ISRCTN17783607 https://doi.org/10.1186/ISRCTN17783607

Evaluation of the impact of SEXIT game as an educational intervention on sexual health and the prevention, diagnosis, and treatment of sexually transmitted infection

Submission date
13/02/2024

Recruitment status
No longer recruiting

Registration date
08/03/2024

Overall study status
Completed

Last Edited
10/09/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
The incidence of sexually transmitted infections (STIs) is increasing, especially among young people. Tools are needed to increase knowledge about sex education and STI prevention and treatment. Gamification can be a good training tool for both young people and health professionals. The primary objective of this study is to assess the impact of a training intervention on STI prevention, detection, and treatment in primary care professionals. This project aims to design, develop and evaluate an educational intervention aimed at residents and primary care professionals to improve people's sexual health and the prevention, detection, and treatment of STIs.

Who can participate?
Adults in family and community medicine areas and nursing residents and professionals from primary care centres (PCCs) managed by the Institut Català de la Salut (ICS, Catalan Health Institute), the main primary care service provider in Catalonia.

What does the study involve?
Health centres will be randomly assigned to the intervention or control group. The intervention group will carry out the training intervention. The study will consist of a pre-post evaluation of the intervention: a knowledge test will be administered before and after the intervention and 3 months after the intervention. This test will also be carried out on the same time sequence in the control groups. The impact of the training intervention will be evaluated for 6 months by studying different variables related to the clinical approach to STIs by examining the clinical records of diagnostic tests and antibiotic prescriptions related to the clinical approach to STIs.

What are the possible benefits and risks of participating?
Participating teams will benefit from free training on the prevention and management of STIs and sexual violence. Participation is risk-free as it is a training activity.

Where is the study run from?
The study will be carried out in primary care centres in Catalonia, Spain.

When is the study starting and how long is it expected to run for?
April 2022 to December 2024

Who is funding the study?
The project is carried out with the majority of external funding from the Department of Health of the Generalitat de Catalunya, on a competitive basis, for the funding of research projects in the field of primary health care. This work has also received funding from the semFYC private foundation after obtaining an Isabel Fernández 2023 grant for doctoral theses.

Who is the main contact?
Miss Alba Martinez Satorres, amartinezsat.bcn.ics@gencat.cat

Contact information

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Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PERIS SLT021/21/000062

Study information

Scientific Title
Evaluation of the impact of an online video game as an educational intervention on sexual health and the prevention, diagnosis, and treatment of sexually transmitted infection: a randomized controlled trial

Acronym
SEXIT

Study objectives
Educational intervention will generate knowledge about sexuality education; access to health care; and the prevention, diagnosis, and treatment of sexually transmitted infections. It will contribute to better health care and promote better sexual health at the community level.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/03/2023, Comitè Ètic d'Investigació amb medicaments (CEIm) de l'IDIAP Jordi Gol (Gran Via Corts Catalanes, 587, Barcelona, 08007, Spain; +34 (0)93 482 41 24; idiap@idiapjgol.org), ref: Codi IDIAP: 4R22/046

Study design
Cluster randomized clinical trial with pre-post evaluation

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice, Training facility/simulation

Study type(s)
Diagnostic, Prevention, Screening, Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Medical training, sexual health and the prevention, diagnosis, and treatment of sexually transmitted infections

Interventions
The researchers will design, develop, and evaluate an educational intervention in the form of a video game aimed at primary care professionals. The intervention will be studied and compared with control groups that will not carry out the intervention.

The intervention groups will be given a pre-intervention test which will be repeated right after the intervention and then 3 months later. In the control groups, the test will be administered at the beginning of the study and repeated after 3 months. In addition to questions to assess knowledge, there will be a qualitative assessment satisfaction survey for the participants. This test will also be carried out in the same time sequence on control groups with the same socio-demographic characteristics.
The intervention will consist of an online video game developed by a multidisciplinary team.

Study population, site participation, recruitment
The study is conducted in primary care centres (PCC) managed by the Institut Català de la Salut (ICS, Catalan Health Institute), the main primary care services provider in Catalonia, with the participation of its family and community medicine areas and the nursing residents and professionals from PCCs of the public health system.

Recruitment of participants
The PCCs will be invited to participate in the study via training referents. Participation in the study will be proposed from the primary care training referral platform. A letter and a slide presentation will be made to explain the study. Once the PCCs who wish to participate have been selected, they will be randomly assigned to a control/intervention group.

Assignment of intervention/control groups
The assignment will be randomised by clusters (PCC). The allocation of PCCs to each group will be made by a person outside the circle of researchers using a table of random numbers.
Once the centres have been recruited, they will be stratified and matched according to these variables: teaching/non-teaching; classification according to MEDEA index; percentage of assigned population of migrant origin and number of family doctors and primary care nurses with assigned quotas.
Centres with similar characteristics will be randomly assigned to the control or intervention group.
The control groups will be able to carry out the training activity once the study has been completed.

Intervention Type
Other

Primary outcome measure
The impact of the intervention will be assessed at three levels, following Kirkpatrick's model: reaction, learning, and clinical behaviour change:
1. Reaction: measured by a qualitative survey after the intervention after the intervention

2. Learning: measured by a self-developed questionnaire (score over 25) at baseline, after the intervention, and 3 months later.
3. Evaluation of changes in the application of the knowledge acquired in clinical practice:
3.1. STI tests realized during the study period (6 months)
3.2. Prevalence of STI registered during the study period (6 months)
3.2.1. Multitest urine PCR: Number of tests ordered during the study period (6 months)
3.2.2. Multitest urethral PCR: Number of tests ordered during the study period (6 months)
3.2.3. Multitest vaginal PCR: Number of tests ordered during the study period (6 months)
3.2.4. Multitest pharyngeal PCR: Number of tests ordered during the study period (6 months)
3.2.5. Multitest rectal PCR: Number of tests ordered during the study period (6 months)
3.2.6. Multitest ulcer PCR: Number of tests ordered during the study period (6 months)
3.2.7. Urethral swab cultures: Number of tests ordered during the study period (6 months)
3.2.8. Vaginal swab cultures: Number of tests ordered during the study period (6 months)
3.2.9. Pharyngeal swab cultures: Number of tests ordered during the study period (6 months)
3.2.10. Rectal swab cultures: Number of tests ordered during the study period (6 months)
3.2.11. HIV serologies: Number of tests ordered during the study period (6 months)
3.2.12. Hepatitis A serologies: Number of tests ordered during the study period (6 months)
3.2.13. Hepatitis B serologies: Number of tests ordered during the study period (6 months)
3.2.14. Hepatitis C serologies: Number of tests ordered during the study period (6 months)
3.2.15. Treponema pallidum serologies: Number of tests ordered during the study period (6 months)
3.3. ECAP registration of health problems with an aetiological orientation:
3.3.1. Gonococcal urethritis A54.00: Number of diagnoses registered during the study period (6 months)
3.3.2. Chlamydial urethritis A56.01: Number of diagnoses registered during the study period (6 months)
3.3.3. Trichomonas urethritis A59.03: Number of diagnoses registered during the study period (6 months)
3.3.4. Urethritis (non-gonococcal urethritis) N34.1: Number of diagnoses registered during the study period (6 months)
3.3.5. Early syphilis A51.9: Number of diagnoses registered during the study period (6 months)
3.3.6. Late syphilis A52.9: Number of diagnoses registered during the study period (6 months)
3.3.7. Syphilis A53.9: Number of diagnoses registered during the study period (6 months)
3.3.8. Urethritis (not specified): Number of diagnoses registered during the study period (6 months)
3.3.9. Gonococcus (not specified): Number of diagnoses registered during the study period (6 months)
3.3.10. Unspecified chlamydia: Number of diagnoses registered during the study period (6 months)
3.4. Prescription of antibiotics:
3.4.1. Ceftriaxone: Number of prescriptions during the study period (6 months)
3.4.2. Azithromycin: Number of prescriptions during the study period (6 months)
3.4.3. Penicillin: Number of prescriptions during the study period (6 months)
3.4.4. Doxycycline: Number of prescriptions during the study period (6 months)
3.4.5. Quinolones: Number of prescriptions during the study period (6 months)
3.4.6. Cefixime: Number of prescriptions during the study period (6 months)
3.5. Number of epidemiological surveys realised during 6 months (data provided by the Public Health Agency)

Secondary outcome measures

Changes in clinical attitude measured by the response to the extra question (26) in the knowledge test at baseline, post-intervention, 3 months

Overall study start date
27/04/2022

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Family and community medicine and nursing residents
2. Family doctors and primary care nurses with assigned quotas

Participant type(s)
Health professional, Resident

Age group
Adult

Sex
Both

Target number of participants
300

Total final enrolment
300

Key exclusion criteria
1. Not having devices to play the game online
2. Impossibility of carrying out the follow-up after 6 months
3. Referent in sexually transmitted infections professionals

Date of first enrolment
01/11/2023

Date of final enrolment
01/09/2024

Locations

Countries of recruitment
Spain

Study participating centre

IDIAPJGol
Gran Via Corts Catalanes, 587
Barcelona
Spain
08007

Study participating centre
Societat Catalana de Medicina Familiar i Comunitària
C/ Diputació, 316
Barcelona
Spain
08009

Sponsor information

Organisation
Departament de Salut

Sponsor details
Pavelló Ave Maria, Travessera de les Corts, 131, 159, Distrito de Les Corts
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Sponsor type
Government

Website
http://salutweb.gencat.cat/ca/inici/

ROR
https://ror.org/00nyrjc53

Funder(s)

Funder type
Government

Funder Name
Departament de Salut, Generalitat de Catalunya

Alternative Name(s)
Department of Health, Generalitat de Catalunya, Department of Health, Government of Catalonia

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Spain

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the study will be available upon request from the SEXIT group at sexitcat@gmail.com.

Data available include the database relating to the answers to the pre- and post-intervention questionnaires and the satisfaction survey, the data on pre- and post-intervention knowledge and the data from the satisfaction test that will be obtained through Microsoft Forms (corporate website of the Catalan Health Institute).
The data collected will be anonymous, as at no time will the professionals have to identify themselves with the questionnaire to answer it. The answers to the pre- and post-intervention surveys and the satisfaction survey will be generated in a final Excel spreadsheet that is generated from Microsoft Forms. This Excel spreadsheet will be provided to the Catalan Health Institute of Barcelona's management staff. The data relating to post-intervention participants will be extracted through the Technical Area of the Territorial Management of the ICS Barcelona. In this sense, a final database will be generated (with the answers of the Excel and the extractions) to analyse and exploit the results where the data will be pseudo-anonymised (those coming from the Technical Area) and anonymous those coming from the surveys. This final database will be allocated to the servers of the ICS Barcelona, as the latter will act as the party responsible for the processing and the IP will act as the party in charge of the processing. During the process, all procedures will be put in place to protect the confidentiality of the information and the anonymity of the participants in all research materials, and participants will be informed of the results of the research.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		26/08/2024	02/09/2024	Yes	No