

博士論文

**The role of methadone-assisted treatment program on
improving drug use and preventing HIV infection among
people who inject drugs in Dar es Salaam, Tanzania**

タンザニアのダルエスサラームにおける注射薬物使用者の薬物使
用およびエイズ感染予防に対するメサドン補助療法の役割

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Abbreviations

AOR	adjusted odds ratio
ART	antiretroviral therapy
CI	confidence interval
GEE	generalized estimation equations
HIV	human immunodeficiency virus
MUHAS	Muhimbili University of Health and Allied Sciences
OR	odds ratio
SD	standard deviation
STIs	sexually transmitted infections

Abstract

Background

This thesis had five objectives. The first one was to examine the role of an integrated methadone-assisted treatment program—the intervention in reducing drug use behavior among people who inject drugs. The second one was to examine the role of the intervention in reducing their sharing of injecting needles. The third one was to examine the role of the intervention in reducing their criminal activities. The fourth one was to examine the role of the intervention in improving their condom use. The last one was to examine the role of the intervention in improving their health care seeking behavior in Dar es Salaam, Tanzania.

Methods

A prospective cohort study involved newly enrolled people who inject drugs in the program and their control counterparts from the community. Data were collected at baseline and six months after receiving services from the program. Data of 578 participants were available for analyses at baseline and 466 at follow-up.

Results

After six months of follow-up, participants in the intervention group were less likely to use drugs (AOR: 0.0006, 95% CI: 0.00006 – 0.006), share injecting needles (AOR: 0.02, 95% CI: 0.004 – 0.16), and engage in criminal activities (AOR: 0.05, 95% CI: 0.03 – 0.10) compared with those in the control group. Also, all participants in the intervention sought medical care when in need compared to 63.3% of their counterparts. Condom use, however, was not different between two groups (OR: 0.52, 95% CI: 0.27 – 1.01).

Conclusions

The intervention reduced drug use behavior, sharing of injecting needles, criminal activities, and improved health care seeking behavior of its participants.

CHAPTER 1

Background

1.1 The burden of illicit drugs and their action on the brain

Drug use contributes substantially to the global burden of disease (1). Individuals consume various types of illicit drugs including opiates, cocaine, marijuana, and amphetamines (2). Their consumption may or may not result into a drug use problem. A drug use problem results from the intoxication or regular excessive use of illicit drugs (3). In 2013, about 246 million people had used illicit drugs at least once, but only 27.0 million were problem drug users (2). Moreover, about 12.2 million were people who inject drugs and 13.5% of them were HIV-positive (2). In the same year, about 187,000 people died of drug-related causes. Access to treatment is worryingly low among people who use drugs in spite of such unprecedented rates of mortality. For example, only 1 out of 6 problem drug users have access to treatment globally (2).

Illicit drugs work on the reward pathway or the mesolimbic dopamine pathway in the brain to influence pleasure (4). Frequent illicit drug use stimulates this pathway and makes people who use drugs dependent on them. They alter the normal functions of the brain; however, it adjusts itself to return to its normal functioning level. Such adjustment involves either minimizing the effects of a drug over time or minimizing the need for higher doses of a drug to achieve the same effect. When the drug is removed completely from the system, the brain has to undo all its adaptive changes resulting into a withdrawal syndrome (4). The syndrome is characterized by various symptoms including nausea, sleep disturbances, and aching muscles and signs such as yawning, diarrhea, vomiting, and tremors (5).

1.2 Risk factors and consequences of illicit drug use

Various risk factors are thought to play part in the initiation or continued illicit drug use. They include behavioral, environmental, psychological, social, economical, and genetic factors (6). Examples of behavioral factors include deviant behaviors (6). Deviance usually occurs when individual's values come into conflict with more powerful and influential ones

of another individual (7). For example, an individual is more likely to use illicit drugs if he/she is influenced by a peer who uses them or tolerates their use. Environmental factors include the role of adults and families (8). The risk of drug use increases when one has a family member who uses them (9-11). Psychological factors such as traumatic life events are also associated with drug use (6). Such events may lead to stress, depression, and other mental health illnesses. To cope with such mental health pressure, one may resort into the use of drugs to get temporary relief or excitement (10, 12, 13). In addition, people with socioeconomic disadvantages are also more likely to use drugs (6). Genetic predisposition is also thought to be associated with illicit drug use, however, its pathway or role is not clear (6, 12).

Illicit drug use has various negative social and health effects. Social effects include failed marriages, social isolation, violence, and crime (6, 14, 15). People who use drugs may find it difficult to sustain intimate relationships. This exposes them to low emotional support leading to social isolation (13). Also, drug use may influence individuals to become violent or make them victim of violence (15). They also often engage in crimes to get money to sustain their drugs use behaviors (13). Intoxication from drugs increases their high-risk injecting and sexual behaviors risking contracting infections such HIV, hepatitis, and other sexually transmitted infections (STIs) (16, 17). Also the influence of drugs increases chances of encountering physical injuries (6). Importantly, drug use predisposes people who use drugs into mental health and medical problems such as cardiac and pulmonary illnesses (18).

1.3 Medical and social problems faced by people who inject drugs

People who inject drugs experience various medical and social problems owing to their altered behavior and bodily functions (4). They are at risk of various infectious diseases (19-22). They engage in high-risk injecting and sexual behaviors that predispose them to HIV infection, hepatitis, and STIs (18, 23-25). Other medical problems they face include

tuberculosis (26), skin abscesses and infection, and pulmonary and cardiovascular diseases (18). They also suffer from social problems such as sexual and physical abuse (27). Other social problems include interpersonal violence and employment instability (6, 14, 15). These issues affect their employment opportunities and further push them into criminal activities to obtain money for drugs (28). In addition, drug use may lead to overdose and an escalated risk of mortality (29). Despite such disadvantages, the majority of them have poor access when in need of medical care (30-33) compared to general population (34). Poor access to health care may result in poor health outcomes among them and increase the cost of medical care to an individual and the health system as a whole.

1.4 HIV infection among people who inject drugs

People who inject drugs are at a higher risk of HIV infection compared to other people who use drugs because of their high-risk injecting practices and sexual behaviors (35). High-risk injecting practices include using contaminated needles and syringes and practicing flashblood. Flashblood refers to the sharing of a syringe containing blood drawn from another person who injects drugs (36). People who inject drugs can transmit HIV amongst themselves through such high-risk injecting practices. HIV infection risk is about 0.6 – 2.4% after using an HIV-contaminated needle (about 1 in 125 injections) (37). HIV can also be transmitted amongst people who inject drugs or to the general population through high-risk sexual practices such as unprotected sex, multiple sexual partnerships, and transactional sex (38, 39). The risk of the infection is estimated at 0.02 – 0.05% after having sexual intercourse with an HIV-positive individual (about 1 in 2000 – 5000 sexual encounters) (35). As a result of such elevated risks, HIV prevalence was 1.7 million out of 12.2 million people who inject drugs globally in 2013 (2). Even while faced with such an exceptional HIV burden, they must content with poor access to health services (27, 40).

1.5 Interventions for drug dependence treatment and HIV prevention for people who inject drugs

Various interventions are available for people who inject drugs to prevent HIV infection and provide treatment for drug dependence (41). One of them is provision of opioid substitution therapy. Other interventions include needle and syringe provision programs; HIV testing and counseling; antiretroviral therapy (ART) for those living with HIV; prevention and treatment of STIs; vaccination, diagnosis, and treatment of hepatitis; and prevention, diagnosis and treatment of tuberculosis.

Opioid substitution therapy treats drug dependence using medications that are similar in compounds to the used illicit opioids (4). However, these medications work differently from the illicit drugs. Currently, medications are available to treat dependency from opiates only and not for other types of illicit drugs such as cocaine or cannabis (42). Opioid substitution therapy medicines can either be opioid agonists or antagonists or both. An example of an opioid agonist is methadone. Methadone treats by reducing withdrawal symptoms and craving of illicit drugs (4). Opioid antagonists include naloxone and naltrexone whereas buprenorphine is both an agonist and antagonist (43). Opioid antagonists block the euphoria effects brought about by consumed drugs (4). Methadone, buprenorphine, and naloxone are among the essential medicines listed by the World Health Organization (44). These medications are not stand-alone treatments for drug dependence. They reduce craving for drugs and alleviate withdrawal symptoms to enable patients to participate in rehabilitation more effectively (4).

Other interventions such as needle and syringe provision programs, HIV testing and counseling, screening services for other infectious diseases, and ART help to mitigate transmission of HIV infection and other infectious diseases among people who inject drugs (45). For example, needle and syringe provision programs reduce illicit drug use (46) and

needle sharing (46-48). HIV testing and counseling provides an opportunity for them to know their infection statuses. Knowing their statuses increases their chances to engage in safer injecting and sexual practices (45, 49). In addition, treatment with ART reduces HIV transmission through the reduction of viral load of an HIV-positive individual (50).

1.6 The global state of opioid substitution therapy

Globally, injecting drug use has been reported in at least 158 countries but only 80 of them have opioid substitution therapy programs.

1.6.1 Opioid substitution therapy in high-income countries

Opioid substitution therapy has exhibited good health outcomes among people who use drugs who have enrolled in them. Methadone/buprenorphine maintenance treatment reduced drug use, crimes, and high-risk injecting and sexual behaviors of people who use drugs in various high-income countries such as the US (51, 52), Australia (53, 54), Netherlands (55), and New Zealand (28). Opioid substitution therapy centers also offered an opportunity for clients to be screened for HIV infection in the US (56) and viral hepatitis in Switzerland (57).

Furthermore, opioid substitution therapy improved antiretroviral therapy adherence among its clients in France (58).

1.6.2 Opioid substitution therapy in middle-income countries

A study conducted among people who use drugs enrolled in the first eight methadone clinics in China was effective (59). Twelve months following methadone treatment in the clinics, clients reduced their drug use and drug-related criminal activities. They also reduced poor family relationships and increased harmonious family relationships (59). In China, HIV and hepatitis C test uptake was high among people who inject drugs enrolled in methadone clinics (60) however provision of those screening services were sometimes delayed (61). Methadone treatment also reduced drug use behaviors in Iran (62). A different study in Iran reported a higher reduction in drug use between people who inject drugs who were in methadone

treatment for at least six months compared to the new enrollees (63). The rate of crimes and arrests, however, was not different between the two groups (63). A methadone maintenance treatment integrated with HIV care in Indonesia provided an opportunity for people who inject drugs to get tested for HIV infection and initiate ART (64). However, clients' mortality and virological response were not different from those of people who inject drugs who were not in such a program (64). In Malaysia, people who inject drugs reduced their drug use behavior and HIV risk-taking behaviors after 12 months of methadone treatment, but the reduction in criminal activities from baseline to 12 months following treatment was not statistically significant (65). Furthermore, methadone treatment reduced drug use behavior and improved quality of life of its clients in Vietnam (66). In Myanmar, however, many clients of methadone treatment face challenges including reusing heroin and/or abusing methadone with other opiates (67).

1.6.3 Opioid substitution therapy in low-income countries

Opioid substitution therapy improved health outcomes of people who use drugs in low-income countries. In Afghanistan, one year following opioid substitution therapy, enrollees reported better health status and social integration (68). Enrollees also reported a reduced mental health burden and a reduction in criminal activities (68). Cambodia opened its first methadone clinic for people who use heroin in 2010 but no report is available on its effectiveness on the the health outcomes of its clients (69). Burkina Faso is another low-income country which has an operational opioid substitution therapy programmes (70), although its effectiveness has not been examined. In Nepal, no empirical data are available on the effectiveness of opioid substitution therapy (71), however, people who use drugs reported a reduction in drug use behavior and positive economic and social changes in their lives after receiving methadone treatment (72, 73).

1.7 Injecting drug use in Tanzania

Injecting drug use is a growing problem in Tanzania—a hot spot for major drug trafficking routes in Africa (74). Tanzania is estimated to harbor about 30,000 people who inject drugs (75). Like in other countries, people who inject drugs in Tanzania also engage in high-risk injecting and sexual behaviors (76) and they are at risk of HIV infection (77). As a result, HIV prevalence among them is about 35.0% (75). Such a significant burden far exceeds the 5.1% HIV prevalence rate found in the general population (78). This key population is also known to be vulnerable to tuberculosis (26) and hepatitis (79). Furthermore, people who inject drugs may have poor health care seeking behavior and higher rates of criminal activities in Tanzania, as in other countries (28, 40).

In Tanzania, people who inject drugs may receive care from both publicly and privately run health facilities (80). Health workers include medical specialists, general physicians also known as medical officers, and mid-level providers. Mid-level providers include clinical officers and assistant medical officers. Mid-level providers provide health care to most populations in semi-urban and rural areas and are also referred to as doctors (81). The number of medical doctors is not sufficient to cater to the health care needs of the whole population (81, 82). Therefore, they assume tasks that medical doctors typically undertake. They play a vital role in providing basic care, treatment, and preventive services to the general population including people who inject drugs.

To respond to various problems faced by people who inject drugs in Tanzania, HIV prevention and other health interventions are available for them in a few centers in the country (83, 84). They include needle and syringe provision programs and opioid substitution therapy. Opioid substitution therapy using methadone was first introduced in a public health facility in Tanzania in 2011 (84). Tanzania is among a few countries in Africa to start a public health facility-based, methadone-assisted treatment program (70).

1.8 Research gaps

People who inject drugs face various medical and social problems (26, 27, 85). Despite these needs, many of them have poor access to health services (30, 34, 61). Evidence exists about access to health care among them in high-income countries (31, 86), but it is limited in low-income countries. Tanzania is no exception.

Interventions are known to reduce drug dependence and risk of morbidity and mortality from infections (87, 88). Such interventions include the provision of opioid substitution therapy and HIV testing and counseling. However, such interventions are mostly provided as single interventions (42). Combination of such interventions may be more effective for HIV prevention amongst people who inject drugs and in the general population (35). In addition, a more holistic strategy in this vein may improve the lives of people who inject drugs. It may also improve their health care seeking behavior and reduce their criminal activities. However, limited evidence exists on the effectiveness of combined interventions. In addition, evidence is limited on the effectiveness of combined interventions in Africa, where HIV is still prevalent and drug use is escalating--and Tanzania is no exception.

Opioid substitution therapy using methadone is available in Tanzania. The methadone-assisted treatment program is integrated with other health services including medical care, screening for infectious diseases, and psychosocial counseling (89, 90). Few methadone-assisted treatment programs provide other health services alongside drug dependence treatment globally like the one in Tanzania (42). Moreover, since the program's inception in Tanzania, no study has examined its roles on high-risk behaviors among people who inject drugs.

1.9 Objectives

- i. To examine the role of an integrated methadone-assisted treatment program in reducing drug use behavior among people who inject drugs in Dar es Salaam, Tanzania
- ii. To examine the role of an integrated methadone-assisted treatment program in reducing sharing of injecting needles among people who inject drugs in Dar es Salaam, Tanzania
- iii. To examine the role of an integrated methadone-assisted treatment program in reducing criminal activities among people who inject drugs in Dar es Salaam, Tanzania
- iv. To examine the role of an integrated methadone-assisted treatment program in improving the use of condom among people who inject drugs in Dar es Salaam, Tanzania
- v. To examine the role of an integrated methadone-assisted treatment program in improving health care seeking behavior among people who inject drugs in Dar es Salaam, Tanzania

1.10 Study hypotheses

We hypothesized that the positive changes in risk behaviors would be higher among people who inject drugs enrolled in the integrated methadone-assisted treatment program compared with those not enrolled in the program after 6 months of treatment. Specifically, enrolled people who inject drugs would improve their health care seeking behaviors and reduce their illicit drug use more frequently than those not in the program. In addition, enrolled people who inject drugs would reduce their sharing of injecting needles, reduce their criminal activities and improve their use of condoms more so than those not enrolled in the program.

1.11 A conceptual framework: How the intervention would work

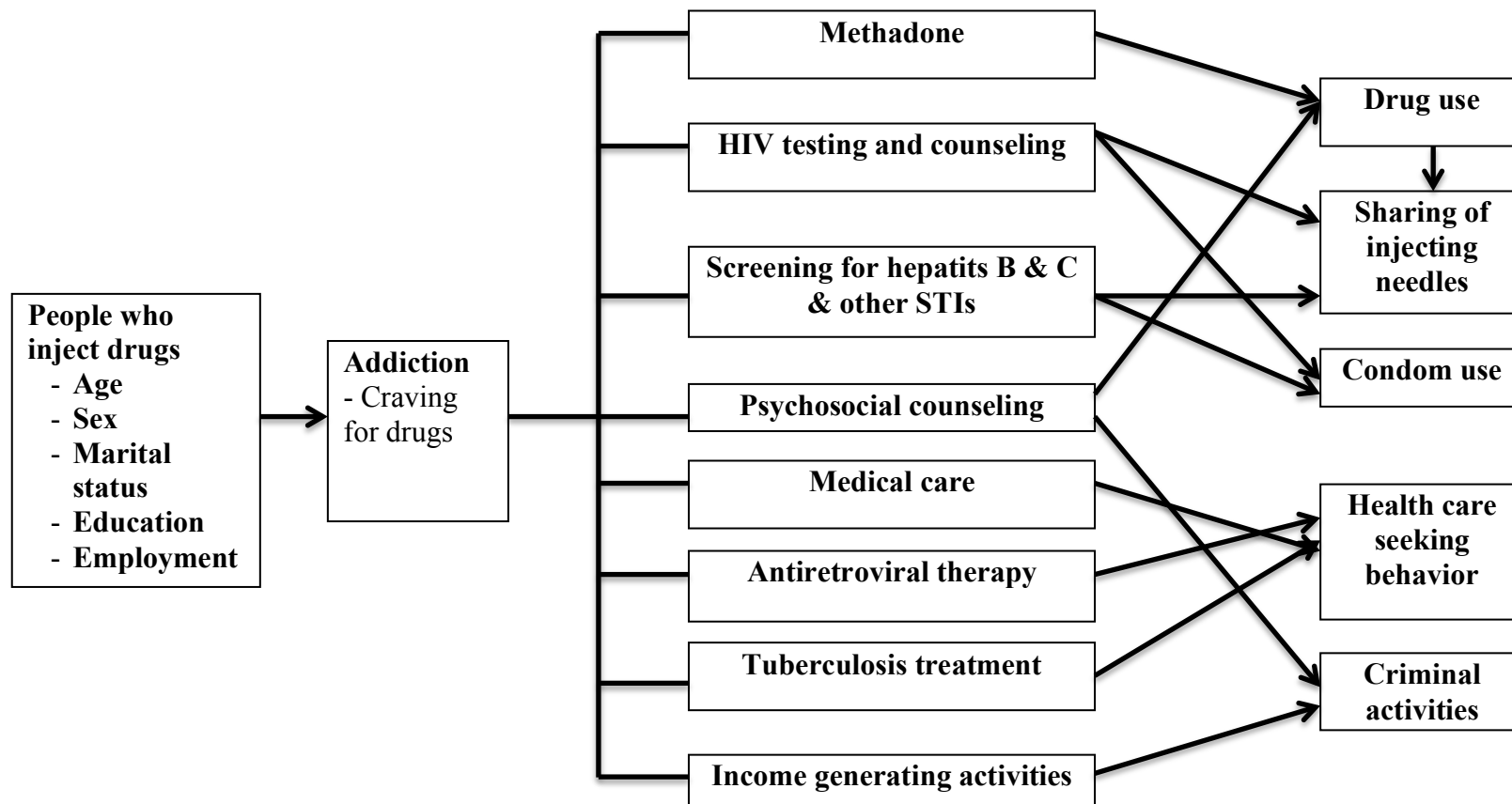
Methadone provided in the integrated methadone-assisted treatment program would reduce drug use behaviors of its enrollees as a result of its pharmacological effects. Methadone reduces craving for illicit drugs among people who inject drugs. It also ameliorates withdrawal symptoms (4) and blocks the euphoric effects of the consumed drugs (91). As a result, the need to use drugs would decrease among them.

The reduction of drug use would decrease criminal activities among enrollees. Usually people who inject drugs engage in criminal activities to get money for drugs. The reduction in drug use would reduce the chances in which they have to engage in crimes. In addition, treatment with methadone would stabilize them and enable them to participate more effectively in normal daily activities and rehabilitation (4, 87). They would therefore be able to act on psychosocial counseling provided in the program.

Stabilization obtained after receiving methadone treatment would further enable them to act on counseling for safer injecting and sexual practices received during HIV testing and screening for other infectious diseases. Eventually, they would reduce their high-risk behaviors such as sharing of injecting needles and improve their use of condom.

Enrolees' health care seeking behavior would improve following enrollment in the program. This is because of the provision of free medical care at the program's clinics. This would reduce the barrier of high cost of medical treatment and transport to go to health facilities when in need of medical care.

Figure 1: A conceptual framework



CHAPTER 2

Methods

2.1 Study design

I conducted a prospective cohort study among people who inject drugs in Dar es Salaam, Tanzania.

2.2 Study area

Dar es Salaam is the business capital of Tanzania, with a population of approximately 4.4 million (92). The region has three municipalities: Kinondoni, Ilala, and Temeke. The types of illicit drugs used include heroin, marijuana, and valium (77). The main patterns of drug use in the region include smoking, sniffing, inhaling, and injecting (93). People who inject drugs are estimated to be 30,000 in the country, and 30-50% of them reside in Dar es Salaam (75).

People who inject drugs engage in high-risk behaviors such as sharing injecting needles, unprotected sex, and multiple sexual partnerships (36, 77). As a result, HIV prevalence among them in Tanzania is 35.0% (75) which is markedly high compared to the 5.1% observed in the general population (78).

2.3 Study participants

Participants included both male and female people who inject drugs. I included two groups of participants— people who inject drugs who were newly enrolled into the integrated methadone-assisted treatment program as the intervention group, and community-recruited people who inject drugs as their control counterparts. For the intervention group, I included those people who inject drugs who were aged 18 years and above, resided in Dar es Salaam, and consented to participate. For the control group, I included people who inject drugs who were not enrolled in the program, were aged 18 years and above, resided in Dar es Salaam, and consented to participate. The exclusion criterion was having a severe mental illness. I conducted a brief interview prior to data collection to assess severe mental illness of participants. The items of this assessment included observing if a participant was grossly disorganized in behavior and speech and if he/she was cognizant in time, place, and person.

These items were used based on the advice of a psychiatrist who treats clients of the integrated methadone-assisted treatment program and the WHO neuropsychiatry assessment tool (94). In this study, a participant was considered to have a severe mental illness if he/she had gross disorganization in behavior and speech and was not cognizant of time, place, and person. Among the participants I approached, none had gross disorganization in behavior and speech. Furthermore, all the participants who were approached were cognizant of time, place, and person. Thus none was excluded from the study.

2.4 Intervention

The intervention of this study was the integrated methadone-assisted treatment program. The program's clinics were located in the Muhimbili National Hospital in Ilala municipality and Mwananyamala Hospital in Kinondoni municipality of the Dar es Salaam region at the time of data collection. The program is integrated with various health services such as methadone treatment; HIV testing and counseling; screening for hepatitis B and C virus and STIs; psychosocial counseling; medical care; antiretroviral therapy (ART); tuberculosis treatment; and training on income generating activities.

Medical and mental health services are available at the clinics. Psychiatrists provide both mental health services and medical care. After being enrolled in the program, psychiatrists screen clients for severity of drug addiction and psychiatry comorbidity using various instruments such as the Addiction Severity Index (95) and Hopkins Symptom Checklist-25 (96). They also screen clients for various medical conditions. Clients undergo several tests including Full Blood Picture, Comprehensive Chemistry Panel, and other relevant investigations depending on their presentation. During the course of the treatment in the program, clients receive mental health services once every month. Psychiatrists also provide medical care for minor ailments to clients and refer them for specialized care whenever necessary.

Screening services are also available at the program's clinics. Clients receive HIV testing and counseling; screening for hepatitis B virus, hepatitis C virus, and STIs (84, 89). They receive screening for these infectious diseases during enrollment and once every six months. Screening services are provided alongside counseling of safer injecting and sexual practices. Counseling on safer practices is provided before and after screening of infectious diseases. Nurses provide these services to clients. Clients diagnosed with infectious diseases are taken to an appropriate department/clinic within the Muhimbili National Hospital and Mwananyamala Hospital to receive further care.

The program provides methadone medication for opioid drug dependence treatment (76). Clients have to go to the clinics every day to receive methadone medication. Trained pharmacists provide methadone doses to the clients based on each client's prescription from a psychiatrist. Clients receive methadone at the pharmacy located within the clinic's premises under direct observation. Clients of the integrated methadone-assisted treatment program are scheduled to receive methadone treatment for at least two years.

Enrollees also receive psychosocial counseling. This includes Brief Motivational Interviewing (BMI) to address other substance dependences other than heroin. Social workers provide this treatment individually at enrollment. Psychologists provide the clients with cognitive behavioral therapy (CBT) and relapse prevention strategies individually at enrollment to improve treatment outcomes which. Clients also attend Methadone anonymous meetings as part of group therapy sessions once every week. During the course of the treatment at the program, clients see these clinicians (social workers/psychologists) once every month and whenever they need care.

ART is another component of the integrated methadone program (90). All clients who are diagnosed to have HIV infection at the programs clinic are referred to HIV care and treatment centers which are located within the Muhimbili National Hospital and

Mwananyamal Hospital premises but in a different location from that of the programs clinics for registration. After registration in the HIV Care and Treatment centers, clients continue to receive ART alongside methadone medication at the program's clinic. Trained pharmacists provide these medications at the program's clinics.

All enrollees receive tuberculosis screening based on their clinical symptoms or complains (90). When diagnosed with tuberculosis, they are referred to the Tuberculosis and Leprosy clinics that are located within the Muhimbili National Hospital and Mwananyamala Hospital premises. After registration in the Tuberculosis and Leprosy clinics, clients continue to receive tuberculosis treatment alongside methadone medication under direct observation (90). Trained pharmacists provide these medications to clients at the program's clinics.

Furthermore, enrollees of the integrated methadone-assisted treatment program have an opportunity to receive training on income generating activities. This is part of the rehabilitation services. Clients are involved in various activities including gardening and making cloths known as "batiki" which is an African print.

2.5 Sampling strategy

I recruited both the intervention and control group participants using convenience sampling.

2.5.1 Intervention group sampling strategy

I selected any new enrollee from the program's clinics at the Muhimbili National Hospital and Mwananyamala Hospital located in Ilala and Kinondoni municipalities, respectively (where any person who inject drugs can enroll in the program). I selected these hospitals because the program's services were available only at these two public hospitals in the country at the time of data collection.

2.5.2 Control group sampling strategy

I selected community-recruited people who inject drugs using snowball sampling. I recruited them from the communities of all three municipalities of Dar es Salaam by visiting sites

where they usually meet to use drugs, known as ‘vijiwe’ or ‘maskani’. These are common sites at which young people hang out and chat with their friends. I identified initial participants from the communities’ sites—‘maskani’ with the help of former people who inject drug who were enrollees and were receiving treatment at the integrated methadone-assisted treatment program. After interviewing the initial participants, these interviewed participants introduced me to other sites—‘maskani’ where I could select other people who inject drugs to participate in the study. The selection of participants continued by moving from one ‘maskani’ to the other in the communities of the Dar es Salaam region with the help of interviewed participants in various ‘maskani’.

2.6 Sample size calculation

I calculated the needed sample size using Power and Precision software. I used the following details in the calculation.

- I used the details of one of the dependent variables of this study—sharing injecting needles at the last injection in the calculation.
- A previous study conducted in Tanzania among people who inject drugs who were not receiving methadone treatment reported sharing of injecting needles at the last injection among them to be 26% (76).
- I estimated that six months following enrollment in the integrated methadone-assisted treatment program, the proportion of sharing injecting needles at the last injection would be 13% among the participants who received services from this program.
- I set the significance (alpha) at 0.05, 2-tailed test and 80% power. I assigned the number of participants to be 50% in the intervention and 50% in the control group.
- I thus obtained a minimum sample size of 302.
- For this distribution, the effect size is 0.5 as a relative reduction in the expected proportion of sharing needles as a result of the intervention.

- To counteract the effects of loss to follow-up and/or missing data, however, I collected data from 598 people who inject drugs.

2.7 Data collection

I collected baseline data from January to April 2014 and follow-up data 6 months later, from July to October 2014. I recruited and trained five research assistants who were involved in service provision at the integrated methadone-assisted treatment program clinics. The contents of the two-day research assistant training covered questionnaire content, data collection procedures, and ethics-related issues.

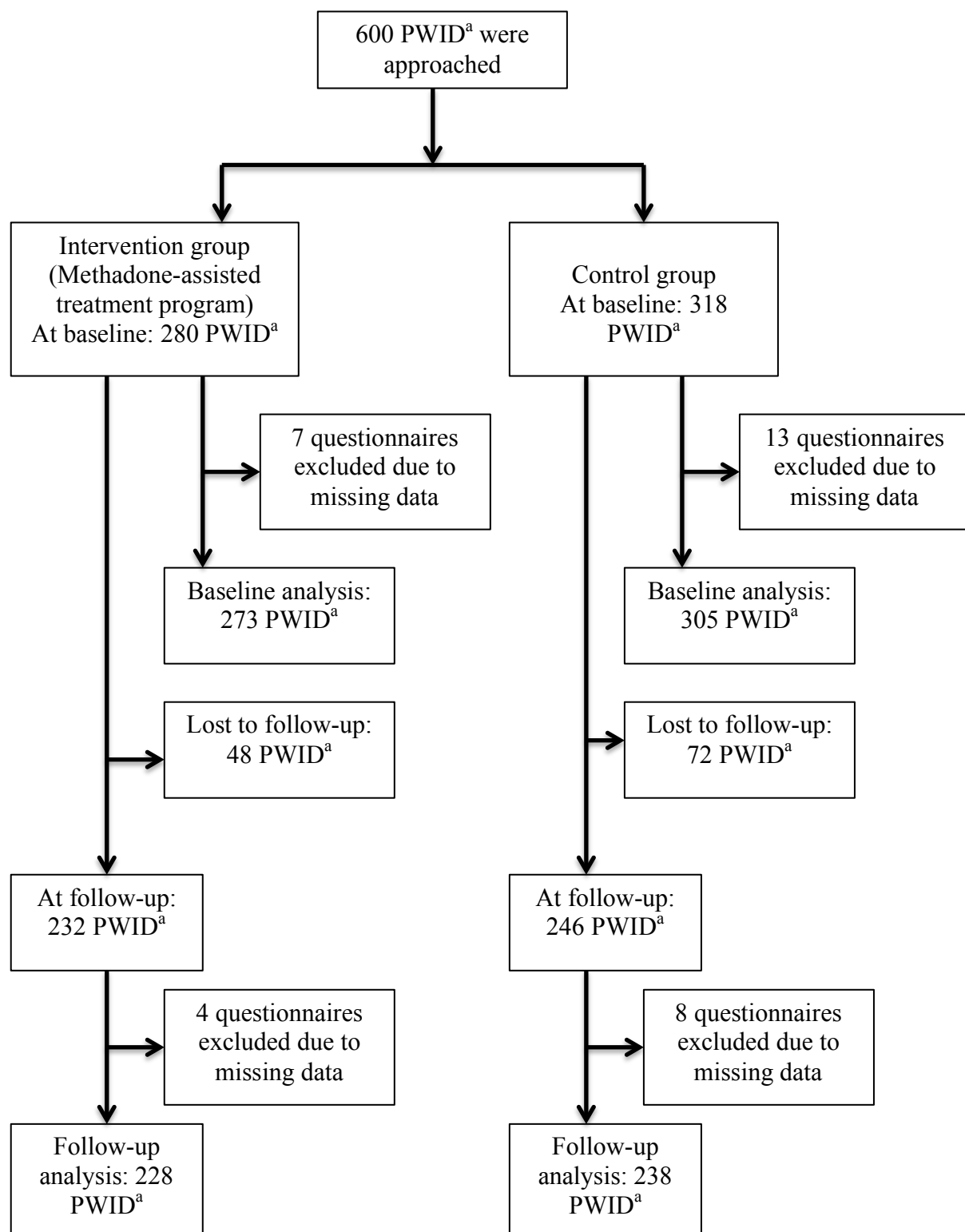
I used a pretested Swahili language questionnaire for the face-to-face interviews. I interviewed new enrollees in consultation rooms at the program's clinics. At baseline, I interviewed new enrollees before they received services of the program.

For the community-recruited people who inject drugs, I approached potential participants in sites where drug users meet to use drugs, which are known as 'vijiwe' or 'maskani.' Former people who inject drugs introduced me to the participants in these 'maskani'. These former people who inject drugs were receiving treatment at the integrated methadone-assisted treatment program clinics. To observe privacy, I conducted the interviews in areas distant from the other people who inject drugs present there at the time. After the interview, I asked some of the participants to direct or take me to other 'maskani' where I could recruit additional people who inject drugs. This method was used until the required sample size was attained. I asked all participants if they had ever received methadone treatment (the only medication for drug dependence available in the country) previously. None of them had a history of methadone treatment.

At baseline, I invited 600 people who inject drugs (280 for the intervention vs. 320 for the control group) to participate in the study, and only two of them refused to do so. At 6-month follow-up, I collected data from 478 participants (232 for the intervention and 246 for

the control group) (Figure 2). A total of 120 people who inject drugs were lost to follow-up (48 for the intervention and 72 for the control group). The reasons for the loss to follow-up were as follows: some of the participants in the intervention group defaulted from the program, while some from the control group could not be later located at the places where they met to use drugs.

Figure 2: Flow diagram of the prospective cohort study



^a PWID: people who inject drugs

2.8 Measurements

2.8.1 Dependent variables

The dependent variables in this study included drug use behavior, having shared injecting needles at the last injection, condom use at last sexual encounter, criminal activities, and health care seeking behavior.

I measured participants' drug use behaviors using questions adapted from the instruments for assessing the health status of the clients at the program's clinics. The health status is assessed for all clients at enrollment and every month during the course of their treatment. The questions I used to assess the drug use behaviours have been used in a previous study among people who use drugs in Tanzania (76). I asked participants (1) whether they had used drugs at least once in the past 30 days, (2) if they had shared injecting needles at the last injection or ever practiced flashblood, and (3) about the types of drugs they had been taking. The types of drugs measured included heroin, other opioids, barbiturates, sedatives, cocaine, stimulants, cannabis, hallucinogens, inhalants, and alcohol. I also measured polysubstance use, defined as the use of more than one type of illicit drug in the past 30 days and lifetime use of various types of drugs.

I also assessed participants' sexual behaviors. I adapted the questions pertinent to these variables from the Tanzania Demographic Health Survey women's and men's questionnaires (97). These included whether they used a condom at the last sexual encounter, whether they had engaged in multiple sexual partnerships, and whether they had engaged in transactional sex. These questions have been used in previous studies conducted among people who use drugs (76) and the general population in Tanzania (98).

I measured participants' criminal activities using questions from the fifth edition of the Addiction Severity Index (95). The Addiction Severity Index is being used for routine health status assessments of the clients in the integrated methadone-assisted treatment program

clinics in Dar es Salaam. Specifically, I asked participants if they had engaged in any activities such as stealing, robbery, or selling stolen goods in the past one month.

I assessed participants' health service utilization patterns. I used modified versions of questions previously used to examine access to health services among people who inject drugs in the US (30). Examples of these questions included, 'When you have a medical problem that needs a doctor's attention, do you regularly see a doctor?', and 'Do you know an affordable place to go for medical care?' I defined 'regularly' to mean almost all the time. I assessed the need to seek care based on the participants' perceptions regarding the seriousness of the medical problem to need doctor's attention. Additionally, I asked participants whether they had fallen ill in the past 30 days and, if so, whether they had sought care following their illnesses.

2.8.2 Covariates

I measured participants' sociodemographic characteristics as covariates. Such items included participant's age, sex, education level, marital status, employment status, and income levels. I extracted all questions about age, sex, education level, marital status, employment, and income from the Addiction Severity Index questionnaire (95). This instrument is used to assess clients' health status prior to and during treatment at the integrated methadone-assisted treatment program clinics.

I assessed participants' age in years and asked them about their gender. The risks of substance use and its consequences and risk behaviors are associated with various factors including age and gender (99, 100). People of various ages engage in illicit drug use. Also both male and female engage in drug use although more males engage in drug use than female. Globally, one in five people who use illicit drugs is a woman (2). Also females face worse outcomes compared to males once they have initiated illicit drug use (101, 102).

I assessed participants' various levels of their education. Education predicts a diagnosis of an infectious disease. Having education level less than high school predicted HIV seroconversion among people who inject drugs (103). The various levels of education which I assessed participants included no formal education, primary education, secondary education, post secondary education, and higher levels of learning. I categorized the education levels into two categories: (1) primary education or lower and (2) secondary education or higher.

I assessed participants' marital status. Being married was associated with a previous diagnosis of STIs among people who inject drugs in Uzbekistan (104). In this study, I asked participants whether they were single, married, re-married, widow, separated, or divorced. I dichotomized marital status into two: married and unmarried.

I assessed whether participants engaged in any economic activity. Having employment was associated with having multiple sexual partners among people who inject drugs in Uzbekistan (104). In this study, I considered participants to be employed if they engaged in any economic activity. I considered them to be unemployed if they did not engage in any economic activity. In addition, I measured participants' sources of income such as from employment, relatives/friends, and illegal sources. I obtained participants' total income by summing income obtained from all sources.

I assessed all the measurements using the same instruments for the intervention and the control group.

2.9 Ethical considerations

This study was approved by the Research Ethics Committee of The University of Tokyo and by the Senate Research and Publications Committee of Muhimbili University of Health and Allied Sciences. Before data collection, I explained the objectives and the procedures of the study to participants. I informed them that their participation would not affect their treatment

at the integrated methadone-assisted treatment program clinics (for participants in the intervention) or have legal implications stemming from their drug use. I obtained verbal informed consent from all participants prior to data collection, all participants who consented to participate in the study, signed the consent forms. Participation was voluntary, and confidentiality was maintained. Participants received 1000 Tanzanian shillings (about 0.63 US \$) for their participation at baseline and at 6-month follow-up.

2.10 Data analysis

I analyzed the data of 578 participants at baseline and 466 at 6-month follow-up. The attrition was mainly due to the loss to follow-up as explained above; the other reason was exclusion of questionnaires with missing data (12 questionnaires). I used both descriptive and regression methods to analyze the data. For the descriptive analyses, I compared the characteristics of the intervention and control groups using chi-squared tests and independent sample t-tests. I assessed the changes in the participants' behaviors from baseline to six months follow-up using Differences-in-difference analysis technique.

I used three different types of analyses to examine the role of the integrated methadone-assisted treatment program on the dependent variables of interest. I assessed the health care seeking behavior dependent variable using the chi-squared test. I used this method because participants who fell ill at baseline were different from those who fell ill at 6-month follow-up. In addition, all participants in the intervention group who fell ill at 6-month follow-up sought care at a health facility. For the dependent variable of the drug use behavior, meanwhile, I used logistic regression analysis because all the participants were using drugs at baseline and variability would only have occurred at follow-up.

Finally, I examined the role of the integrated methadone-assisted treatment program on the remaining dependent variables using generalized estimating equations (GEE). The outcomes included sharing of injecting needle at the last injection, condom use at the last

sexual encounter, and criminal activities. I assessed condom use among sexually active participants only. I used GEE for this purpose because it provides population average effects for correlated data, and the data for the outcome variables had variability at baseline and at follow-up. Statistical significance was set at $p < 0.05$. I used STATA 12 for all analyses.

CHAPTER 3

Results

3.1 Sociodemographic characteristics of participants

Table 1 shows the sociodemographic characteristics of all participants. The mean age of all participants was 34.6 years (standard deviation [SD] 5.7). Approximately 95% of them were men. Of all participants, 12.1% were married and only 19.2% had education levels higher than primary education. In addition, 70.6% of all participants reported being employed at the time of survey.

Table 1: Sociodemographic characteristics of participants

Variable	Total (n = 578) n (%)
Age mean (SD ^a)	34.6 (5.7)
Sex	
Male	548 (94.8)
Female	30 (5.2)
Marital status	
Married	70 (12.1)
Unmarried	508 (87.9)
Educational level	
Primary or lower	467 (80.8)
Higher than primary	111 (19.2)
Employment	
Yes	408 (70.6)
No	170 (29.4)

^a SD: standard deviation

3.2 Drug use characteristics of participants

Table 2 shows the drug use characteristics of all participants. The mean lifetime drug use duration was 10.3 (SD 5.9) years. Heroin was the lifetime primary choice substance of use for almost all participants (99.1%). Cannabis was the most frequent lifetime secondary choice substance of use (54.3%), followed by cocaine (9.9%). About 27% of participants reported not to have a lifetime secondary substance of use—they reported to use only one type of a substance in their lifetimes. Other drugs used were opioids/analgesics, barbiturates, hypnotics, hallucinogens, inhalants, and alcohol (results not shown). About 56% of participants reported polysubstance use in the past 30 days.

Table 2: Drug use characteristics of participants

Variable	Total (n = 578) n (%)
Lifetime use of drugs in years, mean (SD ^a)	10.3 (5.9)
Lifetime primary substance of use	
Heroin	573 (99.1)
Cannabis	3 (0.5)
Alcohol	2 (0.4)
Lifetime secondary substance of use	
Cannabis	314 (54.3)
Cocaine	57 (9.9)
Alcohol	24 (4.2)
Others ^b	25 (4.3)
None identified	158 (27.3)
Polysubstance use in the past 30 days	
Yes	323 (55.9)
No	255 (44.1)

^a SD: standard deviation

^b Other drugs: heroin, other opioids, sedatives, or stimulants

3.3 Injecting and sexual behaviors of participants

Table 3 shows injecting and sexual behaviors of all participants. Of them, 14.2% reported to have shared a needle at the last injection. Of all participants who were sexually active in the past six months, 10.6% had anal sex, 37.5% had multiple sexual partners but only 17.4% of them had used condom at the last sexual encounter.

Table 3: Injecting and sexual behaviors of participants

Variable	Total (n = 578) n (%)
Sharing needle at the last injection	
Yes	82 (14.2)
No	496 (85.8)
Ever practiced flashblood	
Yes	90 (15.6)
No	488 (84.4)
Ever had transactional sex	
Yes	39 (6.8)
No	539 (93.2)
Anal sex in the past 6 months ^a	
Yes	58 (10.6)
No	489 (89.4)
Multiple sexual partners ^a	
Yes	205 (37.5)
No	342 (62.5)
Condom use at last sex ^a	
Yes	95 (17.4)
No	452 (82.6)
Polysubstance use in the past 30 days	
Yes	323 (55.9)
No	255 (44.1)

^a Among sexually active participants, total n = 547

3.4 Changes in drug use, condom use, and criminal behaviors in the intervention and control groups

Table 4 shows the changes in the dependent variables six months following the intervention. The reduction in drug use behavior was higher in the intervention group compared with that observed in the control group (Differences-in-difference coef: -0.798, $p < 0.001$). Also, the reduction in sharing of injecting needles was higher in the intervention group compared with that observed in the control group (Differences-in-difference coef: -0.165, $p < 0.001$). The increase in condom use, meanwhile, was not different between the two groups (Differences-in-difference coef: -0.008, $p = 0.872$). The decrease in criminal activities, however, was higher in the intervention group compared with that observed in the control group (Differences-in-difference coef: -0.642, $p < 0.001$).

Table 4: Changes in drug use, condom use, and criminal activities among participants

Variable	Total n (%)	Intervention group n (%)	Control group n (%)	Differences- in-difference Coef.	p value
Drug use				-0.798	<0.001
Baseline ^a	n=578	n=273	n=305		
Yes	578 (100)	273 (100)	305 (100)		
No	0 (0)	0 (0)	0 (0)		
Month 6 ^b	n=466	n=228	n=238		
Yes	282 (60.5)	45 (19.7)	237 (99.6)		
No	184 (39.5)	183 (80.3)	1 (0.4)		
Sharing needle at the last injection				-0.165	<0.001
Baseline ^a	n=578	n=273	n=305		
Yes	82 (14.2)	48 (17.6)	34 (11.2)		
No	496 (85.8)	225 (82.4)	271 (88.8)		
Month 6 ^b	n=466	n=228	n=238		
Yes	26 (5.6)	1 (0.4)	25 (10.5)		
No	440 (94.4)	227 (99.6)	213 (89.5)		
Condom use at last sexual encounter				-0.008	0.872
Baseline ^a	n=547	n=249	n=298		
Yes	95 (17.4)	79 (31.7)	16 (5.4)		
No	452 (82.6)	170 (68.3)	282 (94.6)		
Month 6 ^a	n=394	n=167	n=227		
Yes	93 (23.6)	64 (38.3)	29 (12.8)		
No	301 (76.4)	103 (61.7)	198 (87.2)		
Criminal activity				-0.642	<0.001
Baseline ^a	n=578	n=273	n=305		
Yes	507 (87.7)	229 (83.9)	278 (91.2)		
No	71 (12.3)	44 (16.1)	27 (8.8)		
Month 6 ^a	n=466	n=228	n=238		
Yes	243 (52.2)	38 (16.7)	205 (86.1)		
No	223 (47.8)	190 (83.3)	33 (13.9)		

^a Chi-squared test

^b Fisher's exact test

3.5 The role of the integrated methadone-assisted treatment program in improving health care seeking behavior among participants

The change was higher among the participants in the intervention group in the behavior of visiting a health facility when in need of medical care compared with that observed among participants in the control group six months following the intervention (21.4% vs. 0.1%) (Table 5).

Table 5: Health service-related characteristics of the participants

Variable	Total n (%)	Intervention group n (%)	Control group n (%)	p value
Illness within the past 30 days ^a				
Baseline	n=578	n=273	n=305	
Yes	142 (24.6)	28 (10.3)	114 (37.4)	<0.001
No	436 (75.4)	245 (89.7)	191 (62.6)	
Month 6	n=466	n=228	n=238	
Yes	150 (32.2)	33 (14.5)	117 (49.2)	<0.001
No	316 (67.8)	195 (85.5)	121 (50.8)	
Used a health facility when needed medical care				
Baseline ^a	n=142	n=28	n=114	
Yes	94 (66.2)	22 (78.6)	72 (63.2)	0.122
No	48 (33.8)	6 (21.4)	42 (36.8)	
Month 6 ^b	n=150	n=33	n=117	
Yes	107 (71.3)	33 (100.0)	74 (63.3)	<0.001
No	43 (28.7)	0 (0.0)	43 (36.7)	
Know where to seek affordable healthcare ^a				
Baseline	n=578	n=273	n=305	
Yes	331 (57.3)	178 (65.2)	153 (50.2)	<0.001
No	247 (42.7)	95 (34.8)	152 (49.8)	
Month 6	n=466	n=228	n=238	
Yes	322 (69.1)	196 (86.0)	126 (52.9)	<0.001
No	144 (30.9)	32 (14.0)	112 (47.1)	

^a Chi-squared test

^b Fisher's exact test

3.6 The role of the integrated methadone-assisted treatment program in reducing drug use among the participants

Table 6 shows the results of logistic regression analysis on the role of the program in reducing drug use behavior at 6-month follow-up. Participants in the intervention group were less likely to use drugs compared with those in the control group (AOR: 0.0006, 95% CI: 0.00006–0.006).

Table 6: Logistic regression: Role of the integrated methadone-assisted treatment program in reducing drug use among participants (n=466, observations at follow-up)

Variable	AOR ^a	95% CI	p-value
Intervention	0.0006	0.00006 – 0.006	<0.001
Age	0.95	0.90 – 1.01	0.087
Gender (Female)	0.34	0.06 – 2.11	0.248
Current marital status (Married)	0.56	0.24 – 1.31	0.181
Education level (Higher education)	0.74	0.35 – 1.57	0.437
Employment status (Employed)	2.94	0.65 – 13.32	0.161

^a AOR: adjusted odds ratio

3.7 Role of the integrated methadone-assisted treatment program in reducing sharing of injecting needles at last injection among participants

Table 7 shows the results of GEE on the role of the program on reducing sharing of injecting needles at six-month follow-up. Participants in the intervention were 98% less likely to share injecting needles compared with those in the control group (Intervention*time, AOR: 0.02, 95% CI: 0.004–0.16). The Intervention*time variable represents the status of the intervention group in comparison with the control group at six-month follow-up.

Table 7: GEE: Role of the integrated methadone-assisted treatment program in reducing sharing of injecting needles among participants (n=932, sum of observations of participants with both baseline and follow-up data)

Variable	AOR ^b	95% CI	p-value
Intervention*time ^a	0.02	0.004 – 0.16	< 0.001
Time	0.89	0.55 – 1.44	0.626
Intervention	1.70	0.94 – 3.10	0.081
Age	1.04	0.99 – 1.08	0.086
Gender (Female)	1.36	0.50 – 3.73	0.547
Current marital status (Married)	0.59	0.27 – 1.32	0.199
Education level (Higher education)	1.18	0.63 – 2.21	0.606
Employment status (Employed)	1.12	0.65 – 1.93	0.690

^a Intervention*time: represents the status of the intervention group in comparison with the control group at six-month follow-up

^b AOR: adjusted odds ratio

3.8 Role of the integrated methadone-assisted treatment program in improving condom use among the participants

Table 8 shows the results of GEE on the role of the program toward improving condom use at six-month follow-up. The use of condom at the last sexual encounter was not different between the intervention and the control group (Intervention*time, AOR: 0.52, 95% CI: 0.27–1.01). Six months following the intervention, condom use improved (Time, AOR: 2.32, 95% CI: 1.35 – 3.99). At baseline, participants in the intervention group were more likely to have used a condom at the last sexual encounter than those in the control group (Intervention, AOR: 7.20, 95% CI: 3.57 – 14.52).

Table 8: GEE: Role of the integrated methadone-assisted treatment program in improving condom use at last sexual encounter among participants (n=758, sum of observations of sexually active participants with both baseline and follow-up data)

Variable	AOR ^b	95% CI	p value
Intervention*time ^a	0.52	0.27 – 1.01	0.054
Time	2.32	1.35 – 3.99	0.002
Intervention	7.20	3.57 – 14.52	< 0.001
Age	1.01	0.97 – 1.05	0.616
Gender (Female)	0.90	0.33 – 2.47	0.837
Current marital status (Married)	0.59	0.34 – 1.04	0.068
Educational level (Higher education)	1.13	0.64 – 1.98	0.671
Employment status (Employed)	1.37	0.81 – 2.32	0.242

^a Intervention*time: represents the status of the intervention group in comparison with the control group at six-month follow-up

^b AOR: adjusted odds ratio

3.9 Role of the integrated methadone-assisted treatment program in reducing criminal activities among participants

Table 9 shows the results of GEE on the role of the program on reducing criminal activities after six months follow-up. Participants in the intervention group were 95% less likely to engage in criminal activities compared with those in the control group (Intervention*time, AOR: 0.05, 95% CI: 0.03–0.10). Participants who had employment were less likely to engage in criminal activities compared with those without employment (AOR: 0.43, 95% CI: 0.26 – 0.71).

Table 9: GEE: Role of the integrated methadone-assisted treatment program in reducing criminal activities among participants (n=932, sum of observations of participants with both baseline and follow-up data)

Variable	AOR ^b	95% CI	p-value
Intervention*time ^a	0.05	0.03 – 0.10	< 0.001
Time	0.83	0.52 – 1.32	0.433
Intervention	0.98	0.55 – 1.74	0.947
Age	1.01	0.98 – 1.05	0.443
Gender (Female)	1.04	0.39 – 2.74	0.943
Current marital status (Married)	0.61	0.35 – 1.05	0.077
Education level (Higher education)	0.70	0.41 – 1.18	0.179
Employment status (Employed)	0.43	0.26 – 0.71	0.001

^a Intervention*time: represents the status of the intervention group in comparison with the control group at six-month follow-up

^b AOR: adjusted odds ratio

CHAPTER 4

Discussion and policy implications

4.1 Discussion

This is the first study to examine the role of the integrated methadone-assisted treatment program on high-risk behaviors among people who inject drugs in Africa. Six months following the intervention, participants in the intervention group were more likely to engage in safer practices compared to those in the control group. Among participants who had fallen ill in the past 30 days, 100% of those who were in the intervention group sought health care from a health facility, compared with 63.3% of those in the control group (Table 5). Also, participants in the intervention group were less likely to use drugs, less likely to share injecting needles at the last injection, and less likely to engage in criminal activities compared with those in the control group (Tables 6,7, and 9).

Participants in the intervention group were less likely to have used drugs compared with those in the control group. This might be due to the pharmacological effects of methadone. Methadone is an opioid medication that mitigates withdrawal symptoms and reduces craving for heroin (4). Also, it can block the heroin from producing euphoric effects (91). In this way, the desire to seek drugs is reduced. In this study, at baseline all participants were using drugs, and almost all mentioned heroin as one of the drugs they consumed. At six months following the intervention, drug use was 79.9% lower among the participants in the intervention compared with those in the control group. Therefore, methadone might have helped participants in the intervention to experience less or no withdrawal symptoms reducing the need to continue using illicit drugs (105). Similar results have been reported where methadone enabled some people who inject drugs to stop using drugs in high-income countries such as the US (53) and Australia (53) and in middle-income countries such as China (59) and Iran (63). Although no empirical data are available, a reduction in drug use has also been reported in Nepal among people who use drugs who received methadone treatment (73).

Participants in the intervention group were less likely to engage in criminal activities compared with those in the control group. This can be explained by reductions in drug use following methadone treatment and psychosocial counseling. Following from less desire and need to seek drugs after methadone treatment, individuals become more stable and able to participate in normal daily activities and in rehabilitation (4, 87). In this study, following the intervention, participants in the intervention group were 95% less likely to engage in criminal activities compared with those in the control group. People who inject drugs engage in criminal activities to obtain money for drugs and injecting equipment (28). Stopping or reducing drug use reduces the circumstances under which an individual might need to engage in criminal activities. Furthermore, psychosocial counseling provided through the program might also have contributed to reducing these unwanted behaviors following stabilization under methadone treatment (87). Reductions in criminal activities have also been observed previously among people who inject drugs who received methadone treatment in high-income countries such as New Zealand (28). Reduction in criminal activities was also reported among people who use drugs enrolled in an opioid substitution therapy program in Afghanistan—a low-income country (68).

Participants in the intervention group were less likely to share injecting needles compared with those in the control group, though equally as likely to use condoms. These results may be explained by the provision of pre- and post-test counseling during screening for infectious diseases. At the integrated methadone-assisted treatment program clinics, enrollees are screened for infectious diseases including HIV, hepatitis B and C, and other STIs (89). Screening is provided alongside counseling on safer injecting and sexual practices. In this study, participants in the intervention group were 98% less likely to share injecting needles compared with those in the control group. Reductions in the behavior of sharing injecting needles might be attributed to experience of such counseling during screening for

infectious diseases. HIV testing and counseling have been previously shown to reduce high-risk injecting and sexual behaviors (35). Further, the low increases in condom use among the participants in the intervention group could be due to their low motivation to improve such behavior. Both information and motivation are, after all, important to effect behavior change (106). These results underscore the point that behavior change takes time and highlights the need to strengthen counseling services and provide them routinely. Low condom use has also been reported among people who inject drugs in methadone treatment in the US (107, 108). No study in low-income countries has reported the effectiveness of opioid substitution therapy on high-risk injecting and sexual behaviors in which we could compare our results with.

All participants in the intervention group accessed health services when they needed them, compared to 63.3% of those in the control group. This might be due to provision of free medical care alongside other services in the integrated methadone-assisted treatment program and to its location on the hospital premises. Free medical care and the location of the clinics eliminated the barriers related to the cost of medical care and transport to health facilities (27, 40). Notably, health care utilization improved when medical care was available at the methadone clinics in previous studies conducted among people who inject drugs in the US (109, 110). In Afghanistan, people who use drugs reported better health status and reduction of mental health burden one year after being in opioid substitution therapy (68).

The importance of such findings notwithstanding, this study has several limitations. First, I used convenience sampling to recruit participants. This method limits the generalizability of the study results. However, they may be used in Tanzania and other countries with people who inject drugs of similar characteristics. Second, research assistants were involved in providing services at the integrated methadone-assisted treatment program clinics and the data were self-reported. This might have contributed to the risk of a social

desirability bias. However, efforts were made to minimize this risk by ensuring participants that their responses would not affect their treatment at the program's clinics (for the intervention group) and by maintaining privacy during the interviews. Third, some participants were lost to follow-up. However, the attrition rates were not very different between the intervention and control groups, 17.1% and 22.6%, respectively. Also, the attrition of the intervention group was lower than the rate observed in a previous study conducted among clients from the methadone-assisted treatment clinic at the Muhimbili National Hospital in Tanzania, which was 33.0% (111). Fourth, the differences in the characteristics between participants in the intervention and control group might have influenced these results. To minimize this risk, I controlled for these differences of the two groups in the regression analyses.

Despite such limitations, the study has distinct strengths. Namely, it used a prospective cohort study design with a control group. This study design allowed me to observe the changes in behaviors of participants over time, comparing those in and outside of the intervention. In addition, this study is important in that it is the first to examine the roles of an integrated methadone-assisted treatment program in Africa and Tanzania in particular.

4.2 Conclusions

This thesis reports the results of a prospective cohort study I conducted among people who inject drugs in Dar es Salaam, Tanzania. I collected data at baseline and six months following the implementation of the intervention—the integrated methadone-assisted treatment program. The data gathered from this study addressed five objectives contained in this thesis. Namely, I first examined whether the integrated methadone-assisted treatment program could reduce the use of drugs among people who inject drugs. Second, I examined the program's impact on sharing of injecting needles. Third, I examine the program's effect on criminal activities. Fourth, I examine the program's role on improving the use of condoms. Finally, I

examine the program's role on improving health care seeking behaviors among people who inject drugs in Dar es Salaam, Tanzania.

The integrated methadone-assisted treatment program improved most of the high-risk behaviors of people who inject drugs in the intervention group at six-month follow-up. They were less likely to use drugs, less likely to share injecting needles at the last injection, and less likely to engage in criminal activities compared to their control group counterparts. In addition, the intervention improved participants' health care seeking behaviors. All people who inject drugs in the intervention group had sought medical care when they needed it in the past 30 days, compared to only 63.3% of those not exposed to the intervention. However, the use of condom was not different between two groups.

4.3 Policy implications and recommendations

The results of this study highlight the need for a scaling up of the integrated methadone-assisted treatment programs in Tanzania and their establishment in countries with a similar problem and context. This program provided an opportunity for people who inject drugs in Dar es Salaam, Tanzania to receive treatment for drug dependence, psychosocial counseling, counseling and screening for infectious diseases, and access to medical care when in need. As a result, its participants reduced their drug use behaviors, reduced sharing of injecting needles, and reduced criminal activities appreciably. The reduction in criminal activities may bring about societal benefits such as environmental safety and reduce the costs incurred from handling people who committed crimes. On the other hand, the intervention did not improve the use of condom. The level of condom use was not different between those who received the intervention and those who did not. Routine counseling on safer behaviors might help to improve condom use. Furthermore, further explanatory qualitative research is needed to better understand motivations for use and non-use of condoms in this population. To further improve this integrated intervention, it is important to beef it up with more counseling

sessions on safer sexual behaviors. Moreover, this challenge must be taken into account when scaling up the integrated methadone-assisted treatment programs across Tanzania and elsewhere.

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Appendices

Appendix 1: Map of Tanzania and Dar es Salaam region



Dar es Salaam region



Appendix 2: Research questionnaire for baseline data collection - English version

Efficacy of a combined harm reduction intervention to prevent HIV infection among people who inject drugs in Dar es Salaam, Tanzania

Date of assessment..... ID number.....

Age.....yrs Date of birth.....

District..... Street/village.....

Sex 1. ☐ Male 2. ☐ Female

1.	Marital status <i>(Please check where it is correct)</i> :					
	1[<input type="checkbox"/>]	Married	3[<input type="checkbox"/>]	Widow	5[<input type="checkbox"/>]	Divorced
	2[<input type="checkbox"/>]	Re-married	4[<input type="checkbox"/>]	Separated	6[<input type="checkbox"/>]	Single

2.	Number of children	Living with you	Not living with you?
	How many children do you have?		
	How many of them are aged < 18 years?		

3.	Living situation <i>(Please check where it is correct)</i> :	30 days ago	6 months ago
	Spouse and children	1 [<input type="checkbox"/>]	1 [<input type="checkbox"/>]
	Spouse only	2 [<input type="checkbox"/>]	2 [<input type="checkbox"/>]
	Children only	3 [<input type="checkbox"/>]	3 [<input type="checkbox"/>]
	Parents	4 [<input type="checkbox"/>]	4 [<input type="checkbox"/>]
	Other relatives such as aunt etc	5 [<input type="checkbox"/>]	5 [<input type="checkbox"/>]
	Friends	6 [<input type="checkbox"/>]	6 [<input type="checkbox"/>]
	Alone	7 [<input type="checkbox"/>]	7 [<input type="checkbox"/>]
	Prison	8 [<input type="checkbox"/>]	8 [<input type="checkbox"/>]
	No stable living situation	9 [<input type="checkbox"/>]	9 [<input type="checkbox"/>]
	Other (specify)	10[<input type="checkbox"/>]	10[<input type="checkbox"/>]

4.	Education status <i>(Please check where it is correct)</i> :			
	0.[<input type="checkbox"/>]	No formal education	4. [<input type="checkbox"/>]	Post secondary school (O-level), no further training
	1. [<input type="checkbox"/>]	Primary school 1-7	4a[<input type="checkbox"/>]	Post secondary school (O-level), attended certificate/vocational courses. (Specify.....)
	2. [<input type="checkbox"/>]	Secondary school (O-level) 9-12	5. [<input type="checkbox"/>]	Higher learning (Advance Diploma, Bachelor)
	3. [<input type="checkbox"/>]	Secondary school (A-level)13-14	6. [<input type="checkbox"/>]	Masters or higher level (Masters or PhD).

5.	Usual (or last) occupation	Specify
6.	How much money did you receive from the following sources in the past 30 days	
a)	Employment	TZS..... ...
b)	Partner, family, friends	TZS.....

c)	Illegal (drug dealing, stealing, selling stolen goods, prostitution etc.	TZS.....
----	--	------------------

7. ALCOHOL/DRUGS		Note: Route of administration (ROA)	
1	Oral (anything swallowed)	4	Non-IV injection (such as IM or “skin popping”)
2	Nasal (or any other sub-cutaneous membrane administration)	5	Intravenous injection (shooting directly into vein)
3	Smoking		

8.	Type of drug	Past 30 days	Lifetime (years)	(ROA)
a)	Alcohol (any use at all)			
b)	Alcohol – intoxication			
c)	Heroin			
d)	Methadone			
e)	Other opioids/Analgesics			
f)	Barbiturates			
g)	Sedatives/hypnotics/tranquilizers(Valium)			
h)	Cocaine			
i)	Amphetamines/stimulants			
j)	Cannabis			
k)	Hallucinogens			
l)	Inhalants (thinner, petrol, glue ets)			
9a)	More than 1 substance (including alcohol)			
b)	Identify primary substance of abuse			
c)	Identify secondary substance of abuse			

Risky injecting behaviors	
10.	Have you injected drugs at least once in the past 30 days? 0. No [] 1. Yes []
11.	Have you ever practiced “flashblood” 0. No [] 1. Yes []
12.	Did you share syringe with others during injecting drugs at the last time? 0. No [] 1. Yes []
13.	Did you share syringe with others during injecting drugs in the past 6 months? 0. No [] 1. Yes []

Risky sexual behaviors	
14.	Which type of sexual intercourse do you engage in?
	1. [] Vaginal sex 2. [] Anal sex 3. [] Oral sex
15.	How many sexual partners did you have in the last six months?
	1. [] One 2. [] Two to five 3. [] Six to ten
	4. [] Eleven to fifteen 5. [] More than fifteen
16.	Did you/your partner use condom at the last sexual intercourse?
	0. [] No 1. [] Yes
17.	In the past six months, how often did you use condom during vaginal sex?
	0. [] I didn’t engage into sex in the past six months 1. [] Always
	2. [] Often 3. [] Sometimes 4. [] Never
18.	In the past six months, how often did you use condom during anal sex?
	0. [] I didn’t engage into sex in the past six months 1.[] Always
	2. [] Often 3. [] Sometimes 4. [] Never
19.	Have you had sex with a sex worker in the past six months?
	0. [] No 1. [] Yes
20.	Have you engaged in commercial sex work in the past six months?

	0. <input type="checkbox"/> No	1. <input type="checkbox"/> Yes	
21.	With how many clients per day do you usually engage with?		Specify
22.	Have you ever had sexual intercourse with someone because he/she provided you with or you expected that he/she would provide you with something such as money, drugs, food, cosmetics, transportation etc?		
	0. <input type="checkbox"/> No	1. <input type="checkbox"/> Yes	

Healthcare			
23.	When you have a medical problem that needs doctor's attention, do you regularly see a doctor? 0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes		
24.	If no, why don't you see a doctor regularly		
	<input type="checkbox"/> No finance	<input type="checkbox"/> Mistrust/fear	<input type="checkbox"/> No transportation
	<input type="checkbox"/> No time	<input type="checkbox"/> Other(Specify).....	
25.	Did you experience any medical problem in the past 30 days?		Specify..... ..
26.	Where did you obtain medical care?		
	0. <input type="checkbox"/> Private clinic	1. <input type="checkbox"/> Hospital outpatient clinic	2. <input type="checkbox"/> Hospital emergency room
	3. <input type="checkbox"/> Community/government clinic	4. <input type="checkbox"/> Other (Specify).....	
27.	Do you know an affordable place to go for medical care?	0. <input type="checkbox"/> No	1. <input type="checkbox"/> Yes
28.	Have you ever been tested for hepatitis B/C?	0. <input type="checkbox"/> No	1. <input type="checkbox"/> Yes
29.	If yes, what was the result?		
	0. <input type="checkbox"/> Never tested	1. <input type="checkbox"/> Hep negative	2. <input type="checkbox"/> Hep positive
			3. <input type="checkbox"/> Don't know
30.	Have you ever been tested for HIV?	0. <input type="checkbox"/> No	1. <input type="checkbox"/> Yes
31.	If yes, what was the result?		
	0. <input type="checkbox"/> Never tested	1. <input type="checkbox"/> HIV negative	2. <input type="checkbox"/> HIV positive
			3. <input type="checkbox"/> Don't know
32.	Have you ever been tested for tuberculosis?	0. <input type="checkbox"/> No	1. <input type="checkbox"/> Yes
33.	If yes, what was the result?		
	0. <input type="checkbox"/> Never tested	1. <input type="checkbox"/> TB negative	2. <input type="checkbox"/> TB positive
			3. <input type="checkbox"/> Don't know
34.	Have you ever been screened for STIs?	0. <input type="checkbox"/> No	1. <input type="checkbox"/> Yes
35.	If yes, what was the result?		
	0. <input type="checkbox"/> Never tested	1. <input type="checkbox"/> Hep negative	2. <input type="checkbox"/> Hep positive
			3. <input type="checkbox"/> Don't know

Legal status			
36.	How many times have you committed the following?		
	Crime	In the past 30 days	In the past 6 months
a)	Shoplifting/vandalism	<input type="checkbox"/>	<input type="checkbox"/>
b)	Drug charges	<input type="checkbox"/>	<input type="checkbox"/>
c)	Forgery	<input type="checkbox"/>	<input type="checkbox"/>
d)	Weapons offense	<input type="checkbox"/>	<input type="checkbox"/>
e)	Burglary/Larceny/Breaking & Entering	<input type="checkbox"/>	<input type="checkbox"/>
f)	Robbery	<input type="checkbox"/>	<input type="checkbox"/>
g)	Assault	<input type="checkbox"/>	<input type="checkbox"/>
h)	Rape	<input type="checkbox"/>	<input type="checkbox"/>

i)	Homicide/Manslaughter	[]	[]
j)	Prostitution	[]	[]
k)	Other (Specify)	[]	[]
37.	How many times have been imprisoned in your whole life?	[]	

Appendix 3: Research questionnaire for baseline data collection - Swahili version

Matokeo ya matumizi ya mjumuisho wa njia za kupunguza madhara yatokanayo na matumizi ya madawa ya kulevya katika kuzuia maambukizi ya VVU miongoni mwa wajidunga waishio Dar es Salaam, Tanzania.

Tarehe ya kujaza dodoso..... ID namba.....

Umri.....miaka Tarehe ya kuzaliwa.....

Wilaya..... Mtaa/kijiji.....

Jinsia 1. ☐ Mme 2. ☐ Mke

1.	Hali ya ndoa (tafadhali weka tiki jibu sahihi):					
	1[]	Umeoa/olewa	3[]	Mjane/mgane	5[]	Achika
	2[]	Umeoa/olewa tena	4[]	Tengana	6[]	Hajawahi kuoa/olewa

2.	Idadi ya watoto	Wanaoishi nawe	Wanaoishi nje ya nyumbani
	Je, una watoto wangapi?		
	Je, wangapi kati ya watoto wako wana miaka chini ya 18?		

3.	Mpangilio wa kawaida wa kuishi : (tafadhali weka tiki jibu sahihi)	siku 30 zilizo pita	miezi 6 iliyopita
	Na mwenzi na watoto	1 []	1 []
	Na mwenzi tu	2 []	2 []
	Na watoto pekee	3 []	3 []
	Na wazazi	4 []	4 []
	Ndugu wengine kama shangazi nk.	5 []	5 []
	Na marafiki	6 []	6 []
	Pekee	7 []	7 []
	Jela	8 []	8 []
	Hakuna mpangilio thabiti	9 []	9 []
	Nyingine (taja):	10[]	10[]

4.	Elimu uliyomaliza (Tafahali weka tiki jibu sahihi)			
	0.[]	Hakuna elimu	4. []	Baada ya miaka 12, hakuna elimu ya juu
	1. []	Msingi miaka 1-7	4a[]	Baada ya miaka 12, alienda kozi ya kitaaluma
	2. []	Sekondari ya chini ya miaka 9-12	5. []	Hatua ya kwanza ya elimu ya juu(Advance Diploma, Bachelor)
	3. []	Sekondari ya juu miaka 13-14	6. []	Hatua ya pili ya elimu ya juu (Masters au PhD).

5.	Ajira ya kawaida (au ya mwisho)?	Taja
6.	Ni kiasi gani cha pesa ulizopata kutoka kwa vyanzo vifuatavyo katika siku 30 zilizopita?	
a)	Ajira	TZS.....

b)	Mwenza, familia au marafiki	TZS.....
c)	Njia za haramu (drug dealing, stealing, selling stolen goods, prostitution etc.	TZS.....

7. Pombe/Dawa, Angalizo: Njia za Utumiaji (ROA) Aina:			
1	Mdomoni (chochote kinachomezwa)	4	Non-IV injection (such as IM or “skin popping”)
2	Puani (or any other sub-cutaneous membrane administration)	5	Kujidunga kwenye mshipa (kudunga moja kwa moja kwenye mshipa).
3	Kuvuta		

8.	Dawa inayotumika	Siku 30 zilizopita	Maishani (miaka)	Njia ya utumiaji(ROA)
a)	Pombe (kwa matumizi yoyote katika siku 30 zilizopita)			
b)	Pombe – kiwango cha kulewa sana hadi kupata madhara			
c)	Heroini/Unga			
d)	Methadone			
e)	Other opioids/dawa za maumivu			
f)	Barbiturates			
g)	Dawa za usingizi kama Valium			
h)	Kokeni			
i)	Amphetamines/stimulants			
j)	Bangi			
k)	Hallucinogens			
l)	Viyeyusho (<i>thinner, petroli, gundi nk</i>)			
9a).	Zaidi ya dawa moja (pamoja na pombe)			
b)	Tambua dawa kuu inayotumika			
c)	Tambua dawa ya pili kuu inayotumika			

Tabia hatarishi ya matumizi ya dawa	
10.	Je, mteja kajidunga dawa angalau mara moja katika siku 30 zilizopita? 0. Hapana [] 1. Ndio []
11.	Je, umeshawahi kutumia “flashblood”? 0. Hapana [] 1. Ndio []
12.	Je, mteja alishirikiana sindano/bomba la sindano na watumiaji wengine katika kujidunga mara ya mwisho? 0. Hapana [] 1. Ndio []
13.	Je, mteja alishirikiana sindano/bomba la sindano na watumiaji wengine katika kujidunga miezi 6 iliyopita? 0. Hapana [] 1. Ndio []

Tabia hatarishi za kingono			
14.	Utajielezeaje kuhusu unafanya jimai/ngono ya aina gani?		
	0. [] JIMAI/NGONO YA UKENI	1. [] JIMAI/NGONO YA MKUNDU	2. [] JIMAI/NGONO YA KINYWA
15.	Umeshafanya jimai/ngono na wenzi wangapi katika miezi sita iliyopita?		
	1. [] MWENZI	2. [] WENZI 2 HADI 5	3. [] WENZI 6 HADI 10
	4. [] WENZI 11 HADI 15	3. [] ZAIDI YA WENZI 15	
16.	Wewe au mwenza wako alitumia kondomu wakati wa kufanya ngono mara ya mwisho?		
	0. [] Hapana	1. [] Ndio	
17.	Katika miezi sita, ni kwa kiasi gani umetumia kondomu wakati unafanya jimai/ngono ya ukeni?		

	0. [] Sijafanya jimai/ngono ya ukeni kwa miezi sita iliyopita		1. [] Wakati wote
	2. [] Wakati mwingi	3. [] Wakati mwingine	4. [] Hakuna wakati
18.	Katika miezi sita, ni kwa kiasi gani umetumia kondomu wakati unafanya jimai/ngono ya mkundu		
	0. [] Sijafanya jimai/ngono ya mkundu kwa miezi sita iliyopita		1. [] Wakati wote
	2. []Wakati mwingi	3. [] Wakati mwingine	4. [] Hakuna wakati
19.	Katika miezi SITA iliyopita, uliwahi kufanya NGONO na changudoa?		
	0. [] Hapana	1. [] Ndiyo	
20.	Katika miezi SITA iliyopita, uliwahi kujihusisha na biashara ya NGONO?		
	0. [] Hapana	1. [] Ndiyo	
21.	Je, ni wateja wangapi uliwahudumia kwa NGONO kwa siku		Elezea
22.	Je ulishawahi kushiriki NGONO na mtu kwa kuwa alikupatia kitu ama ulitarajia angekupatia vitu kam fedha, madawa, vipodozi, chakula, ama usafiri?		
	0. [] Hapana	1. [] Ndiyo	

Huduma ya afya				
23.	Ukiwa na tatizo la kiafya linalokuhitaji kumuona daktari, huwa unamuona daktari mara kwa mara?			
	0. [] Hapana		1. [] Ndiyo	
24.	Ni kwa nini humuoni daktari mara kwa mara?			
	[] Sina fedha	[] Simuamini/namuogopa	[] Sina usafiri	
	[] Sina muda	[] Nyingine (elezea).....		
25.	Umepata matatizo ya magonjwa ya kimwili kwa kipindi cha siku 30 ziliopita? Taja.....			
26.	Ni wapi ulipopata huduma ya afya?			
	0. [] Hospitali binafsi	1. [] Hospitali inayohudumia wagonjwa wa nje	2. [] Hospitali inayohudumia magonjwa ya dharura	
	3. [] Hospitali/kituo cha afya cha serikali		4. [] Nyingine (elezea).....	
27.	Unajua sehemu ya kwenda kupata huduma ya afya kwa gharama nafuu		0. [] Hapana	1. [] Ndiyo
28.	Je, umeshawahi kupima kubaini kama una maambukizi ya homa ya manjano/homa ya ini (B/C)?		0. [] Hapana	1. [] Ndiyo
29.	Kama ndio, majibu yalikuwa nini kwa kipimo cha homa ya manjano/homa ya ini?			
	0. [] Sikupima	1. [] Hasi (sijaambukizwa)	2. [] Chanya (nimeambukizwa)	3. [] Sijui
30.	Je, umekwisha wahi kupima kubaini kama una maambukizi ya VVU?		0. [] Hapana	1. [] Ndiyo
31.	Kama ndio majibu yalikuwa nin kwa kipimo cha VVU?			
	0. [] Sikupima	1. [] Hasi (sijaambukizwa)	2. [] Chanya (nimeambukizwa)	3. [] Sijui
31.	Umeshawahi kupimwa ugonjwa wa KIFUA KIKUU?		0. [] Hapana	1. [] Ndiyo
33.	Kama ni ndiyo, majibu yalikuwaje?			
	0. [] Sijawahi kupima	1. [] Sikuwa na Kifua kikuu	2. [] Nilipatikana na Kifua kikuu	3. [] Sijui

34.	Umeshawahi kupimwa magonjwa ya zinaa?	0. <input type="checkbox"/> Hapana	1. <input type="checkbox"/> Ndiyo
35.	Kama ni ndiyo, majibu yalikuwaje?		
	0. <input type="checkbox"/> Sijawahi kupima	1. <input type="checkbox"/> sikuwa na magonjwa ya zinaa	2. <input type="checkbox"/> Nilipatikana na magonjwa ya zinaa
			3. <input type="checkbox"/> Sijui

Hali ya sheria			
36.	Ni mara ngapi umefanya yafuatayo?		
	Kosa	katika siku 30 zilizopita	Katika miezi 6 iliyopita
a)	Wizi wa dukani	<input type="checkbox"/>	<input type="checkbox"/>
b)	Kosa la jinai linalohudu madawa ya kulevya	<input type="checkbox"/>	<input type="checkbox"/>
c)	Kugushi	<input type="checkbox"/>	<input type="checkbox"/>
d)	Kosa la silaha	<input type="checkbox"/>	<input type="checkbox"/>
e)	Wizi wa kuvunja	<input type="checkbox"/>	<input type="checkbox"/>
f)	Unyang'anyi	<input type="checkbox"/>	<input type="checkbox"/>
g)	Uvamizi	<input type="checkbox"/>	<input type="checkbox"/>
h)	Kubaka	<input type="checkbox"/>	<input type="checkbox"/>
i)	Uuaji/kuua bila kukusudia	<input type="checkbox"/>	<input type="checkbox"/>
j)	Umalaya/Biashara ya ngono	<input type="checkbox"/>	<input type="checkbox"/>
k)	Mengine (Taja)	<input type="checkbox"/>	<input type="checkbox"/>
37.	Ni mara ngapi umefungwa jela katika maisha yako?		<input type="checkbox"/>

Appendix 4: Research questionnaire for follow-up data collection - English version

Efficacy of a combined harm reduction intervention to prevent HIV infection among people who inject drugs in Dar es Salaam, Tanzania

Date of assessment.....

ID number.....

Age.....yrs

Date of birth.....

District.....

Street/village.....

Sex 1. ☐ Male 2. ☐ Female

1.	Marital status (<i>Please check where it is correct</i>):					
	1 <input type="checkbox"/>	Married	3 <input type="checkbox"/>	Widow	5 <input type="checkbox"/>	Divorced
	2 <input type="checkbox"/>	Re-married	4 <input type="checkbox"/>	Separated	6 <input type="checkbox"/>	Single

2.	Number of children	Living with you	Not living with you?
	How many children do you have?		
	How many of them are aged < 18 years?		

3.	Living situation (<i>Please check where it is correct</i>):	30 days ago	3 months ago
	Spouse and children	1 <input type="checkbox"/>	1 <input type="checkbox"/>
	Spouse only	2 <input type="checkbox"/>	2 <input type="checkbox"/>
	Children only	3 <input type="checkbox"/>	3 <input type="checkbox"/>
	Parents	4 <input type="checkbox"/>	4 <input type="checkbox"/>
	Other relatives such as aunt etc	5 <input type="checkbox"/>	5 <input type="checkbox"/>
	Friends	6 <input type="checkbox"/>	6 <input type="checkbox"/>
	Alone	7 <input type="checkbox"/>	7 <input type="checkbox"/>
	Prison	8 <input type="checkbox"/>	8 <input type="checkbox"/>
	No stable living situation	9 <input type="checkbox"/>	9 <input type="checkbox"/>
	Other (specify).....	10 <input type="checkbox"/>	10 <input type="checkbox"/>

4.	Education status (<i>Please check where it is correct</i>):			
	0. <input type="checkbox"/>	No formal education	4. <input type="checkbox"/>	Post secondary school (O-level), no further training
	1. <input type="checkbox"/>	Primary school 1-7	4a <input type="checkbox"/>	Post secondary school (O-level), attended certificate/vocational courses. (Specify.....)
	2. <input type="checkbox"/>	Secondary school (O-level) 9-12	5. <input type="checkbox"/>	Higher learning (Advance Diploma, Bachelor)
	3. <input type="checkbox"/>	Secondary school (A-level) 13-14	6. <input type="checkbox"/>	Masters or higher level (Masters or PhD).

5.	Usual (or last) occupation	Specify.....
6.	How much money did you receive from the following sources in the past 30 days	
a)	Employment	TZS..... ...
b)	Partner, family, friends	TZS.....

c)	Illegal (drug dealing, stealing, selling stolen goods, prostitution etc.	TZS.....
----	--	------------------

7. ALCOHOL/DRUGS		Note: Route of administration (ROA)	
1	Oral (anything swallowed)	4	Non-IV injection (such as IM or “skin popping”)
2	Nasal (or any other sub-cutaneous membrane administration)	5	Intravenous injection (shooting directly into vein)
3	Smoking		

8.	Type of drug	Past 30 days	Past 3 months	(ROA)
a)	Alcohol (any use at all)			
b)	Alcohol – intoxication			
c)	Heroin			
d)	Methadone			
e)	Other opioids/Analgesics			
f)	Barbiturates			
g)	Sedatives/hypnotics/tranquilizers(Valium)			
h)	Cocaine			
i)	Amphetamines/stimulants			
j)	Cannabis			
k)	Hallucinogens			
l)	Inhalants (thinner, petrol, glue ets)			
9a)	More than 1 substance (including alcohol)			
b)	Identify primary substance of abuse			
c)	Identify secondary substance of abuse			

Risky injecting behaviors	
10.	Have you injected drugs at least once in the past 30 days? 0. No [] 1. Yes []
11.	Have you ever practiced “flashblood” 0. No [] 1. Yes []
12.	Did you share syringe with others during injecting drugs at the last time? 0. No [] 1. Yes []
13.	Did you share syringe with others during injecting drugs in the past 3 months? 0. No [] 1. Yes []

Risky sexual behaviors	
14.	Which type of sexual intercourse do you engage in?
	0. [] Vaginal sex 1. [] Anal sex 2. [] Oral sex
15.	How many sexual partners did you have in the past 3 months?
	0. [] One 1. [] Two to five 2. [] Six to ten
	3. [] Eleven to fifteen 4. [] More than fifteen
16.	Did you/your partner use condom at the last sexual intercourse?
	0. [] No 1. [] Yes
17.	In the past 3 months, how often did you use condom during vaginal sex?
	0. [] I didn’t engage into sex in the past six months 1. [] Always
	2. [] Often 3. [] Sometimes 4. [] Never
18.	In the past 3 months, how often did you use condom during anal sex?
	0. [] I didn’t engage into sex in the past six months 1. [] Always
	2. [] Often 3. [] Sometimes 4. [] Never
19.	Have you had sex with a sex worker in the past 3 months?
	0. [] No 1. [] Yes

20.	Have you engaged in commercial sex work in the past 3 months?		
	0. <input type="checkbox"/> No	1. <input type="checkbox"/> Yes	
21.	With how many clients per day do you usually engage with?		Specify
22.	Have you ever had sexual intercourse with someone because he/she provided you with or you expected that he/she would provide you with something such as money, drugs, food, cosmetics, transportation etc?		
	0. <input type="checkbox"/> No	2. <input type="checkbox"/> Yes	

Healthcare			
23.	When you have a medical problem that needs doctor's attention, do you regularly see a doctor? 0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes		
24.	If no, why don't you see a doctor regularly		
	<input type="checkbox"/> No finance	<input type="checkbox"/> Mistrust/fear	<input type="checkbox"/> No transportation
	<input type="checkbox"/> No time	<input type="checkbox"/> Other(Specify).....	
25.	Did you experience any medical problem in the past 30 days?		Specify.....
26.	Where did you obtain medical care?		
	0. <input type="checkbox"/> Private clinic	1. <input type="checkbox"/> Hospital outpatient clinic	2. <input type="checkbox"/> Hospital emergency room
	3. <input type="checkbox"/> Community/government clinic	4. <input type="checkbox"/> Other (Specify).....	
27.	Do you know an affordable place to go for medical care?		0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes

Legal status			
28.	How many times have you committed the following?		
	Crime	In the past 30 days	In the past 3 months
a)	Shoplifting/vandalism	<input type="checkbox"/>	<input type="checkbox"/>
b)	Drug charges	<input type="checkbox"/>	<input type="checkbox"/>
c)	Forgery	<input type="checkbox"/>	<input type="checkbox"/>
d)	Weapons offense	<input type="checkbox"/>	<input type="checkbox"/>
e)	Burglary/Larceny/Breaking & Entering	<input type="checkbox"/>	<input type="checkbox"/>
f)	Robbery	<input type="checkbox"/>	<input type="checkbox"/>
g)	Assault	<input type="checkbox"/>	<input type="checkbox"/>
h)	Rape	<input type="checkbox"/>	<input type="checkbox"/>
i)	Homicide/Manslaughter	<input type="checkbox"/>	<input type="checkbox"/>
j)	Prostitution	<input type="checkbox"/>	<input type="checkbox"/>
k)	Other (Specify)	<input type="checkbox"/>	<input type="checkbox"/>
29.	How many times have been imprisoned in the past 3 months?		<input type="checkbox"/>

Appendix 5: Research questionnaire for follow-up data collection - Swahili version

Matokeo ya matumizi ya mjumuisho wa njia za kupunguza madhara yatokanayo na matumizi ya madawa ya kulevya katika kuzuia maambukizi ya VVU miongoni mwa wajidunga waishio Dar es Salaam, Tanzania

Tarehe ya kujaza dodoso..... ID namba.....

Umri.....miaka Tarehe ya kuzaliwa.....

Wilaya..... Mtaa/kijiji.....

Jinsia 1. ☐ Mme 2. ☐ Mke

1.	Hali ya ndoa (tafadhali weka tiki jibu sahihi):					
	1[]	Umeoa/olewa	3[]	Mjane/mgane	5[]	Achika
	2[]	Umeoa/olewa tena	4[]	Tengana	6[]	Hajawahi kuoa/olewa

2.	Idadi ya watoto	Wanaoishi nawe	Wanaoishi nje ya nyumbani
	Je, una watoto wangapi?		
	Je, wangapi kati ya watoto wako wana miaka chini ya 18?		

3.	Mpangilio wa kawaida wa kuishi : (tafadhali weka tiki jibu sahihi)	siku 30 zilizo pita	miezi 3 iliyopita
	Na mwenzi na watoto	1 []	1 []
	Na mwenzi tu	2 []	2 []
	Na watoto pekee	3 []	3 []
	Na wazazi	4 []	4 []
	Ndugu wengine kama shangazi nk.	5 []	5 []
	Na marafiki	6 []	6 []
	Pekee	7 []	7 []
	Jela	8 []	8 []
	Hakuna mpangilio thabiti	9 []	9 []
	Nyingine (taja):	10[]	10[]

4.	Elimu uliyomaliza (Tafahali weka tiki jibu sahihi)			
	0.[]	Hakuna elimu	4. []	Baada ya miaka 12, hakuna elimu ya juu
	1. []	Msingi miaka 1-7	4a[]	Baada ya miaka 12, alienda kozi ya kitaaluma
	2. []	Sekondari ya chini ya miaka 9-12	5. []	Hatua ya kwanza ya elimu ya juu(Advance Diploma, Bachelor)
	3. []	Sekondari ya juu miaka 13-14	6. []	Hatua ya pili ya elimu ya juu (Masters au PhD).

5.	Ajira ya kawaida (au ya mwisho)?	Taja
----	----------------------------------	------

6.	Ni kiasi gani cha pesa ulizopata kutoka kwa vyanzo vifuatavyo katika siku 30 zilizopita?	
a)	Ajira	TZS.....
b)	Mwenza, familia au marafiki	TZS.....
c)	Njia za haramu (drug dealing, stealing, selling stolen goods, prostitution etc.	TZS.....

7. Pombe/Dawa, Angalizo: Njia za Utumiaji (ROA) Aina:			
1	Mdomoni (chochote kinachomezwa)	4	Non-IV injection (such as IM or “skin popping”)
2	Puani (or any other sub-cutaneous membrane administration)	5	Kujidunga kwenye mshipa (kudunga mwa kwa moja kwenye mshipa).
3	Kuvuta		

8.	Dawa inayotumika	Siku 30 zilizopita	Miezi 3 iliyopita	Njia ya utumiaji(ROA)
a)	Pombe (kwa matumizi yoyote katika siku 30 zilizopita)			
b)	Pombe – kiwango cha kulewa sana hadi kupata madhara			
c)	Heroini/Unga			
d)	Methadone			
e)	Other opioids/dawa za maumivu			
f)	Barbiturates			
g)	Dawa za usingizi kama Valium			
h)	Kokeni			
i)	Amphetamines/stimulants			
j)	Bangi			
k)	Hallucinogens			
l)	Viyeyusho (thinner, petroli, gundi nk)			
9a).	Zaidi ya dawa moja (pamoja na pombe)			
b)	Tambua dawa kuu inayotumika			
c)	Tambua dawa ya pili kuu inayotumika			

Tabia hatarishi ya matumizi ya dawa	
10.	Je, mteja kajidunga dawa angalau mara moja katika siku 30 zilizopita? 0. Hapana [] 1. Ndio []
11.	Je, umeshawahi kutumia “flashblood”? 0. Hapana [] 1. Ndio []
12.	Je, mteja alishirikiana sindano/bomba la sindano na watumiaji wengine katika kujidunga mara ya mwisho? 0. Hapana [] 1. Ndio []
13.	Je, mteja alishirikiana sindano/bomba la sindano na watumiaji wengine katika kujidunga miezi 3 iliyopita? 0. Hapana [] 1. Ndio []

Tabia hatarishi za kingono			
14.	Utajielezeaje kuhusu unafanya jimai/ngono ya aina gani?		
	1. [] JIMAI/NGONO YA UKENI	0. [] JIMAI/NGONO YA MKUNDU	1. [] JIMAI/NGONO YA KINYWA
15.	Umeshafanya jimai/ngono na wenzi wangapi katika miezi 3 iliyopita?		
	1. [] MWENZI	2. [] WENZI 2 HADI 5	3. [] WENZI 6 HADI 10
	4. [] WENZI 11 HADI 15	2. [] ZAIDI YA WENZI 15	

16.	Wewe au mwenza wako alitumia kondomu wakati wa kufanya ngono mara ya mwisho?		
	0. <input type="checkbox"/> Hapana	1. <input type="checkbox"/> Ndio	
17.	Katika miezi 3 iliyopita, ni kwa kiasi gani umetumia kondomu wakati unafanya jimai/ngono ya ukeni?		
	0. <input type="checkbox"/> Sijafanya jimai/ngono ya ukeni kwa miezi 3 iliyopita	1. <input type="checkbox"/> Wakati wote	
	2. <input type="checkbox"/> Wakati mwingi	3. <input type="checkbox"/> Wakati mwingine	4. <input type="checkbox"/> Hakuna wakati
18.	Katika miezi 3, ni kwa kiasi gani umetumia kondomu wakati unafanya jimai/ngono ya mkundu		
	0. <input type="checkbox"/> Sijafanya jimai/ngono ya mkundu kwa miezi 3 iliyopita	1. <input type="checkbox"/> Wakati wote	
	2. <input type="checkbox"/> Wakati mwingi	3. <input type="checkbox"/> Wakati mwingine	4. <input type="checkbox"/> Hakuna wakati
19.	Katika miezi 3 iliyopita, uliwahi kufanya NGONO na changudoa?		
	0. <input type="checkbox"/> Hapana	1. <input type="checkbox"/> Ndiyo	
20.	Katika miezi 3 iliyopita, uliwahi kujihusisha na biashara ya NGONO?		
	0. <input type="checkbox"/> Hapana	1. <input type="checkbox"/> Ndiyo	
21.	Je, ni wateja wangapi uliwahudumia kwa NGONO kwa siku	Elezea	
22.	Je ulishawahi kushiriki NGONO na mtu kwa kuwa alikupatia kitu ama ulitarajia angekupatia vitu kam fedha, madawa, vipodozi, chakula, ama usafiri?		
	0. <input type="checkbox"/> Hapana	1. <input type="checkbox"/> Ndiyo	

Huduma ya afya			
23.	Ukiwa na tatizo la kiafya linalokuhitaji kumuona daktari, huwa unamuona daktari mara kwa mara?		
	0. <input type="checkbox"/> Hapana	1. <input type="checkbox"/> Ndiyo	
24.	Ni kwa nini humuoni daktari mara kwa mara?		
	<input type="checkbox"/> Sina fedha	<input type="checkbox"/> Simuamini/namuogopa	<input type="checkbox"/> Sina usafiri
	<input type="checkbox"/> Sina muda	<input type="checkbox"/> Nyingine (elezea).....	
25.	Umepata matatizo ya magonjwa ya kimwili kwa kipindi cha siku 30 ziliopita? Taja.....		
26.	Ni wapi ulipopata huduma ya afya?		
	0. <input type="checkbox"/> Hospitali binafsi	1. <input type="checkbox"/> Hospitali inayohudumia wagonjwa wa nje	2. <input type="checkbox"/> Hospitali inayohudumia magonjwa ya dharura
	3. <input type="checkbox"/> Hospitali/kituo cha afya cha serikali	4. <input type="checkbox"/> Nyingine (elezea).....	
27.	Unajua sehemu ya kwenda kupata huduma ya afya kwa gharama nafuu		0. <input type="checkbox"/> Hapana 1. <input type="checkbox"/> Ndiyo

Hali ya sheria			
28.	Ni mara ngapi umefanya yafuatayo?		
	Kosa	katika siku 30 zilizopita	Katika miezi 3 iliyopita
a)	Wizi wa dukani	<input type="checkbox"/>	<input type="checkbox"/>
b)	Kosa la jinai linalohudu madawa ya kulevya	<input type="checkbox"/>	<input type="checkbox"/>
c)	Kugushi	<input type="checkbox"/>	<input type="checkbox"/>
d)	Kosa la silaha	<input type="checkbox"/>	<input type="checkbox"/>
e)	Wizi wa kuvunja	<input type="checkbox"/>	<input type="checkbox"/>
f)	Unyang'anyi	<input type="checkbox"/>	<input type="checkbox"/>
g)	Uvamizi	<input type="checkbox"/>	<input type="checkbox"/>
h)	Kubaka	<input type="checkbox"/>	<input type="checkbox"/>
i)	Uuaji/kuua bila kukusudia	<input type="checkbox"/>	<input type="checkbox"/>
j)	Umalaya/Biashara ya ngono	<input type="checkbox"/>	<input type="checkbox"/>
k)	Mengine (Taja)	<input type="checkbox"/>	<input type="checkbox"/>
29.	Ni mara ngapi umefungwa jela katika miezi 3 iliyopita?		<input type="checkbox"/>

Appendix 6: Interview guide for pre-test

Participants: Twenty people who inject drugs will be conveniently selected to participate in the interview. For the intervention group, participants will be recruited from three hospitals where MAT clinic exists (Methadone clinic at Muhimbili National Hospital, Mwananyamala MAT clinics and Temeke hospital). For the control group, participants will be found from sites where people who inject drugs meet and chat, and use such drugs together, known as ‘vijiwe’ in Dar es Salaam, Tanzania.

Researcher: We would like you (participants) to participate in the interview for pre-testing the questionnaire of a research titled “Efficacy of a combined harm reduction intervention to prevent HIV infection among people who inject drugs in Dar es Salaam, Tanzania”. We would like you to respond to the questions during the interview. Then we will discuss about the interview later.

Time: Time for the whole process is about forty-five minutes.

Place of interview: Selected location with privacy.

Memo: The interview will not be recorded. The memo taken during the interview will be kept confidential and it will be used to make necessary changes to the questionnaires. The memo will be destroyed on completion of the study.

Questions:

1. Were there any questions you didn’t understand? If yes, which ones?
2. Were there any questions you had difficult in answering? If yes, which ones? Do you have any suggestions on how to make them easier?
3. Were there any questions which made you uncomfortable? If yes, which ones?
4. Do you have any other comments?

Appendix 7: Information sheet for participants - pre-test: English version

Study Title: Efficacy of a combined harm reduction intervention to prevent HIV infection among people who inject drugs in Dar es Salaam, Tanzania

Principal Investigators: Masamine Jimba (Tokyo University), Mlunde Linda (Tokyo University),

Co- Investigator: Jessie Mbwambo (Muhimbili University of Health and Allied Sciences)

Dear Sir/Madam

We humbly request your cooperation for a voluntary participation in the Pre-test of a questionnaire for a research titled above. The objective of this activity is to find out if the questionnaire is understood and well suited for data collection. In this activity, we would like you to respond to the questions about your injecting, sexual, health seeking behavior, your history of legal status, and your household characteristics.

We do not ask your name in this interview. So, your identity will not be disclosed. Only the code numbers will be used in the questionnaire. All the information collected during the Pre-test will remain confidential. Your participation in this activity is entirely voluntary. You have the rights to withdraw from the activity at any time without any penalty. The interview will take about 30 minutes. There is no wrong or right answer. Your openness and honest opinions are extremely important. However, you may skip any question you do not want to answer. After the interview, we will discuss the content of the interview for about 15 minutes.

The information we obtain from you will help us structure the questionnaire to be used for data collection of a research named above in a better way. This activity is approved by the Research Ethics Committee of the University of Tokyo and the Muhimbili University of Health and Allied Sciences. The grant is obtained from the Department of Community and Global Health, Graduate School of Medicine, The University of Tokyo.

If you have any questions, please do not hesitate to contact;

Dr. Linda Mlunde and Prof. Masamine Jimba

Department of Community and Global Health, School of International Health, Graduate School of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan Tel: +81-3-5841-3322 E-mail: mjimba@m.u-tokyo.ac.jp

Dr. Jessie Mbwambo

Department of Psychiatry and Mental Health, Muhimbili University of Health and Allied Sciences (MUHAS), P.O.Box 65466, Dar es Salaam, Tanzania. Tel: +255 22 215 0723

Appendix 8: Informed consent form for participants - pre-test: English version

To: The Dean of Graduate School of Medicine and Faculty of Medicine, The University of Tokyo

Study Title: Efficacy of a combined harm reduction intervention to prevent HIV infection among people who inject drugs in Dar es Salaam, Tanzania

Principal Investigators: Masamine Jimba, Mlunde Linda (The University of Tokyo)

Co-Investigator: Jessie Mbwambo (Muhimbili University of Health and Allied Sciences)

I, after reading and having been explained to me the contents of this study, understand what is expected to me as a participant in the pre-test activity of the study.

I understand:

1. The purpose and procedure of the activity
2. The contents of the questionnaire
3. That I will not be placed under any harm or discomfort
4. That I may refuse to answer any question if I don't want to answer
5. That I can withdraw from the study at any time without giving a reason
6. That I can withdraw from the study at any time (during or after study) without any harm
7. That any information I provide will be strictly treated in a confidential manner that I will not be identified in the reporting of the result
8. That information I provide will be totally destroyed after analysis

I, _____ give consent to participate to this activity.

Date: / /

Signature of the person who receives consent: _____ (thumb print)

I, _____, certify that I have explained to the participant the content and procedure of the study according to the attached information page. I have covered all. I will protect the confidentiality of the participants.

Date: / / Name/ Signature of the person who explained consent:

If you have questions, please ask for the below address:

Dr. Linda Mlunde and Prof. Masamine Jimba

Department of Community and Global Health, School of International Health, Graduate School of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan Tel: +81-3-5841-3322

Dr. Jessie Mbwambo

Department of Psychiatry and Mental Health, Muhimbili University of Health and Allied Sciences (MUHAS), P.O.Box 65466, Dar es Salaam, Tanzania. Tel: +255 22 215 0723

Appendix 9: Information sheet and consent form for participants - pre-test: Swahili version (MUHAS IRB recommended)

Nambari ya Usaili

Matokeo ya matumizi ya mjumuisho wa njia za kupunguza madhara yatokanayo na matumizi ya madawa ya kulevya katika kuzuia maambukizi ya VVU miongoni mwa wajidunga waishio Dar es Salaam, Tanzania.

Mtafiti: Linda Mlunde

Anuani: CGH, Chuo Kikuu cha Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japani.

Dhumuni la kufanya huu utafiti

Dhumuni la utafiti huu ni kuangalia matokeo ya matumizi ya mjumuisho wa njia za kupunguza madhara yatokanayo na matumizi ya madawa ya kulevya katika kuzuia maambukizi ya VVU miongoni mwa wajidunga waishio Dar es Salaam, Tanzania.

Habari kuhusu jinsi utafiti utakavyofanywa

Huu utafiti utafanyika kwa watu wanaotumia madawa ya kulevya kwa njia ya kujichoma sindano/kujidunga. Washiriki wataulizwa maswali kuhusu tabia za kutumia madawa ya kulevya, tabia za ngono, upatahi wa huma za afya, na makosa ya jinai.

Utunzaji wa siri

Taarifa zote zitatumizwa kwa siri kwa kutumia namba bila majina ya muhusika.

Hatari zinazoweza kutokea

Hakuna hatari yoyote ambayo unaweza kupata kutokana na kushiriki katika huu utafiti.

Faida zinazoweza kupatikana

Taarifa ambayo utaitoa, itasaidia kuboresha utuaji wa huduma za afya kwa watu wanaotumia madawa ya kulevya.

Kutoendelea kushiriki katika utafiti

Ni hiari kushiriki kwenye utafiti huu na pia unaweza kujitoa wakati wa wote. Hata hivyo kutoshiriki au kujitoa kwenye utafiti hakutakua na adhabu au madhara yoyote.

Kama una tatizo au swali lolote

Kama una tatizo ambalo unafikiri linahusiana na kushiriki katika huu utafiti au una swali lolote kuhusu utafiti huu, tafadhali wasiliana na Linda Mlunde (Namba ya simu ni 0715 889 449)

Haki za mshiriki

Huu utafiti umeruhusiwa na bodi inayohusika na kupitia tafiti mbalimbali ili kulinda usalama wa washiriki ya Chuo Kikuu cha Afya na Tiba Muhimbili. Kama una swali lolote kuhusu haki zako kama mshiriki, tafadhali wasiliana na Dk. Jessie Kazeni Kilonzo Mbwambo, Daktari bingwa (Hospitali ya Taifa ya Muhimbili) na Mtafiti (Chuo Kikuu cha Afya na Tiba Muhimbili), Kitengo cha magonjwa ya afya ya akili, SLP 65466, Dar es Salaam, Tanzania.

Makubaliano ya kushiriki kwa kujitolea

Nimesoma na kuelewa taarifa hiyo hapo juu inayoelezea faida, hatari na jinsi utafiti utakavyofanyika wenye kichwa cha habari “Matokeo ya matumizi ya mjumuisho wa njia za kupunguza madhara yatokanayo na matumizi ya madawa ya kulevya katika kuzuia maambukizi ya VVU miongoni mwa wajidunga waishio Dar es Salaam, Tanzania”. Nimepewa nafasi ya kuuliza swali lolote kuhusu utafiti na kupewa majibu yanayoridhisha. Nakubali kushiriki katika utafiti huu kwa kujitolea.

Sahihi au dole gumba ya mshiriki.....

Sahihi ya mtafiti.....

Tarehe.....

Appendix 10: Information sheet for participants - English version

Study Title: Efficacy of a combined harm reduction intervention to prevent HIV infection among people who inject drugs in Dar es Salaam, Tanzania

Principal Investigators: Masamine Jimba (Tokyo University), Mlunde Linda (Tokyo University),

Co- Investigator: Jessie Mbwambo (Muhimbili University of Health and Allied Sciences)

Dear Sir/Madam,

Thank you very much for your participation in this study. The objective of this study is to examine the efficacy of a combined harm reduction intervention to prevent HIV infection among people who inject drugs in Dar es Salaam, Tanzania

In this study, we would like to interview participants using the structured questionnaire. We will not ask names in this questionnaire. So, the identity of participants will not be disclosed.

If you kindly agree to purpose of this study and participate in the study, you will be interviewed about several things including injecting, sexual, healthcare seeking behaviors, your history of legal status, and your household characteristics. What we learn from you will help to design effective interventions to reduce HIV risks among people who inject drugs and other people who don't use drugs in Tanzania and other countries.

This study is approved by the Research Ethics Committee of the University of Tokyo and Muhimbili University of Health and Allied Sciences of Tanzania. The grant is obtained from the Department of Community and Global Health, Graduate School of Medicine, The University of Tokyo. Your participation for this study is entirely voluntary and you may refuse to answer any question. You may withdraw at any time without any consequences, by informing the researcher with your signature in "Retraction of consent form". Confidentiality is guaranteed and your answer will be part of many other people who inject drugs interviewed so that anonymity is ensured. All the information we obtain will remain strictly confidential and your answer will never be identified. There is no wrong or right answer. Your openness and honest opinions are extremely important. However, you may skip any question you do not want to answer. If you have any questions, please do not hesitate to contact;

Dr. Linda Mlunde and Prof. Masamine Jimba

Department of Community and Global Health, School of International Health, Graduate School of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan Tel: +81-3-5841-3322 E-mail: mjimba@m.u-tokyo.ac.jp

Dr. Jessie Mbwambo

Department of Psychiatry and Mental Health, Muhimbili University of Health and Allied Sciences (MUHAS), P.O.Box 65466, Dar es Salaam, Tanzania. Tel: +255 22 215 0723

Appendix 11: Informed consent form for participants - English version

To: The Dean of Graduate School of Medicine and Faculty of Medicine, The University of Tokyo

Study Title: Efficacy of a combined harm reduction intervention to prevent HIV infection among people who inject drugs in Dar es Salaam, Tanzania

Principal Investigators: Masamine Jimba, Mlunde Linda (The University of Tokyo)

Co-Investigator: Jessie Mbwambo (Muhimbili University of Health and Allied Sciences)

I, after reading and having been explained to me the contents of this study, understand what is expected to me as a participant in the study.

I understand:

1. The purpose and procedure of the study
2. The content of the questionnaire
3. That I will not be placed under any harm or discomfort
4. That I may refuse to answer any question if I don't want to answer
5. That I can withdraw from the study at any time without giving a reason
6. That I can withdraw from the study at any time (during or after study) without any harm
7. That any information I provide will be strictly treated in a confidential manner that I will not be identified in the reporting of the result
8. That information I provide will be totally destroyed after analysis

I, _____ give consent to participate to this study.

Date: / /

Signature of the person who receives consent: _____ (thumb print)

I, _____, certify that I have explained to the participant the content and procedure of the study according to the attached information page. I have covered all. I will protect the confidentiality of the participants.

Date: / / Name/ Signature of the person who explained consent:

If you have questions, please ask for the below address:

Dr. Linda Mlunde and Prof. Masamine Jimba

Department of Community and Global Health, School of International Health, Graduate School of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan Tel: +81-3-5841-3322

Dr. Jessie Mbwambo

Department of Psychiatry and Mental Health, Muhimbili University of Health and Allied Sciences (MUHAS), P.O.Box 65466, Dar es Salaam, Tanzania. Tel: +255 22 215 0723

Appendix 12: Information sheet and consent form for participants: Swahili version (MUHAS IRB recommended)

Nambari ya Usaili

Matokeo ya matumizi ya mjumuisho wa njia za kupunguza madhara yatokanayo na matumizi ya madawa ya kulevya katika kuzuia maambukizi ya VVU miongoni mwa wajidunga waishio Dar es Salaam, Tanzania.

Mtafiti: Linda Mlunde

Anuani: CGH, Chuo Kikuu cha Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japani.

Dhumuni la kufanya huu utafiti

Dhumuni la utafiti huu ni kuangalia matokeo ya matumizi ya mjumuisho wa njia za kupunguza madhara yatokanayo na matumizi ya madawa ya kulevya katika kuzuia maambukizi ya VVU miongoni mwa wajidunga waishio Dar es Salaam, Tanzania.

Habari kuhusu jinsi utafiti utakavyofanywa

Huu utafiti utafanyika kwa watu wanaotumia madawa ya kulevya kwa njia ya kujichoma sindano/kujidunga. Washiriki wataulizwa maswali kuhusu tabia za kutumia madawa ya kulevya, tabia za ngono, upatahi wa huma za afya, na makosa ya jinai.

Utunzaji wa siri

Taarifa zote zitatumizwa kwa siri kwa kutumia namba bila majina ya muhusika.

Hatari zinazoweza kutokea

Hakuna hatari yoyote ambayo unaweza kupata kutokana na kushiriki katika huu utafiti.

Faida zinazoweza kupatikana

Taarifa ambayo utaitoa, itasaidia kuboresha utuaji wa huduma za afya kwa watu wanaotumia madawa ya kulevya.

Kutoendelea kushiriki katika utafiti

Ni hiari kushiriki kwenye utafiti huu na pia unaweza kujitoa wakati wa wote. Hata hivyo kutoshiriki au kujitoa kwenye utafiti hakutakua na adhabu au madhara yoyote.

Kama una tatizo au swali lolote

Kama una tatizo ambalo unafikiri linahusiana na kushiriki katika huu utafiti au una swali lolote kuhusu utafiti huu, tafadhali wasiliana na Linda Mlunde (Namba ya simu ni 0715 889 449)

Haki za mshiriki

Huu utafiti umeruhusiwa na bodi inayohusika na kupitia tafiti mbalimbali ili kulinda usalama wa washiriki ya Chuo Kikuu cha Afya na Tiba Muhimbili. Kama una swali lolote kuhusu haki zako kama mshiriki, tafadhali wasiliana na Dk. Jessie Kazeni Kilonzo Mbwambo, Daktari bingwa (Hospitali ya Taifa ya Muhimbili) na Mtafiti (Chuo Kikuu cha Afya na Tiba Muhimbili), Kitengo cha magonjwa ya afya ya akili, SLP 65466, Dar es Salaam, Tanzania.

Makubaliano ya kushiriki kwa kujitolea

Nimesoma na kuelewa taarifa hiyo hapo juu inayoelezea faida, hatari na jinsi utafiti utakavyofanyika wenye kichwa cha habari “Matokeo ya matumizi ya mjumuisho wa njia za kupunguza madhara yatokanayo na matumizi ya madawa ya kulevya katika kuzuia maambukizi ya VVU miongoni mwa wajidunga waishio Dar es Salaam, Tanzania”. Nimepewa nafasi ya kuuliza swali lolote kuhusu utafiti na kupewa majibu yanayoridhisha. Nakubali kushiriki katika utafiti huu kwa kujitolea.

Sahihi au dole gumba ya mshiriki.....

Sahihi ya mtafiti.....

Tarehe.....

Appendix 13: Ethical approval from The University of Tokyo

倫 理 委 員 会 審 査 結 果 報 告 書

平成25年12月02日

申請者（研究責任者）
国際地域保健学
教授
神馬 征峰 殿

東京大学大学院医学系研究科長・医学部長
宮園 浩平

審査番号 10331

研究課題 タンザニアのダルエスサラーム市における、注射薬物使用者のHIV感染を予防するための統合的ハームリダクション介入の効果

上記研究計画を平成25年11月25日の委員会で審査し下記のとおり判定しました。
ここに通知します。

判 定

☐承認する

☐変更を勧告する

☐該当しない

☐条件付きで承認する

☐承認しない

Appendix 14: Ethical approval from the Muhimbili University of Health and Allied Sciences

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DIRECTORATE OF RESEARCH AND PUBLICATIONS

P.O. BOX 65001
DAR ES SALAAM
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E-mail: drp@muhas.ac.tz

Ref. No.MU/DRP/AEC/Vol.XVIII/53

30th January, 2014

Dr. Linda B. Mlunde,
Department of Community and Global Health,
Graduate School of Medicine,
The University of Tokyo,
7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan.

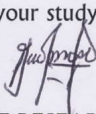
**RE: APPROVAL FOR ETHICAL CLEARANCE FOR A PhD STUDY TITLED
"EFFECTIVENESS OF A COMBINED HARM REDUCTION INTERVENTION TO
PREVENT HIV INFECTION AMONG PEOPLE WHO INJECT DRUGS IN DAR ES
SALAAM, TANZANIA"**

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate approved ethical clearance of the above mentioned study, on recommendation of the Expedited Review Sub-Committee of the Senate Research and Publications Committee held on 24th January, 2014.

The validity of this ethical clearance is one year effective from 28th January, 2014 to 27th January, 2015. You will therefore be required to apply for renewal of ethical clearance on a yearly basis if the study is not completed at the end of this clearance. You are also required to submit a final report upon completion of your study.

Permission to publish your study findings should be sought from appropriate authorities at MUHAS and/MNH.


Prof. Mainen J. Moshi

CHAIRMAN, SENATE RESEARCH AND PUBLICATIONS COMMITTEE

c.c. Deputy Vice Chancellor – ARC, MUHAS.

c.c. Dean, School of Medicine, MUHAS.

c.c. Dr. Jessie K. K. Mbwambo – Student Supervisor, MNH.