Delivering an innovative multi-disease screening and vaccination tool to high-risk migrant populations (ISMiHealth): study protocol of a cluster randomised controlled trial

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BACKGROUND

- Migrant populations are disproportionately affected by key infections, including tuberculosis, HIV, hepatitis B and C virus[1].
- Certain imported infections like strongyloidiasis, schistosomiasis and Chagas disease are of increasing importance in non-endemic areas[2,3].
- Female genital mutilation (FGM) is a neglected condition with a sociocultural component[4].

Integrated programmes represent a key step forward to deliver more cost-effective services adapted to the needs of migrants[5].

Our research group has already developed a novel clinical decision support system (ISMiHealth) that aims to improve the screening performance on communicable diseases and FGM in migrants at primary care level.

Preliminary data from the pilot study:

- ✓ ISMiHealth improves the diagnosis and is feasible to implement[6],
- ✓ acceptable to healthcare professionals, and well adapted to the primary care context[7].

We developed a Spanish guidance on screening recommendations in migrants, based on a consensus of a country-expert transdisciplinary network. National and international guidelines were reviewed.

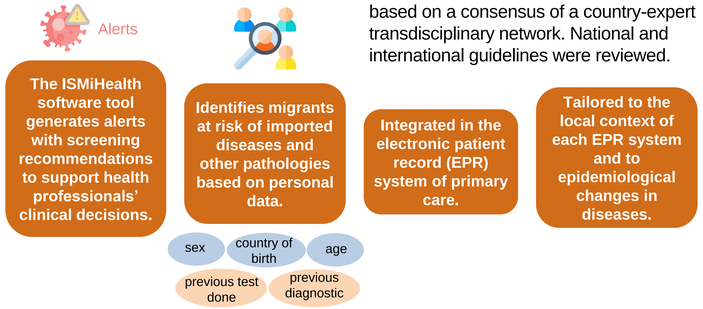

Figure 1. Key features and assets of the ISMiHealth software tool.

AIMS

1. To validate the ISMiHealth tool and evaluate its effectiveness in Catalonia, Spain.
2. To evaluate the feasibility and acceptability of the ISMiHealth tool.
3. To test the ISMiHealth tool in another health information system (in Andalusia, Spain).

POTENTIAL IMPACT

- ISMiHealth will improve the healthcare delivery process. The patient will benefit from an individualized and tailored service. Health professionals will increase their knowledge on migrants' health conditions.
- Our findings will allow for optimization of the ISMiHealth tool before integration into clinical practice. It has the potential to be scaled-up to other health systems.

METHODS

1 Randomized controlled trial in Catalonia, Spain.

We will conduct a pragmatic cluster randomised controlled trial with two parallel groups in 35 primary care centres (PCCs) of Catalonia, Spain.

Intervention centres will implement the screening programme supported by the ISMiHealth software, and they will be compared with control centres, that will follow the standard of care.

Outcomes and data analysis

- We will perform a difference in differences analysis of the diagnostic rates for all aggregated infections and each individual condition.
- For associations between the screening performance, the arm of the study, sociodemographic and epidemiological factors, we will carry out mixed effects logistic regression models.

3 Pilot study in Andalusia, Spain.

We will conduct a pilot cluster randomised controlled trial with two parallel groups in 6 PCCs of Andalusia, Spain.

We will estimate preliminary effectiveness data through logistic regression models. We will evaluate the feasibility, acceptability, and adaptability of the ISMiHealth tool in another health information system.

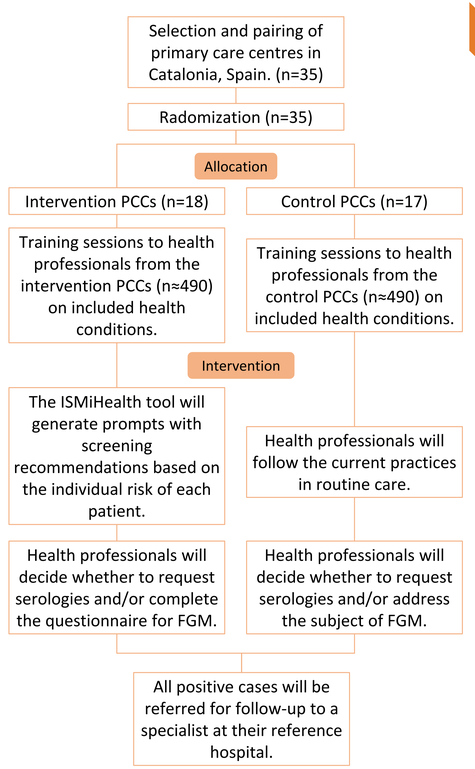

Figure 2. Flow diagram of the ISMiHealth study in Catalonia, Spain.

2 Process evaluation

We will carry out a process evaluation to assess the feasibility and acceptability of the intervention (implementation, integration into clinical practice and challenges), using mixed methodology.

Study stage	Procedures
Pre-intervention stage	Focus group discussions with health professionals and migrant patients, independently.
During intervention	Real-time technical monitoring of the tool. Follow-up survey.
Post-intervention stage	Focus group discussions with health professionals. Ad-hoc survey. Individual interviews with migrant patients who have been screened.

Data analysis

- Focus group discussions and individual interviews will be analysed using a thematic analysis approach.
- For quantitative data, we will conduct univariate analysis against the main variables (sociodemographic, health centre, etc).

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