

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of monetary incentive on HIV self-testing uptake and linkage to care among female sex workers and their clients and partners in Iran: The SELFii study

#### Protocol summary

##### Study aim

To measure the effect of monetary incentive on HIV self-testing uptake and linkage to care among female sex workers and their clients and partners in Iran

##### Design

Two arm parallel group randomized unblinded trial

##### Settings and conduct

Eligible Individuals will be randomized to two study arms in Tehran and Isfahan.

##### Participants/Inclusion and exclusion criteria

We have four types of participants: 1. Eligible female sex workers (FSW) are a) women age 18 years or older, b) had sex for money in the past month, c) have never tested for HIV or tested negative not more recently than 3 months prior. 2. Eligible clients are a) men 18 year or older, b) who paid for sex in the past month 3. Eligible partners are a) men 18 year or older, b) who had unpaid sex with the FSW participant in the past month 4. Eligible peers are a) women age 18 years and older, b) had sex for money in the past month

##### Intervention groups

Study arm 1: FSW participants who accept to distribute HIV self-test among their clients, partner, or peers. Study arm 2: The same as arm 1, but in addition, FSW participants will receive monetary incentives for distributing HIV self test among their clients, partner, or peers

##### Main outcome variables

Uptake of HIV self-testing, self-test results, behavioral change, linkage to care for confirmatory HIV test or ART initiation at 3 and 6 months from enrollment, and adverse events.

#### General information

##### Reason for update

As we planned originally, we have conducted focus group

discussion, individual in-depth interviews to adapt the study design and procedures. Then, we run a small pilot phase to ensure the adapted methods work. Based on findings all these formative/pilot steps, we updated part of the methods sections. Eligibility and outcomes were remained the same. We also changed the name of the trail to SELFii as suggested by participants in the formative/pilot phase.

##### Acronym

Selfii

##### IRCT registration information

IRCT registration number: **IRCT201710039506N1**

Registration date: **2017-10-25, 1396/08/03**

Registration timing: **prospective**

Last update: **2020-01-07, 1398/10/17**

Update count: **2**

##### Registration date

2017-10-25, 1396/08/03

##### Registrant information

###### Name

Soodabeh Navadeh

###### Name of organization / entity

Precision Health Economics

###### Country

United States

###### Phone

001-310-982-6310

###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

National Institute for Medical Research Development

##### Expected recruitment start date

2019-01-15, 1397/10/25

**Expected recruitment end date**

2020-09-20, 1399/06/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of monetary incentive on HIV self-testing uptake and linkage to care among female sex workers and their clients and partners in Iran: The SELFii study

**Public title**

Monetary incentive effect on HIV self-testing uptake and linkage to care outcomes

**Purpose**

Screening

**Inclusion/Exclusion criteria****Inclusion criteria:**

Eligible female sex workers (FSW) are a) women age 18 years or older, b) had sex for money in the past month, c) have never tested for HIV or tested negative not more recently than 3 months prior. Eligible clients are a) men 18 year or older, b) who paid for sex in the past month. Eligible partners are a) men 18 year or older, b) who had unpaid sex with the FSW participant in the past month. Eligible peers are a) women age 18 years and older, b) had sex for money in the past month.

**Exclusion criteria:**

if the FSW would not accept to distribute the HIV self-test among her sexual partners.

**Age**From **18 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **1440****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Eligible female sex workers are being enrolled and complete a self-reported paper-based short survey, and then randomly assigned 1:1 to one of the two study arms (intervention/control). The study is being implemented in Tehran and Isfahan. Random numbers were generated by a web-based free software, MinimRan software.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

We will use Respondent-Driven Sampling (RDS) to recruit study participants.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics in Research Committee of National Institute for Medical Research Development

**Street address**

21 Besat St, West Fatemi Ave, Tehran, Iran

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Tehran

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**Postal code**

1419693111

**Approval date**

2017-09-15, 1396/06/24

**Ethics committee reference number**

IR.NIMAD.REC.1396.113

**2****Ethics committee****Name of ethics committee**

Ethics committee of Kerman University of Medical Sciences

**Street address**

Ebn-e-Sina St, Jahad Blvd

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**Approval date**

2017-03-07, 1395/12/17

**Ethics committee reference number**

IR.KMU.REC.1395.982

**3****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

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81745319

**Approval date**

2017-12-26, 1396/10/05

**Ethics committee reference number**

P/12/4/M/99

## Health conditions studied

### 1

#### Description of health condition studied

HIV and High risk behavior

#### ICD-10 code

B24

#### ICD-10 code description

Unspecified human immunodeficiency virus [HIV] disease

## Primary outcomes

### 1

#### Description

Confirmatory HIV test among FSW

#### Timepoint

3 and 6 months after enrollment

#### Method of measurement

It will be measured by 1) questionnaires that are designed for participants , 2) collecting referral cards from the study collaborating healthcare centers, 3) a health provider at one of the study collaborating healthcare centers reports to us anonymously by completing a paper-based form that has no identifying information and only include the referral card ID.

### 2

#### Description

ART initiation among FSW

#### Timepoint

3 and 6 months after enrollment

#### Method of measurement

It will be measured only among those with a confirmed HIV-positive test by 1) participants' self-report , 2) a health provider at one of the study collaborating healthcare centers reports to us anonymously by completing a form that has no identifying information and only include the referral card ID.

### 3

#### Description

Uptake of HIV self-testing among FSW

#### Timepoint

3 and 6 months after enrollment

#### Method of measurement

It will be measured by 1) self-report, 2) tracking system for self-test kits

### 4

#### Description

HIV self-test results among FSW

#### Timepoint

3 and 6 months after enrollment

#### Method of measurement

It will be measured by 1) self-report, 2) upload a photo of the self-test kit's window results

### 5

#### Description

Behavioral change among FSW

#### Timepoint

baseline, and 3 and 6 months after enrollment

#### Method of measurement

It will be measured by self-report

### 6

#### Description

Adverse events among FSW

#### Timepoint

Continuously monitored during the study

#### Method of measurement

It will be measured by self-report

## Secondary outcomes

### 1

#### Description

Confirmatory HIV test among clients, partners and peers

#### Timepoint

3 and 6 months after enrollment

#### Method of measurement

It will be measured by 1) participants' self-report 2) collecting referral cards from the study collaborating healthcare centers, 3) a health provider at one of the study collaborating healthcare centers reports to us anonymously by completing a paper-based form that has no identifying information and only include the referral card ID.

### 2

#### Description

ART initiation among clients, partners and peers

#### Timepoint

3 and 6 months after enrollment

#### Method of measurement

It will be measured only among those with a confirmed HIV-positive test by 1) participants' self-report , 2) a health provider at one of the study collaborating healthcare centers reports to us anonymously by completing a form that has no identifying information and only include the referral card ID.

### 3

#### Description

Uptake of HIV self-testing among clients, partners and peers

#### Timepoint

3 and 6 months after enrollment

#### Method of measurement

It will be measured by 1) self-report, 2) tracking system for self-test kits

### 4

#### Description

HIV self-test results among clients, partners and peers

**Timepoint**

3 and 6 months after enrollment

**Method of measurement**

It will be measured by 1) self-report, 2) send the photo of the self-test kit's window results to the study mobile number

**5**

**Description**

Behavioral change among clients, partners and peers

**Timepoint**

3 and 6 months after enrollment

**Method of measurement**

It will be measured by self-report

**6**

**Description**

Adverse events among clients, partners and peers

**Timepoint**

Continuously monitored during the study

**Method of measurement**

It will be measured by self-report

**Intervention groups**

**1**

**Description**

Group 1: FSW Participants in the monetary incentive arm (intervention arm) will receive monetary incentives for returning their test results, and for every successful invitation of clients, partners, and peers, and for successful linkage to care.

**Category**

Treatment - Other

**2**

**Description**

Group 2: FSW Participants in the control arm receive no monetary incentive.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Iran Research Center for HIV/AIDS (IRCHA)

**Full name of responsible person**

Dr. Leila Taj

**Street address**

Infectious disease ward, Imam-Khomeini Hospital, Keshavarz Blvd

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**2**

**Recruitment center**

**Name of recruitment center**

Infectious Disease Research Center

**Full name of responsible person**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

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**Grant name**

**Grant code / Reference number**

957506

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

National Institute for Medical Research Development

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

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**Person responsible for general inquiries****Contact****Name of organization / entity**

University of California, San Francisco

**Full name of responsible person**

Ali Mirzazadeh

**Position**

Assistant Professor, MD, PhD, MPH

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available