

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of smart phone based group motivational counseling on safe sex behavior of women living with HIV

Protocol summary

Study aim

Determine the Impact of smart phone based group motivational counseling on safe sex behavior of women living with HIV

Design

The study consists of two group, intervention and control groups. Participants were randomly assigned using software. This study not blinded. The sample size is 100, and the trial is in phase three.

Settings and conduct

The study is conducted at the Center for Behavioral Diseases of Emam Khomeini Hospital.

Participants/Inclusion and exclusion criteria

1- Iranian nationality 2- In the age range of 19 to 49 years 3. Reading and writing ability 4. Having smartphone and access to cyberspace 5- Having web-based software on mobile 6. Having sexual activity in the last three months.

Intervention groups

The samples are provided in two groups: Counseling (intervention) and receiving routine care (control). Consultation with the help of the formation of a virtual group takes place. The intervention group will receive five sessions of 45 minutes of cyber-based counseling (Farsi-based web messenger) with a motivational interviewing approach to reduce risk and safe sexual behavior on a weekly basis. The first meeting will be held in person and individually with the participants and other meetings using the formation of a virtual group whose admin is the researcher of the project. It will be on the web and using smartphone. Follow-up to the consultation sessions will also be virtual and If there are questions or to provide an assignment, participants can be privately contacted by admin. In both groups, the questionnaires will be completed before, after completing the sessions and three months later.

Main outcome variables

Knowledge about HIV/AIDS; Safe sex behavior; safe sex negotiation; HIV specific social support

General information

Reason for update

The end of the RCT

Acronym

HIV

IRCT registration information

IRCT registration number: **IRCT20161230031662N7**

Registration date: **2018-07-28, 1397/05/06**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-25, 1400/05/03**

Update count: **1**

Registration date

2018-07-28, 1397/05/06

Registrant information

Name

Razieh Lotfi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3430 4433

Email address

raziehlotfi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-03, 1397/04/12

Expected recruitment end date

2018-08-05, 1397/05/14

Actual recruitment start date

2018-07-03, 1397/04/12

Actual recruitment end date

2018-08-05, 1397/05/14

Trial completion date

2018-10-13, 1397/07/21

Scientific title

Effect of smart phone based group motivational counseling on safe sex behavior of women living with HIV

Public title

Effect of motivational counseling on safe sex behavior

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian nationality In the age range of 19 to 49 years
Ability to read and write Having smartphone and access to cyberspace Having web-based software on mobile
Having sexual activity in the last three months

Exclusion criteria:

Getting Advanced Stages of Disease (AIDS) Those who disable their profile during the course Unwillingness to continue to participate in the study Severe mental illness
Not attending similar educational and intervention classes in the last 6 months

Age

From **19 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the sampling will be available and according to the active records in the center. Then they will be divided into two groups based on random blocks. Also for statistical matching, the statistical tests are used to match the underlying variables The randomization method is done using block randomization so that the sample size of both groups is equal.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Alborz University of Medical Sciences, Shahrake Edari, North Taleghai square, Karaj, Iran

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2018-06-30, 1397/04/09

Ethics committee reference number

IR.ABZUMS.REC.1397.031

Health conditions studied

1

Description of health condition studied

Safe sex behavior

ICD-10 code

Z70.1

ICD-10 code description

Counselling related to patient's sexual behaviour and orientation

Primary outcomes

1

Description

safe sex behavior

Timepoint

before, 1 month , and 3 month after intervention

Method of measurement

Self- played questionnaire score

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group, 50 women with positive HIV status, have criteria for entering the study, receive 5 sessions of 45 minute group counseling based on motivational interviewing sessions on a weekly basis. Topics of the content of the sessions include acquaintance, emotion, assessment of advantages and disadvantages, values, final vision

Category

Behavior

2

Description

In the control group they will receive just routine voluntary and counseling protocol for HIV consultation

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Imam khomani hospital voluntary and counseling center

Full name of responsible person

Zeinab Talebi Tamajani

Street address

The Department of Infectious and tropical Disease, Imam Khomeini Hospital, Keshavarz Blvd

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http://ircha.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

دانشگاه علوم پزشکی و خدمات بهداشتی درمانی البرز

Full name of responsible person

دکتر محمد نوری سپهر

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Email

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

دانشگاه علوم پزشکی و خدمات بهداشتی درمانی البرز

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

Person responsible for general inquiries

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

ZeinabTalebiTamajani

Position

BsC. in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Department of Nursing and Midwifery, Alborz University of Medical Science, Golestan1, Eshteraki St., Baghestan, Karaj

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Dr. Razieh Lotfi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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Other areas of specialty/work

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Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

as an English article we published data.

When the data will become available and for how long

10 month later

To whom data/document is available

Iranian research center for HIV/AIDS , Alborz University of Medical Sciences

Under which criteria data/document could be used

For complementary researches such as Path analysis
Sending e-mail to the main researcher

From where data/document is obtainable

Alborz University of nursing and Midwifery and Iranian research center for HIV/AIDS.

What processes are involved for a request to access data/document

send an email to Dr. Razieh Lotfi.

Comments

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Trial results

Please tick if results have been published

Yes

Summary result posting date

2021-07-25, 1400/05/03

Table of baseline comparison

		Control group	intervention group
Variables	p-value	SD±Mean	SD±Mean
Age*	0.662	6.64± 34.45	7.10± 34.97
Age at first sex**	0.434	4.03 ± 20.08	4.4± 19.31
Duration of the disease**	0.908	3.57 ± 5.32	5.10 ± 6
Duration of membership in a Positive club**	0.595	2.45 ± 3.10	3.68 ± 3.43
Average monthly income (IRR) **	0.674	910317.9 ± 1198649	2079496 ± 1634146
		(%)N	(%)N
Marital status **	0.398		
Married (permanent marriage)		(54%) 27	(48%) 24
Married (temporary marriage)		(14%) 7	(20%)10
Single		(10%) 5	(2%) 1
Widow		(6%) 3	(6%) 3
Divorced		(16%)8	(24%) 12
Number of partners****	0.251		
1		(50%) 25	(50%) 25

2-3		(38%) 19	(32%) 16
4-5		(10%) 5	(6%) 3
6 or more		(2%) 1	(12%) 6
Having a contraception method***	0.326	(84%) 42	(74%) 37
Type of contraception method****	0.975		
Withdrawal		(34.9%) 15	(30.8%) 12
Condom		(53.5%) 23	(59%) 23
Intra uterine device		(4.7%) 2	(5.1%) 2
Tubal ligation		(7%) 3	(5.1%) 2
Level of education ***	0.557		
Elementary and middle school		(20%)10	(30%)15
High school and diploma		(64%)32	(56%)28
Academic		(16%) 8	(14%)7
Spouse's condition (HIV+)****	0.408	(78%) 39	(64%) 32
Spouse education level ****	0.643		
Illiterate		(8.2%) 4	(8.2%) 4
Elementary and middle school		(34.7%) 17	(40.8%)20
High school and diploma		(40.8%) 20	(28.6%) 14
Academic		(16.3%) 8	(22.4%) 11
Employment status ***	0.416		
Unemployed		(54%) 27	(64%)32
Employed		(46%) 23	(36%)18
Route of HIV contamination ****	0.408		
Unsafe sex		(66%) 65	(64%)32
Injecting drug use		(2%) 1	(6%) 3
Blood injection		(0%) 0	(6%) 3
Unknown		(22%) 11	(16%)8
Other cases		(10%) 5	(8%) 4
Reasons not to use condom****	0.693		
No condom		(6.9%) 2	(11.5%) 3
Expensive		(6.9%) 2	(0%) 0
Missing woman's interest in using		(20.7%) 6	(15.4%) 4
Opposition by husband / sex partner		(48.3%) 14	(50%)13 1
Use of other preventive methods		(10.3%) 3	(7.7%) 2
inattentiveness of condom use		(3.4%) 1	(7.7%) 2
Negative husband / partner test		(3.4%) 1	(0%) 0
Confidence in husband / partner		(0%) 0	(7.7%) 2
Use of antiretroviral drugs***	0.678	(96%) 48	(92%) 46

* Independent T-test. ** U- Mann-Whitney Test. *** Chi-Square test. **** Fisher's exact test

Significant at P < 0.05

Participant flow diagram

Table of variable outcomes' results

Variables	Groups	Before intervention	one month months after intervention	three month months after intervention	Friedman test results in each group(** p-value)
		SD ±Mean	SD ±Mean	SD ±Mean	
Safe sex behavior	intervention	2.08 ± 7.76	1.84 ± 8.04	1.88 ± 8.00	0.187
	Control	1.90 ± 7.02	1.90 ± 7.02	1.95 ± 6.92	0.368
	Result p-value*	0.068	0.008	0.008	
knowledge about HIV / AIDS and ways of transmission and prevention	intervention	3.46 ± 7.86	1.53 ± 10.63	1.39 ± 10.71	0.000
	Control	2.88 ± 7.50	2.54 ± 8.14	2.39 ± 8.66	0.000
	Result p-value*	0.194	0.000	0.000	
Ability of Condom negotiation	intervention	4.14± 16.84	3.79 ± 18.63	4.18 ± 18.08	0.000
	Control	4.89± 15.19	4.93 ± 15.000	4.99 ± 14.76	0.069
	Result p-value*	0.044	0.000	0.000	
HIV specific perceived social support	intervention	3.000±12.41	2.47± 13.06	2.45 ±13.10	0.000
	Control	2.95 ± 11.28	2.74 ±11.11	2.87 ± 11.04	0.016
	Result p-value*	0.195	0.001	0.002	

Table of adverse events

First publication date

2019-09-09, 1398/06/18

Abstract of published paper

Condom use was practiced only by 22.2% in all their vaginal and anal sexual intercourse during the three months, and 77.8% of the women never used condoms or failed to use them continuously. Their sexual partners were HIV-positive in 71% of cases. The mean ± SD of awareness score about HIV/AIDS was 7.60 ± 3.31, indicating average awareness of the subjects in the study. A total of 49.1% of the participants stated that their sexual partners' reluctance was the most important reason for non-use of condoms, while women were not willing to use condoms in 18.2% of cases