Lessons learned (10 minutes)** -Ask participants what they learned and write on flipchart **Pair share (15 minutes)** -How to plan for regular exercise -When you should go to see a doctor? **Relaxation exercise (10 minutes)** -Relaxation activity **Goal setting (5 minutes)** - Review Guidelines for Good Goals on Flipchart -Ask participant for personal goal for the week **Wrap-up (5 minutes)** -Tell one positive thing they gained from the group -Preview next session and encourage attendance	

Session 6 - Relationship, stress and stigma management, legal empowerment

Outcome

Participants able to develop future plans, reduce tension and increase social support and community participation, encourage feeling to legal empowerment

Skill

-Discuss workplace difficulties, discrimination, legal protection, health and human right

-Develop knowledge in future plan, physical and social areas.

-Formulate the objectives for the future

-Discuss to join the social and community activities

-Find out the situation that you got tension and practice methods to reduce stress and worries.

-Conclude and sum up the intervention

Time total (90 minutes)	Materials
Check-In (10 minutes) -Introductions/Ice Breaking -Introduce tokens -Group rules -Review goal last week -Review of this session	-Token -Flipcharts -Pens
Pair share (15 minutes) -Identify a situation where you felt stressed or worried last week -How do you do when you feel tension? -Role play: act out as a mother getting severely ill and try to talk with her child -How is your community? (general view) / How is the relationship with your old friends? Do you have new friends? What are activities you join with people in your community? -Ask for volunteers give reports to group	Write on Flipchart ahead of time: Today's Topic/Goals for the session
Practice with relaxation way (5 minutes) -Deep breathing	

-Muscle stretching **Let's talk (Discussion & share experiences) (15 minutes)** -Effective communication (assertiveness) and management -Prepare long term plan for children e. g. child custody plan, community/social support **Pair share (15 minutes)** -Talking to person who will take care your child after you pass away, perception from society -Tell some good things that you want them to occur with other HIV+ persons -What are the strengths of joining with groups (here and other groups), getting more information? -Legal provision, anti discrimination, stigma and equality (reach up to zero) -Discuss how to raise voice of unity and human right -Sharing **Lessons learned (10 minutes)** -Ask participants what they learned and write on flipchart **Relaxation exercise (10 minutes)** -Relaxation activity **Conclude and sum up (20 minutes)** Tell one positive thing they gained from the group -Encourage for follow up and continue growing and evolving	

ANNEX-V: Attitude evaluation form for each session of manual

Session 1 assessment form

Items	Strongly disagree	Disagree	uncertain	Agree	Strongly agree
I can eat always together with family	1	2	3	4	5
I am a healthy person as others	1	2	3	4	5
I can sleep well in night	1	2	3	4	5
I can do my daily work as others	1	2	3	4	5
I cannot blamed or feel guilty due to HIV	1	2	3	4	5

Session 2 assessment form

Items	Strongly disagree	Disagree	uncertain	Agree	Strongly agree
I must have self-esteem	1	2	3	4	5
I can disclosure my status	1	2	3	4	5
HIV status disclosure have not demerits	1	2	3	4	5
Stigma is not curse of HIV	1	2	3	4	5
I cannot reduce unnecessary thinking	1	2	3	4	5

Session 3 assessment form

Items	**Strongly disagree**	**Disagree**	**uncertain**	**Agree**	**Strongly agree**
HIV can be cured	1	2	3	4	5
Sexual contact is not only the route of transmission	1	2	3	4	5
Only condom can prevent sexual transmission	1	2	3	4	5
ART can not cure HIV	1	2	3	4	5
HIV can increase other infection	1	2	3	4	5

Session 4 assessment form

Items	**Strongly disagree**	**Disagree**	**uncertain**	**Agree**	**Strongly agree**
HIV is not the cause of conflict in family	1	2	3	4	5
Involvement in society reduce conflict in society	1	2	3	4	5
Effective communication increase social and family relation	1	2	3	4	5
Discrimination is not the fate of HIV people	1	2	3	4	5
I can make good relation with family and society	1	2	3	4	5

Session 5 assessment form

Items	Strongly disagree	Disagree	uncertain	Agree	Strongly agree
Self-care can reduce vulnerability of disease	1	2	3	4	5
Balance diet can improve health	1	2	3	4	5
I cannot reduce stress using illicit drugs	1	2	3	4	5
I cannot smoke	1	2	3	4	5
I cannot drink alcohol	1	2	3	4	5

Session 6 assessment form

Items	Strongly disagree	disagree	uncertain	Agree	Strongly agree
Law related to HIV can reduce discrimination	1	2	3	4	5
Joining community activities can benefited for PLH	1	2	3	4	5
Social work make happy to PLH	1	2	3	4	5
I must have similar health rights as others	1	2	3	4	5
Human right is equal to HIV people as others	1	2	3	4	5

ANNEX-VI: Ethical approval letters

AF/04-05/01.1

Faculty of Medicine, Prince of Songkla University

This document is to certify that

REC Number: 57-4146-18-5

Project entitled: Efficacy of social-self value package to improve empowerment and quality of life among people living with HIV under antiretroviral treatment in Nepal: a randomized controlled trial

Principle Investigator: Mr. Dhanna Nand Bhatta

Affiliation: Epidemiology Unit, faculty of Medicine, Prince of Songkla University

Sub-investigator: Assoc. Prof. Tippawan Liabsuetrakul

Affiliation: Epidemiology Unit, faculty of Medicine, Prince of Songkla University

Document acceptances:

1. Submission form version 2.0 date 16 July 2014
2. Study protocol version 2.0 date 16 July 2014
3. Participant information sheet version 2.0 date 16 July 2014
4. Informed consent form version 2.1 date 16 July 2014
5. Clinical record form version 1.0 date 2 June 2014
6. Curriculum Vitae

have been reviewed by the Research Ethics Committee meeting date 24 June 2014, agenda 4.2.03) is in full compliance with the Declaration of Helsinki and the International Conference on Harmonization in Good Clinical Practice ICH-GCP) Guidelines. Please submit the progress report every 12 month

(Assoc.Prof. Boonsin Tangbakuvanich, M.D.)

Vice Chairman of Ethics Committee,

Vice Dean in Research Affair

Date of approval: July 30, 2014

Date of expiration: July 29, 2015

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Government of Nepal Phone: 4253395
Ministry of Health and Population
Department of Health Services
Sukraraj Tropical and Infectious Disease Hospital
Teku, Kathmandu, Nepal

Ref. No.: 063/071/72

02 August 2014
Mr. Dharma Nand Bhatta
Principal Investigator
Nobel College, Pokhara University
Sinamangal, Kathmandu

Ref: Approval of Research Proposal entitled **Efficacy of social-self value package to improve empowerment and quality of life among people living with HIV under antiretroviral treatment in Nepal: a randomized controlled trial.**

Dear Mr. Bhatta,

It is my pleasure to inform you that the above mentioned proposal submitted on 02 June 2014 (Ref. no. 063/071/72 please use this Reg. No. during further correspondence) has been approved by Institutional Review Board of this hospital as per the National Ethical Guidelines for Health Research in Nepal and Standard Procedures, Section C. point no. 6.3 through Expedited Review Procedures.

As per the rules and regulations, the investigator has to strictly follow the protocol stipulated in the proposal. Any change in objective(s), problem statement, research question or hypothesis, methodology, implementation procedure, data management and budget that may be necessary in course of the implementation of the research proposal can only be made so and implemented after prior approval from this council. Thus, it is compulsory to submit the detail of such changes intended or desired with justification prior to actual change in the protocol.

Further, the researchers are directed to strictly abide by the National Ethical Guidelines published by Nepal Health Research Council during the implementation of their research proposal and submit progress report and full of summary report upon completion.

If you have any questions, please contact the Ethical Review and research section of this institute.

Thanking you.

.....
Dr. Sher Bahadur Pun
Member-Secretary
Institutional Ethical Review Board

Manuscript-I

Accepted by Journal: AIDS Care

Design and feasibility of a social self-value intervention package to empower people living with HIV

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Abstract

Human immune deficiency virus (HIV) infection affects the quality of life of infected people. It is well-known that empowerment is important for appropriate access to health care and quality of care. However, there is currently limited availability of explicit methods to increase the empowerment of HIV infected people. This study aimed to develop and test the feasibility of a social-self value package as an empowerment intervention method for HIV infected people. The feasibility of the intervention package was conducted in Nepal. The validated package was implemented as a group session.

One group included 8-10 participants and each session lasted for one and half hours. Six sessions in total were developed and one session was conducted in one week. Different contents were developed for different sessions. A total of 66 participants, were randomly selected for participating in the package, assessed its feasibility both quantitatively and qualitatively. The average age of the participants was 36.4 years and 63.6% were receiving antiretroviral treatment for one to two years. Attitudes towards HIV-related issues significantly and positively changed after each session. Client satisfaction and acceptability of the intervention was very high indicating high feasibility with good design. The qualitative findings also supported the quantitative findings where both participants and counselors accepted and were satisfied with the structure and contents of the package. Both counselors and participants provided their recommendations for improvements in the package to enhance its feasibility. This study revealed that providing an inclusive 6-week social self-value package for HIV infected Nepali people appears to be feasible. Its effect on empowerment intervention will be measured by a randomized controlled trial.

Keywords*: intervention; HIV; feasibility; acceptability; empowerment*

Introduction

Toxicity and resistance of antiretroviral therapy (ART), and other co-infections have increased the morbidity and mortality which in turn affects the quality of life of HIV infected people (Anastos et al., 2005; Hessamfar-Bonarek et al., 2009; S. Hosek, Brothers, Lemos, & the Adolescent Medicine Trials Network for HIV/AIDS Interventions, 2012; Laurent et al., 2005; Murphy et al., 2013; Stringer et al., 2006). Lack of skills to compromise with risky sexual behavior and other multiple clinical and social problems among HIV infected people has emphasized an urgent need for continuing empowerment for this population (Quinlivan et al., 2013; Van Devanter, Duncan, Birnbaum, Burrell-Piggott, & Siegel, 2011; Wingood & DiClemente, 2000).

Empowerment is a way of dealing with problems of comparatively immobilized populations and by arbitrating the role helplessness plays in making and enabling social anxieties (Gutierrez, 1990; Pinderhughes, 1989; Solomon, 1976). Empowerment theory forced to increase people's power and behaviors through social interactions (Gutierrez, 1990; Kelly, Murphy, Sikkema, & Kalichman, 1993; Kieffer, 1984; H. Land, 1994; Levine et al., 1993; Rappaport, 1987; Solomon, 1976). In addition, this empowerment is also an optimistic strength in the life's of disenfranchised groups (Bricker-Jenkins, 1986; Gutiérrez, Oh, & Gillmore, 2000; Katz, 1984) which are essential but highlighted by only a few studies among HIV infected subgroups (Brothers, Harper, Fernandez, Hosek, & Interventions, 2014; Fisher & Smith, 2009; Gutiérrez et al., 2000; S. Hosek et al., 2012).

Explicit interventions are sparse that focused to empowering HIV infected people. Therefore, we developed a social self-value package for empowering HIV infected people based on different theories including social learning for behavioral change, social action, pedagogy and empowerment (Bandura, 1969; Bandura & McClelland, 1977; Ewart, 1991; Fisher & Smith, 2009; Freire, 2000; Gutiérrez et al., 2000; Gutierrez, 1990; Katz, 1984; Rappaport, 1987; Zimmerman, 1995; Zimmerman & Rappaport, 1988). The empowerment intervention mainly focused on autonomy and community activism, self-esteem/self-efficacy, self-care, optimism and control over the future, family and social relationships, power-powerlessness, management of stress and righteous anger, stigma and discrimination issues, legal provisions, and human and health rights. This study aimed to develop and test the feasibility of the package as an empowerment intervention among HIV infected people using a randomized controlled trial.

Methods

Study design and setting

This study is a part of trial entitled "efficacy of social self-value package to improve empowerment and quality of life among people living with HIV under antiretroviral treatment in Nepal: a randomized controlled trial". The study was

conducted at an ART center at Sukraraj Tropical and Infectious Disease Hospital, Kathmandu, Nepal during December and November 2014.

Study samples

All HIV infected people aged above 18 years who registered for and started ART from six months to two years prior to the study at this center were included. Those who could not communicate in Nepali language, were involved in any other education programs within the last three months, had seriously medical or psychiatric problems which could prejudice their participation in the study or had not planned to stay at least six months in the study were excluded. A total of 66 HIV infected people were randomly selected for intervention.

Development of a social-self value package

Course and content

A group-based method with interactive participatory techniques was applied. Eight to ten participants were included in a group to follow the schedules of each section. Each session took one and a half hours and was conducted weekly for six weeks. Participatory rural appraisals, role play, lecture and audio/video methods were used. The literature on relevant interventions for improving quality of life, strengthening empowerment and social support and reducing the stigma associated with HIV infected people were reviewed to identify evidence-based intervention.

Expert and other consultation

First, the contents and course were shown to two experts who worked in the national HIV/AIDS program and three HIV infected persons for the informal acceptability and feasibility of the package. Second, the modified contents and course were discussed with two trained counselors who were public heath graduated national trainers for the HIV/AIDS program and facilitated our course. The package was firstly developed in English and translated into Nepali. The package was developed to accept local culture and context which also respected local terms and dialects.

Testing the package

Groups consisting of 10 HIV infected people receiving ART who met the eligibility criteria of the trial but were not included in the trial were invited for testing the package. The final comprehensive overview of the contents of the package with each session's goals is shown in Table 1.

Data collection

The study was approved by the Ethics Committee of the Faculty of Medicine, Prince of Songkla University and ART center. Participants were provided travel allowances and refreshment. A total of seven groups were formulated with 8 to 10 participants in each group.

Variables

Quantitative outcomes included improvement in attitude and retention rate of session attendance at the end of each session, and satisfaction and acceptability at the end of all sessions. Attitudes on the contents of each session (Table 1) was assessed using a 5-point Likert scale ranging from 1 = "strongly disagree" to 5 = "strongly agree". Each session contained five items resulting in a total score ranging from 5 to 25 for each session. High scores indicate highly positive attitudes.

Satisfaction was measured using the client satisfaction questionnaire version 8 (CSQ-8) at the end of the sixth session (Larsen, Attkisson, Hargreaves, & Nguyen, 1979). The CSQ-8 contains eight items with four categorical responses.

Acceptability was measured using the session evaluation form (SEF) at the end of the sixth session (Harper, Contreras, Bangi, & Pedraza, 2003). The SEF contains ten 4-point Likert scale items ranging from 1 = "strongly disagree" to 4 = "strongly agree". The number of sessions attended by each participant was determined to measure the retention rate.

One participant in each group who participated actively in the group session and the counselors were approached and invited to participate in an in-depth interview leading to a total of seven representatives of participants and two counselors. In-depth

interviews aimed to obtain their perceptions on the overall feasibility and acceptability of the package.

Data analysis

Attitude scores of each session were compared before and after the package using Wilcoxon's signed rank test. The percentages of satisfaction of each item for CSQ-8 were calculated. Means and standard deviations of each item of the SEF were presented. Retention rate of session attendance was presented descriptively.

All interviews were tape-recorded and transcribed verbatim. Thematic analysis was performed by two independent researchers and final themes and subthemes were developed.

Results

Quantitative findings

Among the 66 study participants, 47% were female. The mean (SD) age was 36.4 (6.8) years (Table 2). Cronbach's alpha for the attitude items in each session ranged from 0.85 to 0.93. Attitudes after the session were significantly higher compared to those before (Table 3). Table 4 shows the participant's satisfaction for various aspects of the package. Almost all (>93%) participants wanted to join the program again, were willing to come back again and would recommend the program to others. Table 5 shows the acceptability of the package. All the items in the session evaluation form indicated a high level of acceptability. Figure 1 depicts the frequency of retention in the session. The overall retention rate in the intervention was 96.6%.

Qualitative findings

Three main themes were identified: acceptability and feasibility of the package, usefulness of the package's contents and weakness of the package's feasibility. A summary of themes and subthemes are presented in Table 6. Participants and counselors agreed on the acceptability and feasibility of the package, usefulness of the package's contents and provided suggestions for improvement of the package.

Discussion

Both qualitative and quantitative findings suggested that the intervention package was feasible and acceptable for HIV infected Nepali patients.

Significant improvement on the attitude of HIV infected people regarding HIV/AIDS related issues was also revealed similar to findings of previous experimental studies among general people and HIV infected people with a comparison group (Elamin, Ahmed, & Ali, 2015; Jemmott 3rd, Jemmott, & Fong, 1992; Wiley, Edwards, & Dilworth, 1991).

High satisfaction is linked with adherence and compliance of practice (Machtinger & Bangsberg, 2005). In our study, a high proportion of positive satisfaction in all aspects of the package was found. A systematic review suggested that there was a variation among satisfaction measurement for HIV services and no gold standard method was found (L. Land, Nixon, & Ross, 2011). Our findings were similar with previous studies that highlighted high satisfaction and acceptability on comprehensive topics, group sessions, activities and time settings (Brothers et al., 2014; Corneli et al., 2014; Villegas et al., 2014).

Acceptability was found higher in our study while the finding was similar with previous studies measured by SEF (Brothers et al., 2014; S. G. Hosek, Lemos, Harper, & Telander, 2011). Further recommendations for improvement from participants were recorded in our study which were similarly highlighted in previous studies (Brothers et al., 2014; Villegas et al., 2014).

In our study the overall retention of the sessions was high which was a little surprising because previous studies have noted that the panic of disclosure and stigmatization can influence the feasibility of interventions among HIV infected people (Okoror, BeLue, Zungu, Adam, & Airhihenbuwa, 2014). This might be due to the well-planned group dynamics, respects their values without arising conflict, giving the opportunities to express their activities and motivational rapport building (Brothers et al., 2014).

The strengths of this study are pilot testing and expert's extensive review of the package increased its content and structure reliability. A high retention rate was maintained. Feasibility and acceptability was supported by both quantitative and qualitative findings. However, there were some limitations. First, the HIV infected patients come from only one clinical site which may limit the study's generalizability, although the characteristics of our study subjects were similar to other settings. Second, the sample size was considered for a randomized trial, not this feasibility study. Third, this package was developed in English and translated into Nepali. However, the contents of the package can be applied to other country contexts with modifications.

Conclusion

This study reveals that providing an inclusive 6-week intervention package for HIV infected Nepali people is feasible. Its effect on empowerment intervention will be measured by a randomized controlled trial.

Acknowledgements

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Authors' contributions

DNB designed the study, performed statistical analysis, and wrote the manuscript. TL designed the study, interpreted the results and revised the manuscript.

Conflict of interest

The authors declare that they have no conflict of interest.

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Table 1 Final comprehensive contents of a social-self value package

Session	Goals
Session 1: Rapport building, living with emotions, mind, sentiments and its management	• Identify comfortable and uncomfortable situations • Discuss part events and pity for healing to participants' history • Discuss feelings and experiences within group • Produce knowledge and build up abilities in emotions and sentiments • Identify all the tension and produce idea to cope with tension reveal unnecessary thinking and circumstances and fight with negative thoughts. • Good thinking and things living with HIV, irritations and its types, and learn alternatives to irritations.
Session 2: Meaning of HIV positive and disclosure	• Discuss the meaning of self-respect/confidence/self-worth • Perform the self-respect actions that discover the aspects of one's personality. • Strategies, barriers and facilitate to safe disclosure • Develop knowledge in stigma, study the character of stigma in one's life and discuss how to defeat with it.

Session 3: Healthy body after being HIV positive	• Produce knowledge in sexual, sentimental, emotional and physical areas • Explore what it mean to be HIV positive or negative to be a men or women • Discuss about treatment, care after positive, sexuality and barriers. • Discuss transmission and prevention for being a healthy sexual person
Session 4: Relationship	• Produce knowledge and build up abilities in the social/community/family areas. • Find out the distinction among harmful and healthy relationships. • Discuss the way to identify and cope with harmful relationship. • Develop strategies to establish effective communications with the wishes, sentiments and desires. • Planning the social and family role maintain.
Session 5: Drug, self care and relationships	• Produce knowledge and build up abilities in the sexual, social areas • Perform excellent communication and listening abilities • Aware of opportunistic infections, other diseases and partners sexual behaviors • Discuss the impacts of drug, alcohol, and smoking to one's life. • Eating habits, diets, and exercise effects on one's life
Session 6: Relationship, stress and stigma management, legal empowerment	• Discuss workplace difficulties, discrimination, legal protection, health and human right. • Formulate the objectives for the future • Discuss to join the social and community activities, strategies to raise voice • Find out the situation that you got tension and practice methods to reduce stress and worries. • Conclude and sum up the intervention program

Table 2 Background characteristics

Characteristic	**Participants = 66 n (%)**
Age in years (Mean:36.35, SD:6.77)	
24 to 35	33 (50.0)
36 to 56	33 (50.0)
Sex	
Male	35 (53.0)
Female	31 (47.0)
Ethnicity	
Non-indigenous	39 (59.1)
Indigenous	27 (40.9)
Education	
Less than higher secondary	46 (69.7)
Higher secondary and above	20 (30.3)
Religion	
Hindu	44 (66.7)
Other	22 (33.3)
Marital status	
Married	49 (74.2)
Widowed	16 (24.2)
Divorced	1 (1.5)
Duration of ART received	
6 months to < 1 years	24 (36.36)
1 to 2 years	42 (63.64)
Duration living with HIV	
≤ 1 years	34 (51.51)
> 1years	32 (48.49)

Table 3 Comparison of attitude scores before and after each session

Session	Participants = 66 Cronbach's alpha	Before median (IQR)	After median (IQR)	P-value
1	0.92	10 (8,12)	21 (20,22)	<0.001
2	0.91	12 (11, 13)	19 (18, 20)	<0.001
3	0.85	14 (13, 15)	20 (19, 21)	<0.001
4	0.93	10 (8, 11.8)	21 (20, 22)	<0.001
5	0.91	18 (15, 20)	23 (22, 24)	<0.001
6	0.91	10 (10, 11)	21 (20, 22)	<0.001

Table 4 Participants' satisfaction on the package

Item	N (%)
Quality of program	
Excellent	60 (90.9)
Good	6 (9.1)
Fair	0
Poor	0
Wanted for program	
Yes, definitely	63 (95.5)
Yes, generally	3 (4.5)
No, not really	0
No, definitely	0
Program met need	
Almost all of my needs have been met	59 (89.4)
Most of my needs have been met	7 (10.6)
Only a few of my needs have been met	0
None of my needs have been met	0

Like to recommend the program to friends	
Yes, definitely	62 (93.9)
Yes, I think so	4 (6.1)
No, I don't think so	0
No, definitely	0
Satisfaction with the amount of help	
Very satisfied	61 (92.4)
Mostly satisfied	5 (7.6)
Mostly dissatisfied	0
Very dissatisfied	0
Program helped to deal with problems	
Yes, they helped a great deal	60 (90.9)
Yes, they helped	6 (9.1)
No, they didn't really help	0
No, they seemed to make things worse	0
Overall satisfaction with program	
Very satisfied	60 (90.9)
Mostly satisfied	6 (9.1)
Mostly dissatisfied	0
Very dissatisfied	0
If you were to seek help again, would you come back to our program	
Yes, definitely	63 (95.5)
Yes, probably	3 (4.5)
No, probably not	0
No, definitely not	0

Table 5 Acceptability of all sessions

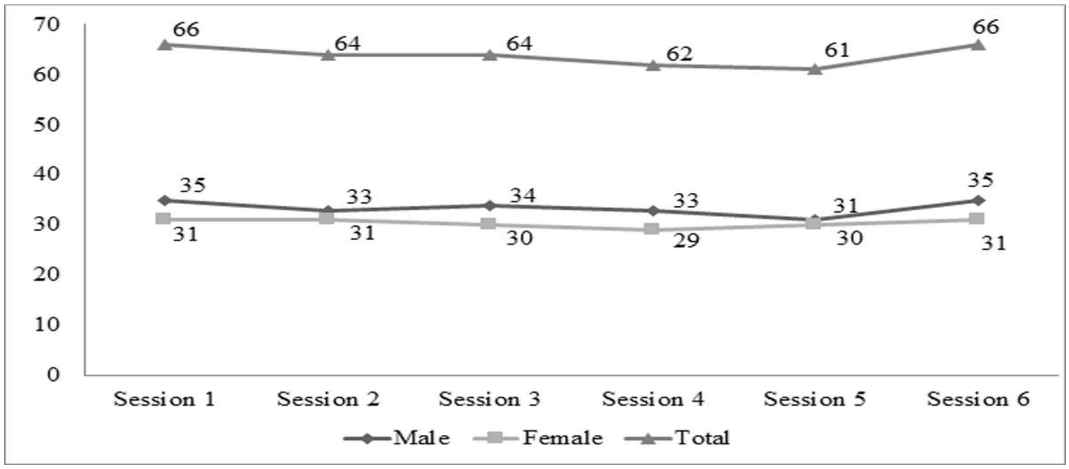
Items	Participants = 66 Mean (SD)
Learned a lot of skills	3.76 (0.43)
Able to apply the knowledge	3.68 (0.47)
Given an opportunity to participate	3.74 (0.44)
Well organized program	3.80 (0.40)
Interesting sessions	3.82 (0.39)
Presenter stimulated my interest during the sessions	3.77 (0.42)
Relevant with the context	3.82 (0.39)
Enjoyable learning experience	3.77 (0.42)
Would recommend to others	3.73 (0.45)
Comfortable participation	3.71 (0.46)

Table 6 List of themes and subthemes

Themes	Subthemes
Acceptability and feasibility of package	Comprehensive topics with details
	Group sessions and settings
	Goal settings and grounded rules
	Active participation and interactions
	Personal feelings and link with care
	Appropriate time for allocation of activities
Usefulness of the package's contents	Healthy and self-health care
	Positive relationship with society and family
	Stigma and coping
	Stress and anger management
	Protective sexual behavior
	HIV disclosure among family and others

	Laws and empowerment
	Self-esteem and self-confidence
	Sustainability of the program
Weaknesses of package's feasibility	Limited time for practice
	Home assignments

Figure 1 Frequency of retention attendance by session and gender



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Social self-value intervention for empowerment of HIV infected people using antiretroviral treatment: a randomized controlled trial

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Abstract

Background: Prevention and antiretroviral therapy (ART) management for human immunodeficiency virus (HIV) infected people need to have long-term health care. An empowerment focused intervention is a procedure by which HIV infected people obtain combined possession of programs to attain mainly cost-effective HIV outcomes and deal with social and structural difficulties related to their universal health access and human rights. Empowerment is a key approach for addressing HIV related issues that focuses on addressing a broader context. However, the practices of empowerment based approaches are sparse. We assessed the effect of an intervention to empower HIV infected people receiving ART.

Methods: In this open-label randomized controlled trial, HIV infected people from Nepal who were using ART from six to twenty four months and were aged 18 years and above

were randomly assigned to receive either the intervention or routine care. The intervention was led by two counselors for a period lasting six weeks. Participants were followed up at three and six months after the baseline. The primary outcome was change in empowerment scores, analyzed by using Difference-in-Difference (DiD). This trial was registered with the Thai Clinical Trials Registry, number TCTR20140814002.

Results: Between September and November 2014, 1447 HIV infected people were screened, of whom 132 were randomly assigned to the intervention (n=66) or control (n=66) group. All the participants completed the 3- and 6- months follow up. A significant difference in mean empowerment score was found between the groups at 3- (46.77, p-value <0.001) and 6- (49.71,p-value <0.001) months follow up. The average treatment effect (after matching intervention and control individuals) showed that the participants who received the intervention increased their mean empowerment scores from baseline by 47.05 (p-value <0.001, at three months) and 49.87 (p-value <0.001, at six months) than those who did not receive the intervention. No adverse events were reported.

Conclusion: Social self-value intervention provided to HIV infected people during ART increased their empowerment. This intervention can be expanded to be utilized in routine services.

Keywords: *adherence; ART; disclosure; self-esteem; unprotected sexual intercourse*

Background

Morbidity and mortality due to human immunodeficiency virus (HIV) infections can be reduced by preventing new HIV infections [1-3]. Globally, an estimated two million people were newly HIV infected in 2014 [4]. Viral load status of HIV in HIV positive people and risky sexual behavior with HIV uninfected people is the first and foremost way of transmission of HIV [5]. HIV transmission could be potentially reduced through interventions given at every step of the HIV care continuum including an efficient diagnosis system, adherence to medical care, suppression of viral load, and

quality of antiretroviral treatment [6, 7]. Continuous intervention of medical care, treatment, counseling and screening might help to reduce HIV transmissions [8-10]. Persons who are HIV positive but ignorant of their HIV status have more risk behaviors of HIV transmission than those who were conscious of their infection [11, 12]. Reduction of HIV transmission is associated with antiretroviral treatment (ART) and maintaining a high retention rate in medical treatment is essential to gaining access to ART and suppression of HIV viral load [13, 8, 9].

Universal access to treatment for those who need ART is very low [14, 4]. In addition, antiretroviral drug toxicity, resistance and non infectious developments are the major challenges for maintaining a higher retention rate in regular medical care [15-17]. Furthermore, low negotiation skills of risky sexual behavior with sexual partners, social problems, co-infections and re-infections make HIV infected people more vulnerable [18, 19]. Existing studies of HIV interventions and non-interventions have focused on primary and secondary prevention of subgroups and clinical implications for mortality and morbidity rather than the possible outcome for HIV prevention among all HIV infected people [6, 7, 20-24]. Moreover, overambitious targets related to HIV including zero new infections, discrimination and stigma have been established by various agencies [25-27]. However, gold standard interventions have been unable to address those targets. An empowerment approach would be an asset to achieve above HIV related inequalities and targets [28-31]. While health outcomes and self care behaviors are linked to empowerment methods with a supportive social environment, it must be considered for implementation in programs and policies to increase epidemiological profits on investment [32, 33].

An empowerment approach has not yet been developed and tested for all HIV infected people. Empowerment is a cost-effective approach to reduce HIV transmission, improve treatment retention, and reduce social, physical and psychological problems [34, 35]. This social self-value intervention package was developed on the basis of the diffusion model of innovations study [36]. The concept of social action and

empowerment theories were used to enhance self-efficacy, self-care, family and social relationships, stigma and discrimination issues [37-41] which are the major obstacles among HIV populations. As a result, self-esteem, autonomy, social adaptation or relationship and behavior change for structural prevention as an empowerment framework could be strengthened [42, 43, 20-24]. We aimed to assess the effect of this intervention on empowerment of HIV infected people receiving ART.

Methods

Study design, settings and participants

This open label, parallel, randomized controlled trial was conducted in Kathmandu, Nepal. HIV infected participants receiving antiretroviral treatment (ART) from ART centers of Kathmandu district of Nepal were recruited. The study was conducted from September 2014 to June 2015. The study site was Sukraraj Tropical and Infectious Disease Hospital (STIDH), Teku, Kathmandu run by the government of Nepal and was a part of the National Center for AIDS and STD Control (NCASC) [44]. This site is the largest ART center catering to both rural and urban people living in Nepal. It has provided multidisciplinary clinical and laboratory services and treatment for HIV infected people since 2004 [45]. Figure 1 shows details of the study design and participant enrollment.

Eligible participants included HIV infected people aged 18 years or above, willing to participate in either intervention or control arm, and had been receiving ART between six to 24 months prior to the study according to the ART criteria as per the guidelines of NCASC [46]. We excluded participants who were exposed to similar educational programs or any other intervention, expressed inability to attend all the study follow up periods, suffering from health problems (psychotic disorders, visual and hearing problems), and unwilling to disclose their HIV status among other participants.

A total sample size of 132 participants (66 in the control arm and 66 in the intervention arm) would achieve 80% power to detect a significant mean difference of empowerment scores at a level of 0.05. Since, no previously published study was found

for the mean change of intervention ($\mu_1 - \mu_2$), a 20% mean difference was applied which was equal to 0.52 standard deviation (σ). The formula for testing the difference between two means (two-sample t-test) was used to arrive at the sample size.

Randomization and masking

Participants were randomly allocated to either the intervention or control arm with a ratio of 1:1. Randomization was performed by a random number generator with permuted blocks of six. Allocation concealment was done by using sequentially numbered opaque sealed envelopes. The independent data manager generated the randomly sequence numbers. The sequence numbers were masked from other research staff and participants. None of the research team members and participants was involved in the randomization process and subsequent to randomization none of the participants were able to modify their assignment. Enumerator and analysis assessor were masked from baseline to follow-up data by using a unique code. The unique code was developed for all the participants by the team leader to maintain the anonymity of the participants.

Intervention procedures

Many theories were followed to develop the intervention package. The intervention contents were developed based on social learning, social action, and pedagogy theory and empowerment principles for HIV prevention and treatment [20-24, 37-43].

All the participants completed a baseline survey before the intervention began. Once participants were recruited and assigned their allocation baseline characteristics were collected.

All participants who met the selection criteria were informed about the study process, design and goals. All subjects in the intervention group attended six intervention sessions of one and half hours duration at the ART center. Intervention sessions were conducted once per week and per session eight to ten participants were included. All the sessions were led by two national level trainers with public health degrees. The

intervention sessions were as follows: first session covered rapport building, sharing uncomfortable situations and management of negativity; second session started with barriers and strategies of HIV disclosure and defeat with stigma and self-esteem; third session covered healthy body and healthy mind, healthy sexual relations, means to be HIV infected or non-infected to be a man or woman, sexuality, adherence of ART and other treatment and prevention strategies after infection; fourth session started with strategies to plan for healthy relations with family members, the community and society, effective communication, and responsibilities in the society; fifth session discussed negative effects of illicit drugs, alcohol, and smoking, skills for co-infection, re-infection and partner's sexual behavior, diet and exercise; sixth session educated about legal empowerment, human rights, legal protection, discrimination, stress, rising voice together against discrimination and rights and future goals.

Acceptability, applicability and relevancy of the intervention contents were discussed with two experts, three HIV infected people and two counselors. After necessary amendment, the contents for all six sessions were pre-tested among ten HIV infected people. Participatory learning activities, buzz sessions, brain storming, lecturers, and discussion techniques were used in the intervention sessions. Participants were instructed to discuss the issues within their group and other participants. Participants were encouraged to communicate with their family members, peer groups, friends related to HIV control, prevention, treatment and disclosure. Participants were assigned home assignments at the end of each session for presentation at the next session. All the participants in the intervention group were compensated for each of their six sessions with an amount equivalent to US $ 20 in the local currency. The control group did not receive any compensation.

Fidelity of the intervention was maintained with continuous monitoring of the allocated time for topics, methods and contents of the sessions by health officers and the research team leader. In addition, anonymity was maintained with a code and participants were assured quality during the discussion sessions. To maintain compliance, at the end of

the each session the counselors motivated participants to participate in the next session, encouraged voluntary independent participation and provided gift vouchers. The overall participant retention rate was 96.6% in the intervention session.

Standard care

All participants received routine standard care as per the NCASC guidelines [46]. This included pre ART counseling, routine medical and laboratory tests and monthly follow up for ART. Standard care in Nepal is provided by government organizations and ART is dispensed free of cost.

Study procedures

Participants were asked to provide information on demographics, empowerment and behaviors at baseline and follow up (first follow up: 3 months after the baseline and second follow up: 3 months after the first follow up).To minimize the errors and enhance quality control, double data entry was employed and extensively supervised by the research team leader. Anonymity and confidentiality were maintained with assigned unique codes. Intervention contents and tools were pre-tested before baseline and follow up data collection.

Measures

Demographic characteristics included age, sex, ethnicity, religion, occupation, education, marital status, children and per capita family income.

The primary outcome was measured by using an empowerment scale developed by Rogers et al. [47], containing a total of 28 items each measured on a four-point agreement scale ranging from strongly disagree to strongly agree. Total empowerment scores ranged from 28 to 112 consisting of five subscales, namely self-efficacy/self-esteem (9-36 score), power–powerlessness (7-28 score), community activism and autonomy (5-20 score), optimism and control over the future (4-16 score) and righteous anger (3-12 score). First, the contents of the questionnaire were discussed with two experts who amended the language for suitability with HIV patients. Further contents were revised to be applicable to the Nepalese culture and contexts. The content was then

discussed with three HIV infected people for clarity and acceptance, and amended accordingly. After development of the revised version with experts and HIV infected people, the final version was pretested among HIV infected people. During the pre-test, no negative comments or difficulties were encountered by participants. Internal consistency, as measured by Cronbach's alpha was 0.97.

Secondary outcome measures were related to behavior and included unprotected sexual intercourse with any partner (coded as yes or no), adherence to ART (coded as yes or no) and disclosure of HIV status (coded as yes or no, if response was yes then the number of persons disclosed was recorded and dichotomized as ≤3 persons or >3 persons). These secondary outcomes were measured to assess the effect of empowerment to patient's behaviors which were important to their health outcomes.

Statistical analyses

Demographic characteristics were compared between the intervention and control group at baseline. Baseline differences between the two groups were tested using Fisher's exact or Chi-squared test for categorical variables and unpaired t-tests or Wilcoxon's signed rank test for continuous variables as appropriate.

Analysis of the primary outcome emphasized the differences of empowerment scores among HIV infected people comparing between the intervention and control groups at baseline (baseline difference or pre-difference) and at 3- (post-difference at 3 months) and 6- month post-intervention (post-difference at 6 months). The impact of the intervention on empowerment was analyzed by comparing Difference-in-Differences (DiD) scores. The impact of the intervention was measured between baseline difference and post difference at 3 months (DiD_{3mo}) and between baseline difference and post difference at 6 months (DiD_{6mo}). The secondary outcomes were analyzed at baseline, 3- and 6- months follow up using univariate analysis. Significant differences among intervention and control were measure using Fisher's exact test.

Difference in Differences (DiD)

DiD methods can be used to estimate causal relationships [48]. DiD compare the differences in outcomes among the intervention group in pre- and post-intervention and involves indentifying similar differences among the control group. We used DiD to compare outcomes between control and intervention groups at baseline, 3- and 6- months follow up [49]. Ordinary Least Square (OLS) with repeated data for control and intervention group for baseline, 3- and 6- month follow up periods produced standard errors and DiD estimates. The equation considered as follows:

$$Y_{ist}=A_s+ B_t+ cX_{ist}+ \beta I_{st}+e_{ist}$$

where empowerment is the outcome of interest, denoted asY_{ist} for the individual of HIV infected *i* in randomized group *s* (control or intervention) by time *t* (the baseline and 3- or 6- months follow up) and I_{st} is an indicator variable representing whether the intervention has affected the group *s* at time *t*. A_s and B_t are fixed effects for the randomized group and time (baseline and follow up) respectively, X_{ist} are applicable individual controls and e_{ist} is the error term. The impact of the intervention was estimated by OLS with β estimation. Means and standard errors were estimated by linear regression. Following linear regression for the individual *i*:

$$Outcome_i = \beta_o+ \beta_1 \text{ x } period_i+ \beta_2 \text{ x } treated_i+\beta_3 \text{ x } period_i \text{ x } treated_i+ e_i$$

where, $\hat{}\beta_3$: is the DiD or impact.

The analyses were done with R and Stata (*diff* command) was used for estimating the DiD [50]. All tests were two sided and a p-value of <0.05 indicated statistical significance.

Ethical considerations

Comprehensive privacy was maintained during the study period. Strict anonymity and confidentiality was maintained throughout the recruitment, intervention and data collection process by using unique codes. A standard protocol was followed to maintain data safety and confidentiality of the study data [51]. In agreement with national guidelines and the principles of the declarations of Helsinki, written informed consent was obtained from all participants prior to enrollment. The right to withdraw at any time

and skip any question was offered to all participants. We provided travel costs and reimbursement during the intervention and follow up periods. Researchers had no direct or financial benefits and declared no conflict of interest.

This project was approved by the Research Ethics Committee, Faculty of Medicine, Prince of Songkla University, Thailand (reference no. 57-0146-18-5) and approved by Institutional Ethical Review Committee of Sukraraj Tropical and Infectious Disease Hospital (STIDH), Nepal (063/071/72) prior to study initiation. The trial was registered through trial registration number TCTR20140814002 (www.clinicaltrials.in.th).

Results

A detail of the trial profile is shown in Figure 1. 132 participants were randomly assigned to receive the intervention (n=66) or no intervention (n=66) between September and November 2014. 1447 individuals were screened and of these, 1125 were ineligible, 180 declined to participate and 10 were excluded due to being transferred out or because they did not come to the center during the recruitment period. All participants in both groups were retained in the study at three and six months follow-up (100% retention rate).

No significant differences at baseline were observed in demographic characteristics of the participants between the intervention and control groups. The mean ages of participants in the intervention and control groups were 36.3 and 35.8 years, respectively. The majority had a low family income, was married and had children (Table 1).

The correlations among empowerment domains and total empowerment score are presented in Figure 2. Total scores of empowerment were positively correlated with the other five domains at baseline, 3- and 6- months follow up. In the intervention group at the 6 months follow up, power-powerlessness, community activism and autonomy, optimism and control over the future were negatively correlated with righteous anger, and were lowly correlated with self-efficacy/self-esteem and righteous anger.

The impact of the intervention on empowerment is presented in Table 2. The baseline difference (pre-difference) of empowerment scores between the intervention and control groups were not significantly different. Difference-in-Difference at 3- (46.77, p <0.001) and 6- months (49.71, p <0.001) were significantly higher for the intervention group in all domains of empowerment.

After standardization of scores for each domain, the impact of the intervention on each domain of empowerment remained equal. Participants who received the intervention increased their empowerment scores by an average of 47.05 points (p-value<0.001, DiD at three months and baseline) and 49.87 points (p-value<0.001, DiD at six months and baseline) more than those who did not receive the intervention, after propensity score matching of intervention and control individuals (data not shown).

Figure 3 depicts the trend of average empowerment scores among the two groups at baseline, 3- and 6- months follow up. The mean post-intervention score of empowerment markedly increased among the intervention group at 3 months but only slightly increased at 6 months, while the mean score for the control group remained constant.

Table 3 shows pre- and post-intervention differences on behavioral and clinical characteristics. From baseline to six months, unprotected sexual intercourse with any partner decreased in the intervention group and increased in the control group. The proportion of those who ever forgot to take ART did not change in the intervention group but the proportion rose from baseline to six months among the control group. No participant forgot to take ART in the past week in the intervention group. The proportion of participants who disclosed their HIV status rose from baseline to six months in the intervention group. Focusing on change from baseline to six months, statistically significant differences between the control and intervention groups were found for unprotected sexual intercourse (p-value <0.001), forgetting to ever take ART (p-value 0.007), forgetting to take ART in the past week (p-value <0.001), and disclosure of HIV status (p-value <0.001).

Discussion

A social self-value intervention package was shown to empower HIV infected people receiving ART and improved their behaviors. Our study highlighted a significantly greater increase in empowerment for HIV infected people at 3- and 6-months from the baseline. Similar findings were highlighted by a quasi-experimental study from Canada that anticipated empowering HIV infected people [52]. However, there are sparse existing studies available related to empowerment of all HIV infected people [52, 53].

Baseline characteristics of the participants were not statistically significant different among the intervention and control groups. Further we collected background characteristics (age, sex, ethnicity, marital status, date ART started) for all the screened participants. There was no difference in these background characteristics between those who agreed to participate in the study and those who refused thus minimizing biological, environmental and socioeconomic bias. The given reasons for refusal to participate were lack of interest, time and perceived need for the intervention. The strong recruitment process enhanced a higher retention rate in the intervention group and lower loss to follow up at 3- and 6- months. The intervention sessions took place in the same center where the controls received ART. This could have increased the chance of contamination among the control group. To reduce this risk, we conducted the intervention after services had finished for the day in each center and participants were counseled not to disclose any activities during the study period. The fact that the findings did not show any changes among the control group after the intervention provides evidence of no or minimal contamination.

The total empowerment score was highly correlated with its different domains but different domains were loaded with various correlations from high (self-efficacy) to low (righteous anger). Self-efficacy/self-esteem domain revealed a significant enhancement at six months which was similar to findings from previous studies using different interventions for HIV infected populations [54, 52, 55]. It was confirmed in a systematic

review on community-based interventions that empowerment intervention had positive effects on self-esteem [56]. Self-esteem is necessary to enhance the management of the negative social, physical and emotional impacts of HIV infection, thus our intervention was useful to support these issues.

Righteous anger domain was negatively correlated with the other domains. This might be the effect of the intervention that operates to reduce feelings of revenge over perceived mistreatment among HIV infected people. In addition, greatly increased righteous anger (reactive feeling of fury over abuse) scores had a positive influence on social and community adaption and adjustment of HIV infected people. Our trial showed a significantly greater increase in community activism and autonomy, power-powerlessness (helpless and totally incompetent) and optimism and control over the future (hope and assurance about the future or successful result of something). This may have affected the capacity to rebalance and reincorporate their lives [57]. HIV infection might guide the person to the destruction of their life goals, as well as absence of autonomy and self-control. Powerlessness and lack of control over the future appears as a diverse risk factor of disease. The impact of the intervention was further validated by using an average treatment effect model with propensity score matching. This was done to reduce the bias, although the participants were randomly assigned and no significant changes were reported after the modeling. Findings revealed significant improvements in empowerment score from baseline to three months follow up, but only minimal improvements at six months. The improvements at three months might be due to the immediate effect of the intervention while lack of further improvements at 6 months is probably due to a ceiling effect – the optimum empowerment score may have already been achieved. However, this needs long-term follow up to illicit the possible effects and reasons.

Our intervention improved not only empowerment but also the behavior of HIV infected people most likely because behavior related contents were included in the intervention package. A systematic review of interventions showed both significant and

non-significant positive effects of interventions to reduce risk behaviors [58]. Our study found that the practice of unprotected sexual intercourse among HIV infected people with any partner was significantly reduced after the intervention. A systematic review on community empowerment interventions for HIV prevention showed a reduction in risky sexual behaviors and increase in condom use among sex workers [59]. Another study related to empowerment of young HIV infected people showed a significant improvement in protected sexual intercourse [55].This trial revealed a significant improvement in adherence to ART among the intervention group and a decrease among the control group. Previous interventions highlighted that the empowerment of HIV infected people showed an improvement in adherence to ART [52, 60]. Our study highlighted a significant increase in HIV status disclosure rate. Disclosure is important to prevent the spread of HIV, increase the wisdom of self-esteem, emotional and practical support from social networks [61]. An empowerment intervention was envisioned with a multi-level construct that entails an understanding of social adaptation or relationship, self-esteem, autonomy, and behavior change for structural prevention throughout the contribution of developed skills, strengths and advocacy to behavioral, social interdependence and cognitive changes. This outcome might be the path of effect that is associated with empowerment theory.

Studies related to empowerment to all the HIV infected people were not available in this region. Although applicable to local culture and context intervention package, a highly experienced interventionist and extensive quality control measure might be the reason for improvement of empowerment scores and behavioral outcomes among the intervention group. Although subgroup analysis was found significant in small sample size and we suggested evaluating in future multicenter and large sample size based intervention and long term effects. An empowerment measurement tool would yield two dimensions of self and community directions to empowerment. Community orientation to empowerment believed that HIV infected people have power inside the society and desire

to encourage community action in an unfriendly world. Self orientations to empowerment believe themselves to be self-esteem, self-efficacious, and optimistic to the future.

Strengths and limitations

This trial was based on randomly assigned participants, a blinded analysis process and use of rigorous outcome analysis guaranteeing high internal validity. The intervention package and measurement tools were pre-tested in different stages which increased its reliability. The intervention package was found acceptable and feasible after measurement by both qualitative and quantitative approaches. A high retention rate in the intervention group as well as during follow up was maintained. The intervention was conducted in the regular health care service setting provided by the Nepalese government which pretend the real world setting and added to the external validity. Our study population characteristics including socio-demographic and clinical features were consistent with other HIV infected populations in Nepal. Therefore, the results can be generalizable to other HIV infected people. We verified participants ART adherence with their records in the ART center to reduce the potential desirability of reporting and recall biases. However, we did not execute the pill count measure.

There were some limitations in this study. First, participants were not blinded to the intervention. However, a rigorous coding system ensuring the anonymity was used with enumerator for data collection, entry and analysis. Second, reduced risky sexual behavior, high adherence and disclosure rate found in this study could be due to the Hawthorne effect (benefit of trial participation in the intervention group), which can eliminate the power to detect a factual difference from a trial [62]. Drug toxicity, accessibility and attitude might be potential confounders for adherence to ART. Further, these changes might have happened due to social desirability bias. However, a good rapport building during the intervention and data collection, familiar enumerator and study settings to participants all helped to reduce this bias. Third, a randomized controlled trial is a dynamic design that can reduce bias due to confounding. However, there are inbuilt biases that might be mostly pertinent in behavioral intervention trials.

Factors such as process of informed consent, study measurement tools that are used many times and reimbursement for participation in the trial could add to changes in behaviors among both control and intervention groups. Fourth, this empowerment intervention did not cover economic aspects. Finally, factor analysis was not used due to sampling inadequacy. However, after face validity and few modifications to language, the reliability was tested and showed good internal consistency. In other settings when empowerment measurement tool will be applied, the validity and reliability should be evaluated before use in different local cultures and contexts.

Conclusion

The efficacy on empowerment of HIV infected people using ART was shown after receiving the intervention. Their risky sexual behaviors were reduced and their adherence to ART and disclosure of HIV were increased. The intervention contents can be utilized in regular services and its effectiveness needs to be evaluated after routine implementation. Further, the empowerment intervention framework and method of measurement can be used in different settings after validating its cultural and contextual acceptability and applicability.

Competing interests

We declare that we have no competing interests.

Authors' contributions

DNB designed the intervention package and conceptualized the study, designed the protocol, coordinated and managed all the aspects of study procedures, reviewed study data, analyzed and interpreted the data, and drafted the manuscript. TL participated in designing the protocol, advised on design and study, reviewed study data, and reviewed and edited the final manuscript.

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Table 1Baseline demographic characteristics

	Control group (n=66)	Intervention group (n=66)	p-value
Age (years)			
Mean(SD)	35.8 (8.8)	36.3 (6.8)	0.71
≤36	36 (54.5)	41 (62.1)	0.48
>36	30 (45.5)	25 (37.9)	
Gender			0.22
Female	39 (59.1)	31 (47)	
Male	27 (40.9)	35 (53)	
Ethnicity			0.60
Indigenous	31 (47.0)	27 (40.9)	
Non-indigenous	35 (53.0)	39 (59.1)	
Religion			0.44
Hindu	49 (74.2)	44 (66.7)	
Others	17 (25.8)	22 (33.3)	
Occupation			0.85
Unemployed	22 (33.3)	21 (31.8)	
Informal employee	25 (37.9)	23 (34.8)	
Formal employee	19 (28.8)	22 (33.3)	
Education level			0.10
Illiterate informal	29 (43.9)	19 (28.8)	
Primary and above	37 (56.1)	47 (71.2)	
Marital status			0.10
Single	17 (25.8)	17 (25.8)	
Married	49 (74.2)	49 (74.2)	

Children			0.09
No	14 (21.2)	6 (9.1)	
Yes	52 (78.8)	60 (90.9)	
Number of children			0.08
≤2	39 (59.1)	50 (75.8)	
>2	13 (19.7)	10 (15.2)	
Family per-capita income (USD*)			
Median(IQR)	50 (30.67)	50 (30.67)	0.81
≤50	41 (62.1)	44 (66.7)	0.72
>50	25 (37.9)	22 (33.3)	

*1USD=100NPR, IQR=inter quartile range, SD=standard deviation

Table 2Impact of intervention on empowerment

	Baseline		3 month follow up		Pre-Diff	Post-$Diff_{3mo}$	DiD_{3mo*} (Impact)	6 month follow up		Post-$Diff_{6mo}$	DiD_{6mo*} (Impact)
	Control	Intervention	Control	Intervention				Control	Intervention		
Empowerment (total score)	46.70	46.38	48.23	94.68	-0.32	46.45	46.77	46.53	95.92	49.39	49.71
Self-efficacy/self-esteem	15.27	15.03	15.39	30.33	-0.24	14.94	15.18	15.12	30.91	14.79	16.03
Power-powerlessness	12.00	12.03	12.26	23.92	0.03	11.67	11.64	11.67	24.18	12.51	12.48
Community activism and autonomy	8.01	8.04	8.65	16.83	0.03	8.18	8.15	8.26	16.92	8.67	8.64
Optimism and control over the future	6.59	6.50	6.61	13.54	-0.09	6.94	7.03	6.36	13.41	7.04	7.14
Righteous anger	4.82	4.77	5.32	10.04	-0.04	4.73	4.77	5.12	10.50	5.38	5.42

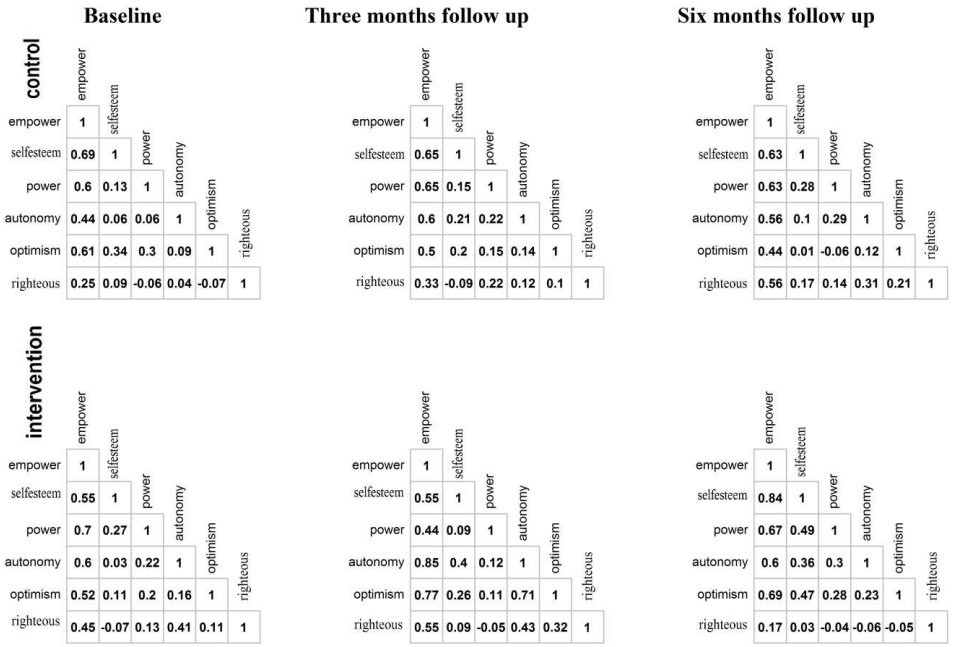
*=p <0.001; Pre-diff: difference at baseline; Post-$diff_{3mo}$: difference at 3 month follow up; Post-$diff_{6mo:}$ difference at 6 month follow up; DiD_{3mo}: difference at baseline and 3 month follow up; DiD_{6mo}: difference at baseline and 6 month follow up

Table 3Pre- and post-intervention differences on behavioral and clinical characteristics

	Baseline			Three month follow up			Six month follow up		
	Control (n=66)	**Intervention (n=66)**	**P-value**	**Control (n=66)**	**Intervention (n=66)**	**P-value**	**Control (n=66)**	**Intervention (n=66)**	**P-value**
Unprotected sexual intercourse with any partner in last 3 months*			0.82			0.001			0.001
No	38 (76.0)	36 (72.0)		19 (35.8)	47 (100.0)		19 (36.5)	45 (95.7)	
Yes	12 (24.0)	14 (28.0)		34 (64.2)	0 (0)		33 (63.5)	2 (4.3)	
Ever forgot to take ART			0.16			0.38			0.007
Yes	23 (34.8)	32 (48.5)		26 (39.4)	32 (48.5)		48 (72.7)	32 (48.5)	
No	43 (65.2)	34 (51.5)		40 (60.6)	34 (51.5)		18 (27.3)	34 (51.5)	
Forgot to take ART in past week			0.78			0.001			0.001
Yes	6 (9.1)	8 (12.1)		56 (84.8)	0 (0)		20 (30.3)	0 (0)	
No	60 (90.9)	58 (87.9)		10 (15.2)	66 (100.0)		46 (69.7)	66 (100.0)	
Disclosure of HIV status with**			0.93			0.001			0.001
≤3 persons	46 (80.7)	45 (77.6)		46 (76.7)	18 (27.3)		44 (73.3)	2 (3.0)	
>3 persons	11 (19.3)	13 (22.4)		14 (23.3)	48 (72.7)		16 (26.7)	64 (97.0)	

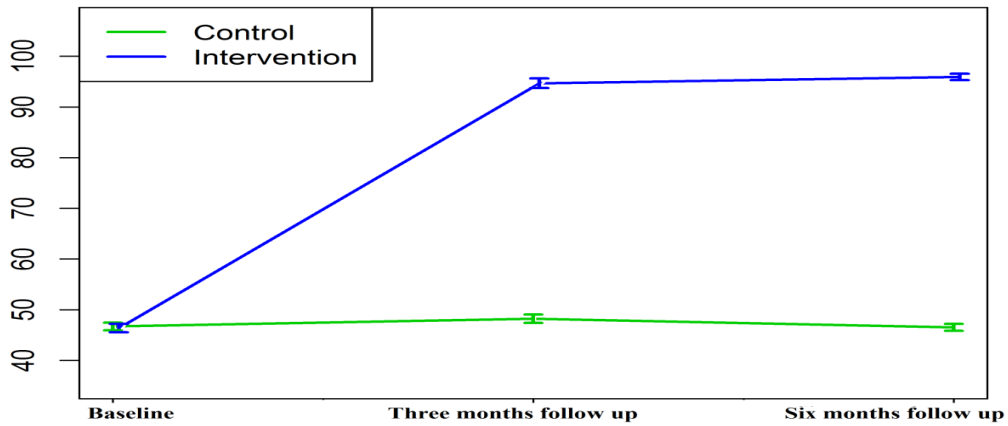
*Missing data **among disclosed, p-value = Fisher's exact test

Figure 2 Correlation among domains and total empowerment score



empower: empowerment total score; selfesteem: self-esteem/self-efficacy; power: power-powerlessness; autonomy: community activism and autonomy; optimism: optimism and control over the future; righteous: righteous anger

Figure 3 Trend of average empowerment score with 95% confidence interval for intervention and control groups



Manuscript-III

Journal: AIDS and Behavior

Efficacy of a social self-value empowerment intervention to improve quality of life of HIV infected people receiving antiretroviral treatment in Nepal: a randomized controlled trial

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Abstract

Background: Antiretroviral treatment (ART) has significantly shifted the epidemic of HIV and improved life-expectancy of HIV infected people. However, toxic effects of the drugs and multiple infections have altered their quality of life (QoL). An empowerment based intervention to HIV is a key process by which HIV infected people develop strength and optimism to overcome structural and social obstacles to their health and human rights. However, empowerment based interventions for this group is sparse. We therefore developed a comprehensive and culturally applicable empowerment intervention social self-value package with an aim to assess its efficacy in order to improve the QoL of HIV infected people receiving ART.

Methods: In this open-label parallel randomized controlled trial, we recruited males and females with HIV, aged 18 years and above, and receiving antiretroviral therapy from six to twenty four months. Participants were randomly allocated to receive either six weekly intervention sessions or standard care. Allocation concealment was done by using sequentially numbered opaque sealed envelopes (ratio 1:1). Participants were followed up after three and six months. The primary outcome was mean change in QoL score and secondary outcomes were stigma and social support. Nonlinear mixed-effects models were performed to compare changes in empowerment scores over time.

Results: Between September and November 2014, 1447 individuals were screened, of whom 132 were randomly assigned to either the intervention (n = 66) or control (n = 66) group. The mean scores of empowerment, social support and quality of life increased and stigma scores were reduced in the intervention group at 3 and 6 months. The intervention had a significant and positive effect on social support, stigma and QoL. No adverse events were reported.

Conclusion: The empowerment intervention was efficacious in improving QoL of HIV infected people. This appropriate and affordable program should be integrated in routine settings.

Trial Registration: www.clinicaltrials.in.th TCTR20140814002.

Keywords: *HIV; stigma; quality of life; social support; empowerment; ART; intervention; adherence*

Background

Epidemiological studies have highlighted decreases in HIV incidence and increased deaths related to HIV/AIDS [1-5]. However, the prevalence of HIV has remained extensive and epidemic contained enormous heterogeneity [4]. Decreasing trends of epidemics and increased life expectancy of people infected with HIV have been reported but risky sexual behaviors have promoted the transmission of HIV among general populations, and re-infections and co-infections among HIV infected people [3,

6]. Disease burdens are reported to be more common among HIV infected populations compared to general populations, altering their quality of life (QoL) [7-9]. The life expectancy among people living with HIV after they have initiated suitable antiretroviral treatment (ART) or combined antiretroviral treatment (cART) is reported to be similar to the general population [10, 11].

Availability of the ART among HIV infected people is very low and combined with psychological distress might lead to the development of anxiety, low QoL and increased stigma [4, 12]. The effect of ART on QoL was found to be reasonable among HIV infected people [13-15]. Further, their quality of life is influenced by health status, economic factors and psychological status [16]. The mechanism of how immunological and virological response influences quality of life among HIV infected people has not been comprehensively studied and therefore the effect of HIV status on QoL is unclear. Albeit, much less has been identified about the QoL of HIV infected people in comparison with other people despite considerable progress in medical prospective [16, 17]. Moreover, the effect of treatment on HIV might be affected by several factors which would help to increase stigma, reduce QoL and social support and disempowerment of HIV infected people [18-21].

Social taboos and stigma are universal socio-cultural barriers for HIV control and prevention [22, 23]. Empowerment and social support could be helpful assets among HIV infected people to enhance their QoL, reduce stigma and improve adherence to ART in resource poor settings [24, 25]. A practical and integrated program is needed for empowerment of HIV infected people [26, 27]. Empowerment would be best approached to reduce HIV risk associated problems with cost effective interventions [28-30]. However, HIV related empowerment based programs are sparse and it has been necessary to strengthen and implement them with usual ART and other programs with political and social transforms [26, 31-33].

Different organizations have set the goal to achieve zero discrimination, transmission and stigma but the interventions are too sparse to cover these goals [2, 34,

35]. In addition, the '90-90-90' target has been set by UNAIDS by the year 2020 [36]. Therefore, extensive socially and culturally accepted cost-effective interventions are needed which enhance QoL and social support, and eliminate stigma among HIV infected people in resource poor settings [15, 37-40]. Unfortunately, most of the interventions were established in developed countries and few from developing countries. There is thus an urgent need to develop a culturally sensitive intervention for use in developing countries. An empowerment intervention program we have developed, designed to improve QoL of HIV infected people, was developed on the foundation of the diffusion model of innovations [41], and followed different theories to connect empowerment framework that assumed to change behavior, self-esteem, social support, discrimination, stigma and QoL [6, 42-52]. The aim of this study was to assess the efficacy of a social self-value empowerment intervention package to improve QoL of HIV infected people receiving ART. Furthermore, we assessed the effect of this intervention to enhance social support and reduce stigma.

Methods

Study design, settings and participants

In this open label, parallel, randomized controlled trial, HIV infected participants receiving antiretroviral treatment (ART) from the ART center in Kathmandu, Nepal were recruited. The study was carried out between September 2014 and June 2015 in Sukraraj Tropical and Infectious Disease Hospital (STIDH), Teku, Kathmandu, which is administered by the National Center for AIDS and STD Control (NCASC) [53]. STIDH is the largest ART center in the country that has been providing multidisciplinary medical services for all HIV infected people since 2004 [54]. Details of the study participants recruitment and design are presented in Figure 1.

To be included in the study, participants had to be HIV infected, aged 18 years or older, and have been receiving ART between six months and two years prior to the study as per the national ART guidelines of NCASC [55]. Participants with severe health problems (including psychotic disorders, visual and hearing problems), had attended

similar intervention programs or any other education programs, were unable to attend all the study follow up visits, or were unwilling to disclose their HIV status among other participants were excluded from the study.

We calculated that 132 participants (66 in each group) would achieve 80% power to detect 20% mean difference in QoL scores between the two groups with a confidence interval of 95%.

Randomization and masking

Eligible participants were randomly allocated (1:1) to receive either the intervention sessions or standard care. Randomization was performed by a random number generator with permuted blocks of six. Allocation concealment was done by using sequentially numbered opaque sealed envelopes. The random number sequence was generated by an independent data manager. Members of the research team and participants were masked to these numbers and the randomization process. None of the participants were allowed to modify their assignments after randomization. The statistician and research staff doing the baseline and follow up assessments were masked to assignment of participants by using a unique code system. Enrollment, randomization and intervention sessions were conducted between September and November 2014. First follow up assessments were done after three months from baseline (January-February, 2015) and six months follow-up assessments were done three months from the first follow up (May-June, 2015).

Intervention procedures

Baseline information was collected after recruitment and allocation of the participants. The intervention was delivered over six sessions held weekly at the ART center lasting one and half hours. Sessions were conducted with a group of 8-10 participants. All the intervention sessions were facilitated by two national level trainers with a public health graduate degree. A facilitator delivered the intervention with participatory learning activities, buzz sessions, brain storming, lecture, and discussion

techniques. Participants were encouraged and motivated to communicate and discuss with different people about prevention, treatment and disclosure of HIV issues.

The development of the intervention contents involved review of existing literature that followed social learning and action theory and empowerment principles for HIV prevention and treatment [6, 42-52]. Culturally accepted and adopted components were developed after several consultations with experts and pre-tested among HIV infected people. Based on the findings from consultants and pre-testing, a complete manual for execution of a six week group intervention was developed by the research team. The empowerment intervention mainly focused on autonomy and community activism, self-esteem/self-efficacy, self-care, optimism and control over the future, family and social relationships, power-powerlessness, management of stress and righteous anger, stigma and discrimination issues, legal provisions, and human and health rights. Details of the empowerment intervention contents are available in Additional Table 1.

Briefly, all intervention sessions were started with group and ground rules, formal opening and closing custom, sharing and discussion. The first session started with rapport building, emotions, sharing uncomfortable situations and management of negative feelings and anger. The second session focused on barriers and strategies of HIV disclosure, self-esteem/self-respect/self-worth, stigma and defeat with stigma. The third session involved discussions about healthy body with healthy mind, healthy sexual relations, means to be HIV infected or non-infected and to be a man or woman, optimism and control over the future, sexuality, adherence of ART and other treatment and prevention options. The fourth session involved educated strategies for planning healthy relations with family members, the community and society, ways of effective communication and maintaining healthy relations, autonomy and community activism, and roles and responsibilities in the society. The fifth session involved education about the effects of alcohol consumption, drug use, smoking, developing skill to prevent co-infection, re-infection and risky sexual behavior, diet and exercise. In the sixth session, participants were educated about legal empowerment, human rights, legal protection,

powerlessness, discrimination, stress, freedom of voice against discrimination, health rights and future goals.

Fidelity of the intervention was maintained with continuous monitoring of the allocated time for topic, methods and contents of the sessions by a health officer and supervised by the research team leader. Participants were assured to receive equal chances on discussion with privacy. A checklist was developed to maintain fidelity of the intervention. The checklist included intervention contents (each session had different contents), time allocated for each activity, participants interaction with listening, openness, attentiveness, engagement, understanding and reinforcement and an agenda for the next session. The percent of items rated as “appropriate” by the reviewer was more than 95%, however we had only one reviewer due to limited manpower in the government agency so we could not calculate the level of agreement. A debriefing session was conducted at the end of each session for the feedback from the reviewer and facilitators. Intervention sessions were not gender-separated. We measured the acceptability using a session evaluation form (SEF) [56] and satisfaction of the participants in the intervention using a client satisfaction questionnaire (CSQ-8) [57] at the end of the intervention. All the items in the SEF indicated a higher level acceptability among the intervention group. The mean score of all items ranged from 3.68 to 3.82 with a standard deviation of 0.39 to 0.47. The total score indicated that participants either agreed or strongly agreed with the sessions. The level of participant satisfaction was high. All the participants stated that the quality of the intervention was excellent. The majority of participants (92.4%) were very satisfied with the amount of help provided to them. Almost all (95.5%) agreed to join the program again and were willing to refer it to others (data not shown).To maintain compliance, at the end of each session the counselors motivated participants to participate in the next session, encouraged voluntary independent participation and provided gift vouchers. The overall retention rate was 96.6% in the intervention session. All the participants were compensated for each of their six sessions with an equivalent of USD 20.

Standard care

All participants received routine standard care as per the NCASC guidelines [55]. This included pre ART counseling, routine medical and laboratory tests and monthly follow up for ART. Standard care in Nepal is provided by government organizations and ART is dispensed free of charge.

Study procedures

Participants were asked to provide information on clinical and behavioral characteristics, QoL, stigma, social support and empowerment at baseline, and at the scheduled 3- and 6- months follow up visits. To minimize data entry errors and enhance quality control, double data entry was employed and extensively supervised by the research team leader. Anonymity and confidentiality were maintained with assigned unique codes at randomization, baseline and follow up. The intervention protocol and tools were pre-tested among ten HIV infected people before data collection. All tools were translated into Nepali and back translated into English and appeared culturally suitable to the experts.

Outcomes

Background, behavioral and clinical characteristics of the participants were collected including age at HIV diagnosis, age at ART initiation, HIV status of spouse, mode of HIV transmission, sexual intercourse in the last 3 months and extra-marital, clinical stage, co-morbidity, adherence to ART (coded as yes or no) and empowerment. The primary outcome was QoL. Secondary outcomes were stigma and social support.

QoL was measured using WHOQoL-HIV [58] which contains 29 items divided into six domains, namely physical, psychological, level of independence, social, environmental and spiritual. It has also one general item score that measures overall quality of life and general health. All the items were rated using a 5-point Likert scale where 1 indicated low or negative perceptions and 5 indicated high or positive perceptions. Higher scores indicated better quality of life. All the domain scores were obtained by adding the component means in the individual domain, and dividing by the number of components in

that domain, and multiplying by 4, so that scores ranged from 4 (worst possible QoL) to 20 (best possible QoL).

Social support was measured using the social support questionnaire number (SSQN) and social support questionnaire satisfaction (SSQS) scales [59]. SSQN indicates number of supportive persons and SSQN indicates satisfaction with available social support. Both domains included six questions. The SSQN collected the number of supportive persons that denotes different types of social support. The SSQS were rated using a 6-point Likert scale ranging from very dissatisfied to very satisfied with available support. Higher SSQN scores indicated a perceived higher level of supportive persons and higher SSQS scores indicated higher level of satisfaction from available support.

Stigma was measured using a 23-item scale questionnaire [60]. Each item was rated using a 4-point agreement scale ranging from strongly disagree to strongly agree. Total stigma scores ranged from 23 to 92. There were three subscales, namely shame/blame/social isolation (10-40 score), perceived discrimination (8-32 score) and equity (5-20 score).

Empowerment was measured using a 28-item scale questionnaire [61] containing a 4-point agreement scale ranging from strongly disagree to strongly agree. Total scores ranged from 28 to 112. Empowerment was then classified into low or high using the first quartile score as the cut-off value to ensure the sample sizes were adequate.

Statistical analyses

Each study group's clinical and behavioral characteristics measured were initially compared using Chi-square tests or Fisher's exact test for categorical outcomes and Wilcoxon's signed rank test and unpaired t-tests for continuous outcomes, as appropriate.

Nonlinear mixed-effects regression models were used to evaluate the effect of the intervention on the primary and secondary outcomes. Covariates included empowerment, adherence to ART, age, sex, time (baseline, 3-, or 6-months follow-up), and group-by-time interactions. The mixed effect model was used to adjust for the underestimation of

variances in analysis for longitudinal data [62]. The effects of empowerment, social support and stigma on the QoL were also analyzed with a mixed effect model.

Nonparametric mixed-effects regression models were also used to evaluate the relative intervention effects on social support, stigma and QoL with and without stratification by empowerment. Relative intervention effects with 95% confidence intervals with and without stratification by empowerment level among both intervention and control groups at baseline, 3- and 6- months follow up were presented. Estimated improvements with 95% confidence intervals were plotted.

All statistical analyses were conducted with R software [63]. P-values less than 0.05 were considered to be significant.

Ethical considerations

Extensive anonymity, confidentiality and privacy were maintained during the recruitment, intervention and data collection process. Confidentiality and safety of the intervention study data were maintained as per the standard protocol [64]. National guidelines and principles of Nepal health research council, and the declaration of Helsinki were followed to obtain written informed consent and enrollment of the participants. Participants were fully informed about time, methods, and their right to withdraw at any time and skip any question for any reason. Reimbursement for travel cost during the intervention and follow up period were provided to all the participants. No conflict of interest and no direct or indirect financial benefits were anticipated by researchers in this intervention.

Research Ethics Committee, Faculty of Medicine, Prince of Songkla University, Thailand (57-0146-18-5) and Institutional Ethical Review Committee of Sukraraj Tropical and Infectious Disease Hospital (STIDH), Nepal (063/071/72) approved this study. The trial was registered through Thai Clinical Trial Registry with registration number TCTR20140814002 (www.clinicaltrials.in.th).

Results

A total of1447 HIV infected people receiving ART were screened from September to November 2014, of which 1135 were ineligible due to age <18 years (n=75), duration of ART <6 months or >24 months (n=1050), and others (n=10). 180 eligible participants refused to join the study, giving a response rate of 42.3%. Finally, 132 participants were recruited and randomly assigned to the control group (n=66) or intervention group (n=66).The diagram of participant flow is presented in Figure 1. All the recruited participants completed the study at baseline, 3- and 6- months follow up. The overall retention rate was 96.6%. No unfavorable events were reported during the study period.

The mean age of the participants was 36.1 (SD = 7.8) years. Most of the participants were female (53%), non-indigenous (56.1%), could read and write only (28.8%), and were married (74.2%). The majority (84.8%) of participants had an average of two children and there were no significant differences at baseline between the control and intervention groups. Table 1 compares baseline behavioral and clinical characteristics between participants in the two groups. More than 50% of participants were diagnosed with HIV before 33 years of age among both control and intervention groups. Two thirds of participants (62.1%) in the intervention group were infected through sexual contact. Three fourths (75.8%) were sexually active within the last three months. No significant differences of behavioral and clinical characteristics were detected between the two groups.

The mean empowerment, social support, stigma and QoL scores are presented in Table 2. All the scores at baseline were equally static in both groups. The mean scores of empowerment and QoL increased two-fold in the intervention group at 3 months but no further increase at 6 months. Stigma scores were reduced by half at 3 months in the intervention group with no further changes at 6 months. Social support scores increased by 1.5 times higher at 3 months follow up in the intervention group compared to the control group. Overall mean QoL scores at 3 months increased by 80% in the intervention group. The relative intervention effects among total social support with

number (TSSQN), total social satisfaction with support (TSSQS), stigma and QoL had a similar trend in the intervention group (Figure 2). Minimal improvements of outcomes were observed in the control group. Figure 3 reveals the relative intervention effects of social support, stigma and QoL by level of empowerment. The effects of the intervention on social support, stigma and QoL persisted at 6 months regardless of level of empowerment (high vs. low).

Table 3 presents the outcomes from the nonlinear mixed-effects regression model. Empowerment significantly reduced stigma and increased QoL ($p<0.001$ and $p<0.001$) after adjusting for age, gender, adherence to ART, group and time. There was no significant difference in any outcome between the intervention and control group at baseline. There were significant interaction effects of intervention by time indicating that improvements in social support and QoL for the intervention group were significantly higher compared to the control group over time ($p <0.001$), while stigma was significantly lower ($p <0.001$). Estimated differences in improvement in social support, stigma and QoL at 3- and 6- months from baseline between intervention and control were significant (all p-values <0.001). Increasing ART adherence was associated with a reduction of stigma ($p<0.001$). Age and gender were not significantly associated with any outcome.

Predictors of overall QoL are presented in Table 4. Increased empowerment had a significantly higher level of QoL ($p <0.001$). Increased stigma had a lower level of QoL but this was not statistically significant. Social support had no significant effect on QoL. Improvement in QoL remained statistically significant at 3- and 6- months follow up ($p <0.001$).

Discussion

Empowerment, social support, stigma and QoL of HIV infected people at baseline were low among both groups. The improvement of social support, stigma and QoL was seen immediately after 3 months among those in the intervention group and persisted for another 3 months. The intervention positively affected social support, stigma and QoL in

the equivalence regardless of level of baseline empowerment. Empowerment significantly affected social support, stigma and QoL but only empowerment was shown to be a significant predictor of QoL in addition to the intervention.

Clinical and behavioral characteristics were not significantly different at baseline between the two groups. Recruitment process followed strong protocol that assured the high retention rate in the intervention and lower loss to follow up. Most eligible participants declined to participate in the study; however, there was no difference in their background characteristics compared to those who participated in the study. Reasons for refusal to participate in the study were: too busy, unable to manage time for all the intervention sessions, lack of interest in the study and unavailability for follow up.

Social support was significantly improved by enhancing empowerment in the intervention group. As far as in our knowledge, empowerment interventions for all the HIV infected population were not available and comparison of the results with this trial would be difficult. A randomized controlled trial using a group support psychotherapy for HIV infected people as an intervention and measured at the same period as our study also showed an increasing social support after intervention by time [65]. Slightly improved social support in the control group at 3 months might be explained by learning process of participants from the repetitive questionnaires inducing their behavior changes (pretest sensitization effect) and possible effects of the contamination [66]. Stigmatization, discrimination, and cognitive state - the psychological condition that is characterized by a lack of obvious and logical belief and behavior - might be removed with increased social support through empowerment.

Overall stigma decreased after the intervention, more so in the intervention group. This finding was supported by the conclusion of systematic reviews that focused on any interventions for stigma reduction [67, 68]. Further, it has been suggested that the limited interventions were available to combat different forms of stigma and discrimination experienced by HIV infected people [68]. Therefore, our study applied an empowerment strategy to overcome and resist the manifestation of discrimination and stigma among

HIV infected people with the adaptation of local context and culture. In addition, empowerment would help to defeat symptoms of stigma among HIV infected people and our trial found that increased empowerment could significantly reduce stigma. This result was similar to a systematic review and meta-synthesis which highlighted increased adherence were linked with decreased stigma [69].

The intervention was found to be significantly effective for improving QoL. Systematic reviews based on different interventions and observational studies which focused on QoL of HIV infected populations showed inconclusive results [70-73]. This might be due to the use of different measurement scales, sampling process and sample size, culture and context of study settings in different studies. Therefore, we used different analytical approaches and pretested cultural and contextual appropriateness of the intervention manual which could improve the reliability of the outcome.

Existing cross-sectional studies from China suggested that social support and stigma were correlated with QoL and social support was the moderator of the impact of stigma on QoL of HIV infected people [74, 75]. A systematic review revealed that social support and ART adherence were associated with QoL of HIV infected people [76]. However, in this study, social support, stigma and ART adherence were not statistically significant but increased stigma showed negative effects on QoL. The small sample size could be the possible reason that we could not established statistically significant results with these variables.

This study has several strengths. First, this randomized controlled trial was based on real world study settings that represent the ART receiving HIV infected individuals. Second, the intervention attendance and retention rate was high which signifies the feasibility and acceptability of the intervention for HIV infected people. Third, this is the first multidimensional outcome related trial in Nepal for HIV infected people. Fourth, the intervention process followed extensive quality control and results on all study effects were large. We followed rigorous analysis methods and reported the effect sizes of all the

outcomes. Lastly, randomization process, pretested tools, intervention manual and blinding analysis assessor increased the validity and reliability.

This study has several limitations. First, we delivered the intervention in a single study setting and participants were not blinded, which could lead to contamination. However, we detected highly significant differences among the intervention and control group at 3- and 6- months after baseline. Second, the intervention was delivered by skilled personnel with public health graduate degrees, thus limited availability of skilled personnel would limit its sustainability and accessibility. Next, the intervention was led by less trained service providers need to be assessed. Third, we did not assess and determine if the benefit of the intervention was sustainable; we only assessed the outcome at 3- and 6-months follow up. Fourth, outcomes of subgroup analyses were difficult to validate due to the small sample size. Finally, we did not cover the economic and biomarker aspects.

Conclusions

Rigorously designed intervention indicates that empowerment intervention can increase QoL of HIV infected people. Further, it could be useful to reduce stigma and increase their social support network. Findings could be utilized at regular service settings for its sustainability and long-term effect. Although the intervention effects on secondary outcomes were detected, we recommend evaluating in future multicenter studies with large sample sizes for monitoring the long term effects.

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Authors' contributions

DNB designed the intervention package and conceptualized the study, designed the protocol, coordinated and managed all the aspects of study procedures, reviewed study data, analyzed and interpreted the data, and drafted the manuscript. TL participated in designing the protocol, designed the study, reviewed study data, and reviewed and edited the final manuscript.

Competing interests

We declare that we have no conflict of interests.

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Table 1 Clinical and behavioral characteristics

	Control group (n=66)	**Intervention group (n=66)**	**P-value**
Age at HIV diagnosis			
Median (IQR)	33 (26.5, 41)	33(30, 40)	0.56
≤33 years	34 (51.5)	34 (51.5)	0.10
>33 years	32 (48.5)	32 (48.8)	
Age at ART initiation			
Median (IQR)	35 (28, 42.8)	35 (30.2, 40.8)	0.55
≤35 years	36 (54.5)	38 (57.6)	0.86
>35 years	30 (45.5)	28 (42.4)	
Duration of ART			0.60
<1 year	38 (57.6)	34 (51.5)	
≥1 years	28 (42.4)	32 (48.5)	
Spouse HIV status			0.15
Negative	16 (27.6)	26 (41.9)	
Positive	42 (72.4)	36 (58.1)	
Mode of HIV transmission			0.16
Others	34 (51.5)	25 (37.9)	
Sex-worker	32 (48.5)	41 (62.1)	
Sexual intercourse in last 3 months			1.00
Yes	50 (75.8)	50 (75.8)	
No	16 (24.2)	16 (24.2)	

Extra-marital sex			0.78
Yes	7 (14)	9 (18)	
No	43 (86)	41 (82)	
Clinical stage			1.00
I & II	34 (51.5)	35 (53)	
III & IV	32 (48.5)	31 (47)	
Known co-morbidities			0.80
Tuberculosis	10 (15.2)	8 (12.1)	
Other	56 (84.8)	58 (87.9)	

Table 2 Mean values of empowerment, stigma, social support and quality of life scores among HIV infected people

	Baseline		**3 months follow up**		**6 months follow up**	
	Control	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**
Empowerment	46.70	46.38	48.23	94.68	46.53	95.92
Social support						
TSSQN	15.04	14.70	16.92	28.09	18.58	30.70
TSSQS	15.04	15.42	17.44	29.00	19.44	32.67
Overall stigma	76.03	76.50	72.91	39.41	73.03	38.26
Shame/blame/social isolation	33.11	33.64	32.21	16.89	31.27	16.76
Perceived discrimination	26.00	26.17	24.36	14.45	24.95	13.86
Equity	16.92	16.70	16.33	8.06	16.80	7.64
Overall quality of life	7.76	7.68	8.46	15.47	8.15	15.81
Physical	8.06	7.89	8.59	15.74	8.23	15.88
Psychological	7.78	7.76	8.10	16.04	8.05	15.99
Independence	7.42	7.32	8.58	15.51	8.32	15.65
Social relations	7.61	7.53	8.74	15.47	8.17	15.82
Environment	7.48	7.48	8.20	15.14	7.98	15.68
Spiritual/religious/personal belief	8.45	8.27	8.88	15.12	8.39	15.92
General overall health	11.97	11.58	10.64	13.76	9.88	15.03

TSSQN: total social support with number; TSSQS: total satisfaction with social support

Table 3 Effect of empowerment intervention on social support, stigma and quality of life using nonlinear mixed-effects regression model

Parameter	TSSQN			TSSQS			Stigma			Quality of life		
	Estimate	SE	p-value	Estimate	SE	p-value	Estimate	SE	p-value	Estimate	SE	p-value
Empowerment	-0.010	0.038	0.795	-0.024	0.040	0.544	-0.127	0.038	<0.001	0.057	0.009	<0.001
Age	-0.001	0.028	0.997	-0.038	0.029	0.196	0.005	0.016	0.744	0.005	0.005	0.289
Male vs. female	1.196	0.449	0.008	1.215	0.464	0.009	0.315	0.250	0.208	-0.009	0.074	0.896
ART adherence	-0.681	0.393	0.083	-0.424	0.409	0.300	-1.300	0.402	<0.001	0.145	0.105	0.151
Intervention vs. control at baseline	-0.496	0.532	0.351	0.243	0.550	0.659	0.388	0.425	0.360	-0.060	0.109	0.579
Time (months)			<0.001			<0.001			<0.001			<0.001
Intervention × Time			<0.001			<0.001			<0.001			<0.001
Difference in improvement from baseline between intervention and control group												
Three months follow up	11.983	1.868	<0.001	12.304	1.936	<0.001	-28.028	1.890	<0.001	4.430	0.474	<0.001
Six months follow up	12.967	1.977	<0.001	14.041	2.049	<0.001	-28.927	1.998	<0.001	4.904	0.501	<0.001

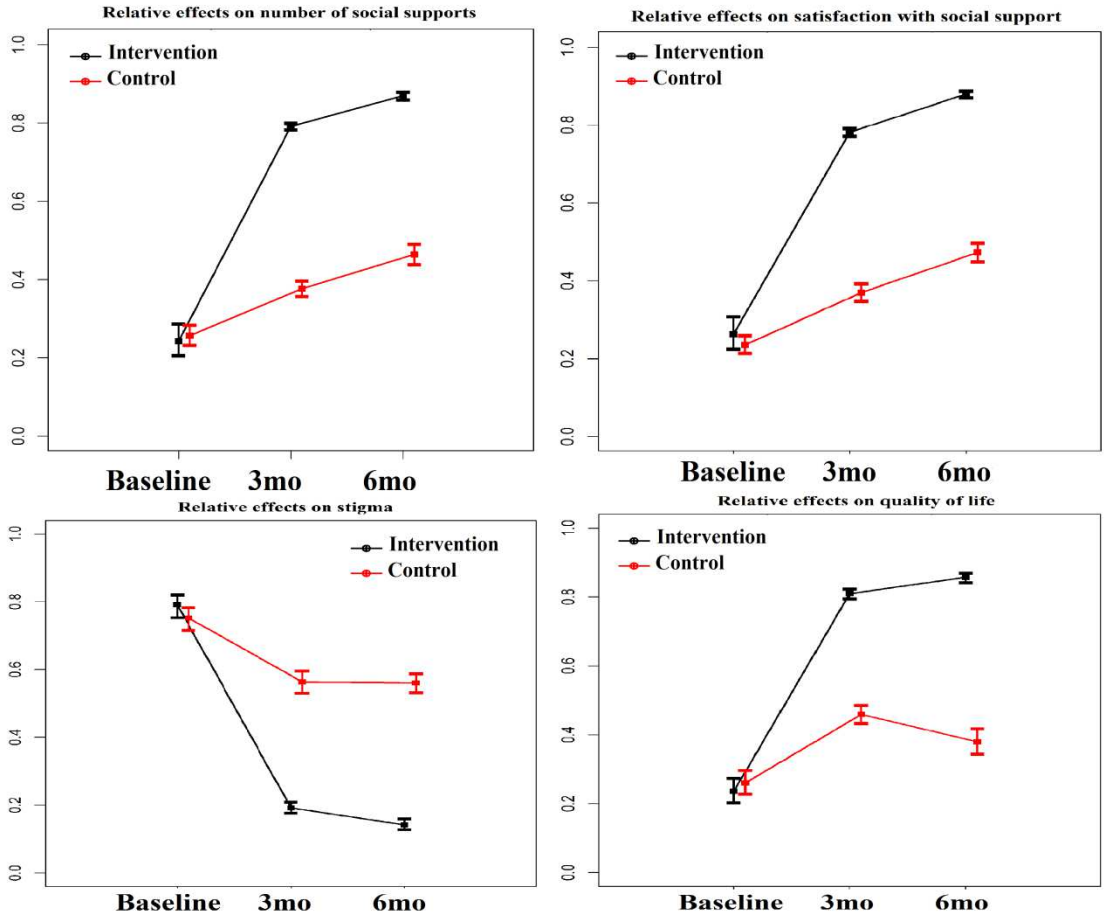
SE: standard error; TSSQN: total social support with number; TSSQS: total satisfaction with social support

Table 4 Prediction of QoL by intervention group after adjusting for level of empowerment, social support and stigma using nonlinear mixed-effects regression model

Parameter	Quality of life		
	Estimate	**SE**	**p value**
Empowerment	0.057	0.009	<0.001
TSSQN	0.007	0.012	0.574
TSSQS	-0.009	0.011	0.410
Stigma	-0.004	0.012	0.771
Intervention effect at baseline (Intervention vs. Control)	-0.051	0.108	0.371
Time (in Months)			<0.001
Intervention × Time			<0.001
Estimated difference in improvement in QoL from baseline (Intervention vs. Control)			
Three months follow up	4.310	0.610	<0.001
Six months follow up	4.788	0.642	<0.001

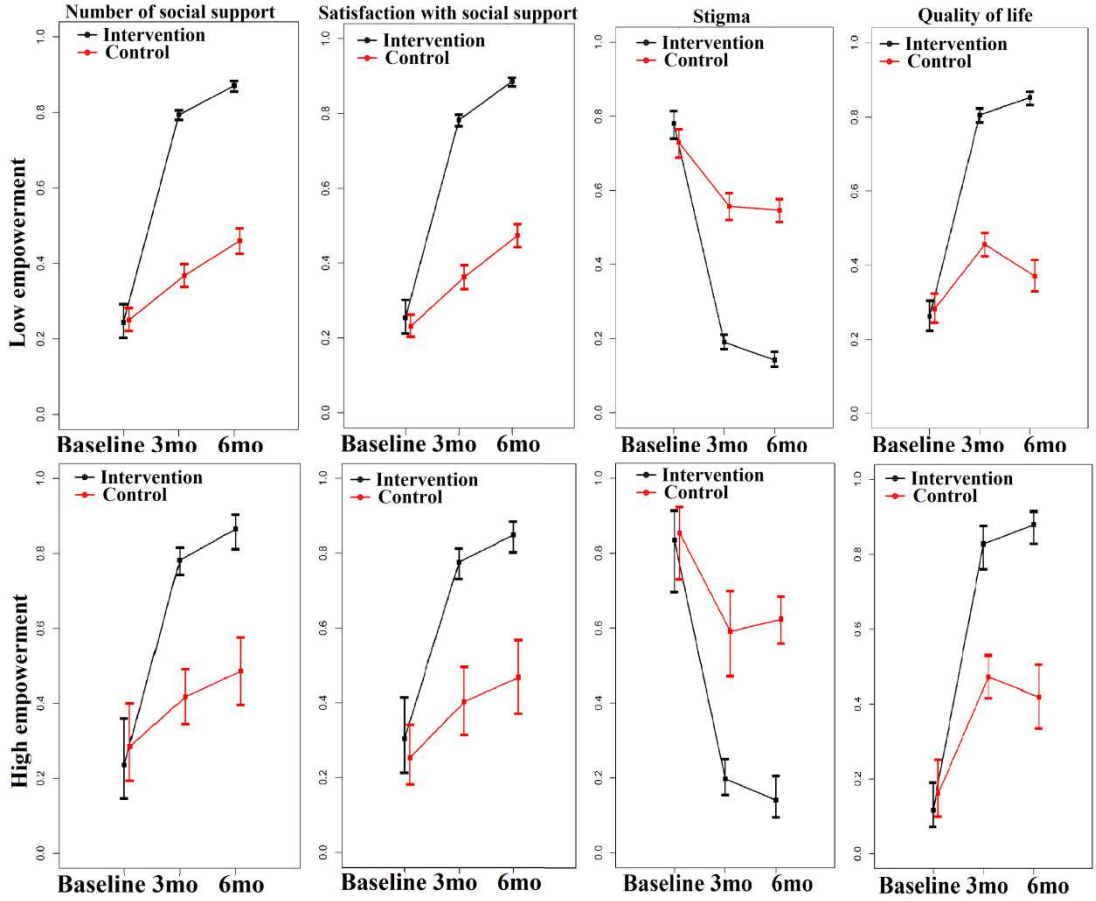
SE = standard error

Figure 2 Relative intervention effects on social support, stigma and quality of life using nonlinear mixed-effect model



All p-values for time trend between intervention and control on each outcome were significantly different with $p<0.001$, 3mo = Three months follow up, 6mo = Six months follow

Figure 3 Relative intervention effects on social support, stigma and QoL stratified by empowerment using nonlinear mixed-effect model



All p-values for time trend between intervention and control on each outcome were significantly different with p<0.001, 3mo = Three months follow up, 6mo = Six months follow up

VITAE

Name **Dharma Nand Bhatta**

Student ID **5610330011**

Educational Attainment

Degree	Name of Institution	Year of Graduation
PhD in Epidemiology	**Prince of Songkla University**	**2016**
MPH	**State University of Bangladesh**	**2009**

Scholarship Awards during Enrollment

Graduate School Grant, Prince of Songkla University, Thailand 2014

Discipline of Excellence in Epidemiology Scholarship, Prince of Songkla University 2015

TEACHING EXPERIENCES

Pokhara University, Nobel College Kathmandu, Nepal

Assistant Professor February 2012-Present

- Taught research methodology and basic and applied epidemiology for graduate and undergraduate public health, nursing and medical students
- Facilitated community diagnosis and survey, research works, and weekly journal clubs

Pokhara University, Nobel College Kathmandu, Nepal

Lecturer February 2009-February 2012

- Taught research methodology and basic and applied epidemiology for graduate and undergraduate public health, nursing and medical students
- Facilitated community diagnosis and survey, research works, and weekly journal clubs

Tribhuwan University, Institute of Medicine

Kathmandu, Nepal

Visiting Faculty June 2011-Present

- Communicated special lecturers on research methodology and epidemiology for graduate and undergraduate public health and medical students. Provided consultation for research work.

Purbanchal University, Affiliated Colleges

Kathmandu, Nepal

Visiting Faculty January 2012-Present

- Facilitated guest lecturers on research methodology and epidemiology for undergraduate public health students

ADDITIONAL WORK EXPERIENCES

Tamimi Global Co. (Contractor DoD and KBR USA) Balad, Iraq
Medical Organizer November 2004-March 2007

- Arranged emergency medical facilities and basic health services for base camp employees

Marie Stopes International (Sunaulo Parivar Nepal) Banke, Nepal
Assistant Coordinator July 2000-July 2001

- Provided reproductive health services for underprivileged and rural population

EXTRA ACTIVITIES

Nepal Health Research Council and Ministry of Health and Population
Kathmandu, Nepal
Resource Person January 2010 -Present

- Guided research training, workshops and program development
- Advised research review and ethical committee as a member

People's Dental College
Kathmandu, Nepal
Resource Person July 2013-Present

- Research training and workshops for graduate medical students and faculty members

Pokhara University, Nobel College Kathmandu, Nepal
Member Research committee December 2010-Present

- Developed strategies for research and advise institutional review board

Reviewer
Global Health Action, AIDS care, Health Psychology and Behavioral
January 2014 -Present

- Reviewed scientific articles.

LEADERSHIP EXPERIENCE

Pokhara University Pokhara, Nepal
Subject committee member September, 2010-June, 2012

- Prepared, developed and revised curriculum for undergraduate and graduate public health course
- Supervised undergraduate and graduate research work

PROFESSIONAL TRAINING

INSTITUTES	DATES	Title of Training
University of Gothenburg, Sweden	8 April -12 April 2013	Ethics of public health and biomedicine in a nutshell.
University of the Philippines, Manila, Philippines	10 June - 28 June 2012	Basic biostatistics & Epidemiology
State University of Bangladesh, Bangladesh	11 May - 03 June 2008	Research Methodology
Nagarjun Development Committee, Nepal	13 Sept.-14 Sept. 2001	HIV/AIDS and STDs Prevention
Nepal STD and AIDS Research Center, Nepal	11 Dec.-11Dec. 2001	HIV/AIDS, STDs Education and Counseling
Adventist Development and Relief Agency (ADRA), Nepal	13 July-28 July 2000	Comprehensive Family Planning and Counseling
Center for Technical Education and Vocational Training, Nepal	Aug. 1997- Feb. 1998	Community Medicine Assistant

SKILLS and INTERESTS

-Computer: R, SPSS, STATA, EndNote, Epidata and AMOS
-Multivariate (SEM), survival, longitudinal and period data analysis and modeling
-Facilitated research trainings and workshops
-Travelled Asia and Middle East

SELECTED AWARDS AND RECOGNITIONS

Nepal Vidhyabhushan ‘B’ for excellent result in MPH, President of Nepal 2011

MEMBERSHIP

International Society of Infectious Diseases
European Public Health Association

RESEARCH/PUBLICATION

1. **Bhatta DN**. Involvement of male in antenatal care, birth preparedness, exclusive breast feeding and immunization for child in Kathmandu, Nepal. *BMC Pregnancy and childbirth.* 2013; 13:14.
2. **Bhatta DN**, Koirala AK, Jha N. Adolescent students’ attitude towards premarital sex and unwanted pregnancy. *Health Renaissance.* 2013; 11: 145-149.

3. **Bhatta DN**, Aryal UR, Khanal K. Education: the key to curb HIV and AIDS epidemic. *Kathmandu University Medical Journal*. 2013; 42:158-161.
4. **Bhatta DN**. HIV related sexual risk behaviors among male-to-female transgender people in Nepal. *International journal of infectious diseases.* 2014; 22:11-15.
5. **Bhatta DN**. Shadow of domestic violence and extramarital sex cohesive with spousal communication among males in Nepal. *Reproductive Health.* 2104; 11:44.
6. **Bhatta DN**, Haque A. Health problems, complex life and consanguinity among Muslim ethnic minority population in Nepal. *Ethnicity and health.* 2014; 1-17.
7. Karki S, **Bhatta DN**, Aryal UR. Older people's perspectives on an elderly-friendly hospital environment: an exploratory study. *Risk Management and Healthcare Policy*. 2015; 8: 81-89.
8. Gautam A, **Bhatta DN**, Aryal UR. Knowledge, attitude and practice among diabetic patients in Nepal. *BMC Endocrine Disorder*. 2015; 15:25.
9. **Bhatta DN**, Aryal UR. Paternal factors and inequity associated with access to maternal health care service utilization in Nepal: a community based cross-sectional study. *PLoS ONE*. 2015; 10(6):e0130380.
10. Koirala AK, **Bhatta DN**. Low-birth-weight babies among hospital deliveries in Nepal: a hospital-based study. *International Journal of Women's Health*. 2015; 7:581-585.
11. Aryal UR, **Bhatta DN**. Perceived benefits and health risks of cigarette smoking among young adults: insights from a cross-sectional study. *J Tobacco Induced Diseases*. 2015; 13:22.
12. Aryal UR, **Bhatta DN**. Smoking susceptibility and intention to smoke among secondary school adolescents in Nepal. *Journal of Nepal Health Research Council*. 2015; 13(29):26-30.
13. Aryal UR, **Bhatta DN**, Shrestha N, Gautam A. Assessment of nicotine dependence among smokers in Nepal: a community based cross-sectional study. *J Tobacco Induced Diseases*. 2015; 13:26.
14. Bhatta DN, Liabsuetrakul T. Design and feasibility of a social-self value intervention package to empower people living with HIV. AIDS Care. Accepted
15. Bhatta DN, Liabsuetrakul T. Social self-value intervention for empowerment of HIV infected people using antiretroviral treatment: a randomized controlled trial. BMC Infectious Diseases. Under review.
16. Bhatta DN, Liabsuetrakul T. Efficacy of social-self value empowerment intervention to improve quality of life of HIV infected people receiving antiretroviral treatment in Nepal: a randomized controlled trial. AIDS and Behavior. Under review.

EDITORIAL

1. Bhatta DN. Moral Dimensions of Research Ethics: Ethical Dilemmas and Challenges in Human Participants' Research among Different Settings. Journal of Preventive Medicine, 2013; 1(3): 19-21.
2. Bhatta DN. Ebola: governance response and public health emergency in developing countries. Iran J of public health, 2015; 44(2): 285-286.

BOOK/THESIS

1. Bhatta DN. Text book of research methodology: a short manual; first edition.

Intellectual publication, Kathmandu, Nepal, 2009.
2. Bhatta DN. Men's participation in reproductive health in Kathmandu, Nepal. Academic research thesis, State University of Bangladesh: Bangladesh; 2008.

CONFERENCE PAPER

1. **Bhatta DN**. Communication between spouses on family planning, extra marital sexual relations and domestic violence among married males in Nepal. 44th Asia Pacific Consortium for Public Health (APACPH), 14-17, October, 2012, Srilanka.
2. **Bhatta DN**. Improving quality of life among people living with HIV infection under antiretroviral therapy in Nepal: an operational research. The 16th annual research conference of epidemiology program, Thailand, 26-27 March, 2014, Thailand.
3. **Bhatta DN**, Aryal UR, Regmi S. Paternal factors are associated with access to institutional delivery utilization in Nepal. First National Summit of Health and Population Scientists in Nepal. Organized by Nepal Health Research Council Nepal, 11-12, April, 2015, Nepal.
4. Aryal UR, **Bhatta DN**, Karki S. Smoking Susceptibility and Intention to Smoke among secondary school adolescents in Nepal. First National Summit of Health and Population Scientists in Nepal. Organized by Nepal Health Research Council Nepal, 11-12, April, 2015, Nepal.
5. Aryal UR, **Bhatta DN**. Psycho-social factors influencing smoking behavior of Nepalese adolescents. International conference on adolescent medicine & child psychology, 28-30, September, 2015, Houston, USA.
6. **Bhatta DN**, Liabsuetrakul T. Social-self value intervention for empowerment of HIV infected people using antiretroviral treatment: a randomized controlled trial. University of Malaya, 23-24 November, 2015, Malaysia.
7. **Bhatta DN**. Paternal factors are associated with access to institutional delivery utilization in Nepal. 8th Asia Pacific Conference on Reproductive and Sexual Health and Rights", 23-26, February 2016, MICC – II , Nay Pyi Taw, Myanmar.