Outreach program for residents of two migrant workers' hostels in Ile-de-France aimed at improving health literacy

Submission date 25/01/2024	Recruitment status No longer recruiting	Prospectively registered
		Protocol
Registration date	Overall study status	Statistical analysis plan
01/02/2024	Ongoing	Results
Last Edited	Condition category	Individual participant data
16/01/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Residents of migrant workers' hostels (foyers de travailleurs migrants [FTM]) accumulate risk factors for their overall health and mental health, such as difficult living conditions, arduous work, financial insecurity, and lack of knowledge of the healthcare pathway. The empirical findings of primary care professionals (nurses, GPs) working with FTM residents are as follows: the living conditions and the low health literacy of FTM residents interfere with their health, their access to care and their participation in preventive actions. To precisely measure the benefits of outreach actions to improve health literacy, researchers are conducting a pilot study in two FTMs: Yonki Saha (health in Soninké). The main objectives of this pilot study are to evaluate the effectiveness of an intervention to promote health literacy in this population, and to assess the acceptability and satisfaction of those who have benefited from the intervention, with a view to transferring the action to numerous FTMs in mainland France. The secondary objective of this study is to establish an overview of the health, healthcare utilization and renunciation, health literacy and social situation of FTM residents - an under-studied group.

Who can participate?

FTM residents over 18 years old who declare that they live in one of the two hostels surveyed (i. e. sleep there at least 4 nights a week)

What does the study involve?

The study involves answering questionnaires. Participation in workshops is encouraged but not compulsory.

The research will be carried out in three stages: an initial questionnaire will be administered to all residents of the two selected FTMs. The questionnaire will cover a range of topics: health status, use of and refusal to use healthcare, health literacy, and social situation.

One-year outreach intervention to promote health literacy: The intervention program consists of eight sessions. Each session will be led by a team comprising a state-registered nurse and a health mediator. At least one member of the team will speak Soninke or Arabic in addition to French. A session will take place as follows: 2 hours of group workshops prepared in advance and adapted to the area of intervention will precede 2 hours of individual support sessions (opening

of entitlements, prescription explanations, help with making appointments, etc). To ensure that participants can benefit from the program in its entirety, the intervention team will be made available to carry out these sessions three times a year. The times and days of the sessions will vary to enable participants to reconcile these sessions with their personal and professional constraints. At the end of each session, participants will be asked to complete an anonymous satisfaction questionnaire.

One year after the initial questionnaire: a final questionnaire was administered to all residents of the two selected MTFs, covering the same themes as the initial questionnaire, as well as a satisfaction questionnaire.

What are the possible benefits and risks of participating? The possible benefits are improved health literacy, improved access to care and better health. No risks have been anticipated.

Where is the study run from? Sorbonne University (France)

When is the study starting and how long is it expected to run for? September 2021 to January 2026

Who is funding the study?
GIRCI (Ile de France inter-regional clinical research and innovation grouping) (France)

Who is the main contact?
Sarah Robert, sarah.robert@sorbonne-universite.fr

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Sarah Robert

Contact details

27 rue Chaligny
Paris
France
75012
+33 (0)140011397
sarah.robert@sorbonne-universite.fr

Additional identifiers

EudraCT/CTIS numberNil known

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Projet RESPIR 2021010

Study information

Scientific Title

Effectiveness and acceptability of a primary care outreach program for residents of two migrant workers' hostels in Ile-de-France aimed at improving health literacy - a before-and-after pilot study

Acronym

Yonki Saha

Study objectives

Residents of migrant workers' hostels have a lower level of literacy than the general population. This lower level could be linked to poorer health, due to the accumulation of risk factors for overall and mental health (difficult living conditions, difficulties at work, financial insecurity, lack of knowledge of care pathways, etc).

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 28/10/2022, Sorbonne University Research Ethics Committee (27 rue Chaligny, Paris, 75012, France; +33 (0)140011397; cer@sorbonne-universite.fr), ref: CER-2022-079

Study design

Observational 2-year longitudinal before-and-after study

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Community, GP practice

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Improving the health literacy of migrant workers

Interventions

The research will be carried out in three stages:

T0: an initial questionnaire will be administered to all residents of the two selected FTMs. The questionnaire will cover a range of topics: health status, use of and refusal to use healthcare, health literacy, and social situation.

One-year outreach intervention to promote health literacy: The intervention program consists of eight sessions. Each session will be led by a team comprising a state-registered nurse and a health mediator. At least one member of the team will speak Soninke or Arabic, in addition to French. A session will take place as follows: two hours of group workshops prepared in advance and adapted to the area of intervention will precede two hours of individual support sessions (opening of entitlements, prescription explanations, help with making appointments, etc). To ensure that participants who have agreed to take part in the study can benefit from the program in its entirety, the intervention team will be made available to carry out these sessions three times a year. The times and days of the sessions will vary to enable participants to reconcile these sessions with their personal and professional constraints. At the end of each session, participants will be asked to complete an anonymous satisfaction questionnaire

One year after the initial questionnaire: a final questionnaire was administered to all residents of the two selected MTFs, covering the same themes as the initial questionnaire, as well as a satisfaction questionnaire.

Intervention Type

Behavioural

Primary outcome measure

Health literacy is measured using the HLS EU Q 16 questionnaire at baseline and 1 year after the inclusion

Secondary outcome measures

- 1. Health status is measured using the Minimum European Health Module at baseline and 1 year after the inclusion
- 2. Healthcare use is measured using questions (e.g. having a GP, number of visits to the GP in the last year, other places where care is sought, reasons for not seeking care) at baseline and 1 year after the inclusion

Overall study start date

01/09/2021

Completion date

01/01/2026

Eligibility

Key inclusion criteria

- 1. Age ≥18 years
- 2. Declare that they live in one of the two hostels surveyed (i.e. sleep there at least 4 nights a week)
- 3. Be a volunteer to take part in the study

Participant type(s)

Resident

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

150

Total final enrolment

114

Key exclusion criteria

- 1. Minors
- 2. Persons under legal protection, persons unable to give informed consent
- 3. People who do not wish to participate

Date of first enrolment

01/01/2023

Date of final enrolment

30/06/2024

Locations

Countries of recruitment

France

Study participating centre

Foyer de résidents de travailleurs migrants - Coallia- Tolbiac

80 rue de Tolbiac

Paris

France

75013

Study participating centre Foyer de travailleurs migrants - Adoma - Pinel

43 rue Pinel

Paris

France

93200

Sponsor information

Organisation

Sorbonne University

Sponsor details

General Practice Department 27 rue Chaligny Paris France 75012 +33 (0)1 78 96 90 14 bastien.mezerette@girci-idf.fr

Sponsor type

University/education

Website

https://www.sorbonne-universite.fr

ROR

https://ror.org/02en5vm52

Funder(s)

Funder type

Research organisation

Funder Name

GIRCI (Ile de France inter regional clinical research and innovation grouping)

Results and Publications

Publication and dissemination plan

Planned publication of the first results of this work at the end of 2024.

Intention to publish date

01/06/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Sarah Robert (sarah.robert.mg@gmail.com).

The type of data that will be shared: anonymous data from the initial questionnaire Dates of availability: until 01/01/2028

Whether consent from participants was required and obtained: authorization was required and obtained for each participant

Comments on data anonymization: data are anonymized with lyme survey Any ethical or legal restrictions: none

All personal data will be stored for 2 years in the active database and 15 years in the archiving database on two USB keys encrypted by the principal investigator (key no. 1.1 for the St-Denis household and key no. 1.2 for the Paris Tolbiac household). The data were collected using secure software (limesurvey).

IPD sharing plan summary

Available on request