ISRCTN13212899 https://doi.org/10.1186/ISRCTN13212899

Mobile phone for sexual health in youth

Submission date
22/06/2017

Recruitment status
No longer recruiting

Registration date
22/06/2017

Overall study status
Completed

Last Edited
11/07/2023

Condition category
Urological and Genital Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chlamydia trachomatis (C.trachomatis) is the most commonly reported sexually transmitted infection (STI) worldwide. It is considered a major public health problem as it could lead to reproductive health issues such as infertility. It also increases the chances of getting the HIV infection. Secondary preventive strategies such as testing and treatment are important as they enable new cases to be detected and treated, interrupting the transmission chain. Many screening programs focus on secondary preventive strategies, alongside a varying element of prevention. Despite the recent focus on diagnosis and treatment, there has been a steady rise in infection rates among youth in Stockholm over the last two decades. However, primary preventive strategies such as condom campaigns, sexual education, and increased knowledge regarding STIs are equally, if not more, important in order to avoid new infections in the first place. A recent large population survey showed that a large number of youth reported not using a condom and did not use a condom with a new partner during their last intercourse. Staff in the Youth Health Clinics are stretched and therefore sometimes constrained with the preventive work they can do. Previous work from our research group has indicated that youth have varying level of knowledge and motivations to adopt safe sexual practices. C.trachomatis infection is highest in the youth, a group indeed familiar with and high consumers of mobile phone technology. The aim of this study is to evaluate the effects of a smart phone application to increase condom use and reduce risky sexual behaviour to see if it can be delivered to large groups of youth in Sweden and elsewhere at a low cost and support the preventive work of the screening programs.

Who can participate?
Youth aged 18 to 23 who own a smart phone and are sexually active.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the mobile application called “"Skyddslaget”. This application provides information about sexual health and tips on a daily bases and send reminders to the users. Participants can use the application to complete challenges, quizzes, self-reflection and gain information about STIs and condom use. The application will include new activities for users. Participants in the second group receive a “dummy” or fake application. All participants are assessed before the study and again at three and six months with questionnaires to assess their sexual health habits and to compare the results between the groups.

What are the possible benefits and risks of participating?
Participants may benefit from the opportunity to reflect on their sexual behavior and this may help them engage in safe sexual practices. As sexual health is a sensitive topic, there is a risk that participants may feel uncomfortable.

Where is the study run from?
This study is being run by the Karolinska Institute (Karolinska Institutet) (Sweden) and takes place in eight youth health clinics in Sweden.

When is the study starting and how long is it expected to run for?
January 2017 to September 2018

Who is funding the study?
FORTE Swedish Research Council for Health, Working life and Welfare (Sweden)

Who is the main contact?
Mrs Anna Nielsen
anna.nielsen.1@ki.se

Study website
www.skyddslaget.se

Contact information

Type(s)
Scientific

Contact name
Mrs Anna Nielsen

ORCID ID
http://orcid.org/0000-0002-5189-6949

Contact details
Karolinska Institute (Karolinska Institutet)
Department of Women's and Children's Health (KBH)
K6, Division of Obstetrics and Gynecology
Karolinska Universitetssjukhuset
Kvinnokliniken
Stockholm
Sweden
17176
+46 70 4078496
anna.nielsen.1@ki.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol Version 1.9

Study information

Scientific Title
A parallel group, individually randomized clinical trial to evaluate the effect of a mobile phone application to improve sexual health among youth in Stockholm County

Acronym
MOSEXY - TRIAL

Study objectives
The smart phone intervention designed to promote safe sexual practices will increase condom use and therefore reduce the rate of new infections, among sexually active youth in Stockholm County.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Regional Ethical Board in Stockholm (EPN Regionala Etikprövningsnämnden i Stockholm), 26/08/2017, ref: 2017/651-31/4

Study design
Multicentre interventional pragmatic randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Sexually Transmitted Infection / Condom Use

Interventions

Participants are individually randomly allocated to one of two groups. The randomisation allocation sequence is generated using a central computer-generated random numbers and is stratified by sex.

Intervention group: Participants receive the intervention in the form of a smart phone application called "Skyddslaget". The application delivers information and activities on a daily bases and users are reminded of the application by push-notices. The application includes things like condom-tips, self-reflections exercises, challenges, and information about sexually transmitted infections. The application will have one permanent part containing facts about STI and condoms and a second dynamic more interactive part. These include challenges and quiz, personal stories from peers, and self-rapport (elucidating ones behaviour in relation to sexual practices). Activities/information within each of these functions will be dynamic, i.e. change periodically over time such as activities. New information will be added in the application in a daily basis for 180 days. Participants are assessed at baseline and at follow up at three and six months to assess their sexual health.

Control group: Participants download a dummy application that only contains the baseline and follow-up questionnaires at three and six months.

Intervention Type
Behavioural

Primary outcome measure
Self-reported condom use during the past six months is measured using the assessment questionnaires at baseline, at three and six months.

Secondary outcome measures
1. Number of partners during the study period is measured using assessment questionnaires, at three and six months
2. Number of tests during the study period is measured using assessment questionnaires at six months
3. Occurrence of STI during the study period measured using assessment questionnaires at six months
4. Occurrence of pregnancy during study period is measured using assessment questionnaires at six months

Overall study start date
23/01/2017

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Youth aged 18-23
2. Youth who own a smart phone
3. Youth who are sexually active (had at least two partners during the past six months). Added 16 /10/2017: This criteria is to ensure youth included in the trial have recently had sex outside a stable relationship

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
23 Years

Sex
Both

Target number of participants
446

Total final enrolment
433

Key exclusion criteria
Current exclusion criteria as of 20/11/2017:
1. Youth who do fulfil inclusion criteria
2. Youth who do not wish to participate
3. Women who only have sex with women will be excluded from the study as the interventions mainly focuses on safe sexual practices related to condom use
4. Close friend/sibling recruited into the trial

Exclusion criteria as of 05/09/2017:
1. Youth who do fulfil inclusion criteria
2. Youth who do not wish to participate
3. Women who only have sex with women will be excluded from the study as the interventions mainly focuses on safe sexual practices related to condom use

Previous exclusion criteria:
1. Youth who do fulfil inclusion criteria
2. Youth who do not wish to participate

Date of first enrolment
01/09/2017

Date of final enrolment
18/04/2018

Locations

Countries of recruitment
Sweden

Study participating centre
Södermalm ungdomsmottagning (Youth Centre)
Sweden
118 46

Study participating centre
Nacka ungdomsmottagning (Youth Centre)
Sweden
131 53

Study participating centre
Farsta ungdomsmottagning (Youth Centre)
Sweden
123 47

Study participating centre
Tyresö ungdomsmottagning (Youth Centre)
Sweden
135 40

Study participating centre
Skärholmen ungdomsmottagning (Youth Centre)
Sweden
127 48

Study participating centre
Midsommarkransen ungdomsmottagning (Youth Centre)
Sweden
126 32

Study participating centre
Järva ungdomsmottagning (Youth Centre)
Sweden
164 40

Study participating centre

Västerort ungdomsmottagning (Youth Centre)
Sweden
162 61

Sponsor information

Organisation
FORTE Swedish Research Council for Health, Working life and Welfare

Sponsor details
Östra Järnvägsgatan 27
Stockholm
Sweden
101 37
+46 8 775 40 70
forte@forte.se

Sponsor type
Research council

Website
www.forte.se

ROR
https://ror.org/02d290r06

Funder(s)

Funder type
Research council

Funder Name
Forskningsrådet om Hälsa, Arbetsliv och Välfärd

Alternative Name(s)
Swedish Research Council for Health, Working Life and Welfare, FORTE

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location

Sweden

Results and Publications

Publication and dissemination plan
The results of the trial will be published in a peer-reviewed journal. It will be of a doctoral thesis describing testing habits; sexual risk-taking and preventive strategies among youth in Stockholm County. All participants in the trial will, if they so wish, be notified about the findings after the trial period is over. Findings will also be communicated to stakeholders and policymakers in Stockholm County as well as to The Public Agency of Public Health. Finding will also be communicated to the public via media.

Intention to publish date
30/09/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from [anna.nielsen.1@ki.se]

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/02/2018		Yes	No
Results article	results	01/03/2021	05/03/2020	Yes	No
Other publications	Development of the Mobile Phone App	28/01/2020	11/07/2023	Yes	No