Improving screening strategies for migrants in primary care

Submission date	Recruitment status No longer recruiting	Prospectively registered		
11/06/2019		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
26/06/2019	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
08/07/2021	Other			

Plain English summary of protocol

Background and study aims

Migrant health status may be improved if certain health conditions are identified early through a screening program. This is a study conducted in eight primary care centers (PCCs) located in four areas of Catalonia that evaluates the feasibility and cost-effectiveness of a screening program through a digital tool used by medical doctors during their daily consultation. The tool based on origin, age and sex, generates an alarm in the medical record system indicating the specific recommendations for each individual. The seven infectious diseases selected are HIV, hepatitis B, hepatitis C, tuberculosis, strongyloidiasis, schistosomiasis and Chagas disease. Female genital mutilation (FGM) and mental health are also included as they are associated with migration.

Who can participate?

Migrant patients coming from endemic countries for any of the conditions included in the study

What does the study involve?

Participating PCCs are randomly allocated to either use the digital tool or not. A training session concerning migrant screening strategies for each condition is done in all PCCs. The number of diagnoses of all the conditions are extracted from medical records.

What are the possible benefits and risks of participating?

The expected benefits are to increase the number of screened migrants and to improve their health and to increase the awareness of the primary care health professionals about the health needs of the migrant populations.

Where is the study run from?

Eight primary care centers (PCCs) located in four areas of Catalonia (Spain)

When is the study starting and how long is it expected to run for? March 2017 to December 2019

Who is funding the study?

Generalitat de Catalunya - Departament de Salut (Spain)

Who is the main contact? Dr Ana Requena-Méndez ana.requena@isglobal.org

Contact information

Type(s)

Scientific

Contact name

Dr Ana Requena-Méndez

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

SLT002/16/00455

Study information

Scientific Title

Cost-effectiveness of an alert software tool implemented in the medical record system of primary care centres to improve the screening procedure in migrants

Acronym

CRIBMI

Study objectives

The implementation of a decision support system (DSS) of primary care health professionals concerning disease-specific screening in migrant populations may improve the diagnostic yield of health professional and avoid potential complications of the diseases.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/12/2016, Ethics committee of the Hospital Clínic of Barcelona (HCB/2016/0858) and the Jordi Gol i Gurina Foundation (SLT002/16/00455) (Hospital Clínic de Barcelona, Villarroel, 170 – 08036 Barcelona, Spain; Tel: +34 (0)93 227 54 00)

Study design

Cluster randomized study

Primary study design

Interventional

Study type(s)

Screening

Health condition(s) or problem(s) studied

HIV, hepatitis B and C, tuberculosis, strongyloidiasis, schistosomiasis, Chagas disease, female genital mutilation and mental health assessment

Interventions

The study takes place in 8 primary care centers (PCCs) located in four areas of Catalonia. In each area, a digital tool (providing recommendations for migrant screening purpose based on an individual risk assessment) will be randomly allocated to the medical record system of one PPC, and will be compared with other PPCs (control) where no digital tool will be implemented.

Intervention: Implementation of DSS tool in PCC providing individual risk assessment for 9 conditions that should be screened in each individual migrant based upon 3 variables (country of origin, sex and age)

Control: PCC without implementation of DSS

Intervention: 01/03/2018 - 31/12/2018

No follow-up

Intervention Type

Other

Primary outcome(s)

Number of diagnoses of all aggregated conditions included in the study, extracted from medical records between March and December 2018:

Key secondary outcome(s))

Extracted from medical records between March and December 2018:

- 1. Number of HIV diagnoses
- 2. Number of strongyloidiasis diagnoses
- 3. Number of schistosomiasis diagnoses
- 4. Number of tuberculosis diagnoses
- 5. Number of Chagas disease diagnoses
- 6. Number of Hepatitis C diagnoses
- 7. Number of Hepatitis B diagnoses
- 8. Number of mental health diagnoses
- 9. Number of female genital mutilation diagnoses
- 10. Number of early diagnoses of HIV
- 11. Number of early diagnoses of hepatitis B and C and HIV

Completion date

31/12/2019

Eligibility

Key inclusion criteria

Migrant patients coming from endemic countries for any of the conditions included in the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

14598

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/03/2018

Date of final enrolment

31/12/2018

Locations

Countries of recruitment

Spain

Study participating centre CAPBSE

Carrer Roselló 161 Barcelona Spain 08036

Study participating centre

EAP Lleida 1

Rambla Ferran Lleida Spain 25007

Study participating centre EAP Manresa 2

Plaça Catalunya Manresa Spain 08241

Study participating centre EAP Manresa IV

Sagrada Familia Manresa Spain 08243

Study participating centre CAP Sagrada Familia

Carrer Corsega 643 Barcelona Spain 08025

Study participating centre EAP Tortosa 1 (Est)

Plaça Carrilet s/n Tortosa Spain 43500

Study participating centre CAP Tortosa Oest (Baix Ebre)

Avenida Colom 16-20 Tortosa Spain 43500

Study participating centre CAP Primer de Maig

C/ De la Mercè, 5 Lleida Spain 25003

Sponsor information

Organisation

Barcelona Institute for Global Health

ROR

https://ror.org/03hjgt059

Funder(s)

Funder type

Government

Funder Name

Generalitat de Catalunya - Departament de Salut (PERIS SLT002/16/00455)

Alternative Name(s)

Government of Catalonia

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Spain

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ana Requena-Méndez (ana.requena@isglobal.org).

IPD sharing plan summary Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/04/2019		Yes	No
Results article		06/07/2021	08/07/2021	Yes	No