

Research project on young people's health

Submission date 13/12/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/01/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/02/2023	Condition category Other	<input checked="" type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Poor health and poor access to the labour market go hand in hand. NEETs (young people not in employment, education, or training) are at higher risk for poorer mental and physical health, which can make it more difficult for them to get a job. Improving health, health behavior and access to healthcare might improve their access to training and employment. This study aims to test the efficiency of two programs that target young unskilled people from 18 to 25 years old.

Who can participate?

All young people aged 18 to 25 years who come to one of the five selected Missions locales a second time are invited to participate

What does the study involve?

The first intervention aims to optimize health coverage in order to reduce or eliminate financial barriers to health access. A social worker is in charge of finding the most advantageous coverage, assisting young people during their administrative processing and providing information on the French public health and private insurance systems. The second treatment consists of a double intervention. The first part is the same as the one described as the first intervention, but it is completed with medical consultations. Indeed, participants in this group are encouraged to visit the health professionals of the structure. During these visits, GPs and psychologists are in charge of providing information on the healthcare system and health, doing a global health check-up and sending participants to a specialist if need be.

What are the possible benefits and risks of participating?

Participants might have better health coverage and better health knowledge and consequently better access to healthcare, improving their health and we hope better access to training and therefore to work. No side effects are expected.

Where is the study run from?

The lead centre is Mission Locale de Sénart. The four other centres that take part in this trial are : Mission locale de Toulouse (antenne centre ville), Mission locale de Clichy Sous Bois, Mission locale de Poitiers, Mission locale de Reims.

When is the study starting and how long is it expected to run for?

March 2010 to April 2014

Who is funding the study?
Le Fond d'expérimentation de la jeunesse

Who is the main contact?
Pierre Chauvin
pierre.chauvin@inserm.fr

Contact information

Type(s)
Public

Contact name
Dr Sarah Robert

Contact details
Pierre Louis Institute for Epidemiology and Public Health (IPLESP/ INSERM UMR_S 1136)
Department of Social Epidemiology (ERES)
Faculté de Médecine Saint-Antoine
27 rue de Chaligny
Paris
France
75012

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PRESAJE

Study information

Scientific Title
Effects of a systematically offered social and preventive medicine consultation on training and health attitudes of young people not in employment, education or training (NEETs)

Acronym
PRESAJE

Study objectives
Poor health and poor access to the labour market go hand in hand. NEETs (young people not in employment, education, or training) are at higher risk for poorer mental and physical health, which can make it more difficult for them to get a job. Improving health, health behavior and access to healthcare might improve their access to training and employment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study protocol was approved by the competent French authorities, CNIL, in accordance with French legislation, 23/12/2011, No. 1527880

Study design

Unmasked randomised controlled parallel interventional multicentre study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

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

Professional training and social autonomy of unemployed youth

Interventions

This study, conducted in five Missions locales, aims at testing the efficiency of two programs. The randomisation was done using a computer-generated random list in the order of the inclusion of the participants. Both interventions target young unskilled people from 16 to 25 years old. The first intervention aims to optimize health coverage in order to reduce or eliminate financial barriers to health access. A social worker is in charge of finding the most advantageous coverage, assisting young people during their administrative processing and providing information on the French public health and private insurance systems. The second treatment consists of a double intervention. The first part is the same as the one described as the first intervention but it is completed with medical consultations. Indeed, participants randomized in this group are encouraged to visit the health professionals of the structure. During these visits, GPs and psychologists are in charge of providing information on the health care system and health, doing a global health check-up and sending participants to a specialist if need be. The intervention lasted for one year from 03/01/2011 to 02/01/2012 (one year). The follow-up was from the 03/01/2012 to the 02/01/2013 (one year).

Intervention Type

Behavioural

Primary outcome measure

Participation in a training session during the year following study inclusion, measured using a questionnaire at one year after inclusion

Secondary outcome measures

1. Access to employment during the year following study inclusion, measured using a questionnaire at one year after inclusion
2. Health status, health care, health knowledge, and health-related behaviours, measured using a questionnaire at one year after inclusion

Overall study start date

01/03/2010

Completion date

15/04/2014

Eligibility

Key inclusion criteria

All young people aged 18 to 25 years who come to one of the five selected Missions locales a second time were invited to participate

Participant type(s)

Other

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

A preliminary study estimated that 55% of the young people who visited the MLs participated in a training session during the year following the start of their follow-up. To detect a 10-point increase for each of the interventions in relation to the control group, it was estimated that 409 patients were needed in each group with a power of 90% and a type I (alpha) risk of 0.05 (one-sided test). The theoretical lost to follow-up rate was estimated at 15%. It was therefore necessary to include 481 patients in each group.

Total final enrolment

976

Key exclusion criteria

Participants were ineligible if they were unable to speak or understand French because the consent forms and questionnaire were provided only in French.

Date of first enrolment

03/01/2011

Date of final enrolment

02/01/2012

Locations

Countries of recruitment

France

Study participating centre

Mission locale de Sénart

462 rue Benjamin Delessert

Immeuble le Sextant

Moissy-Cramayel

France

77550

Study participating centre

Mission locale de Toulouse

54 B, rue Bayard

Toulouse

France

31000

Study participating centre

Mission locale de Clichy Sous Bois

4 Bis Allée Romain Rolland

Clichy-sous-Bois

France

93390

Study participating centre

Mission locale de Poitiers

30 Rue des Feuillants

Poitiers

France

86000

Study participating centre

Mission locale de Reims

34 Rue de Trianon

Reims
France
51100

Sponsor information

Organisation

Pierre Louis Institute for Epidemiology and Public Health (IPLESP/ INSERM UMR_S 1136)
Department of Social Epidemiology (ERES)

Sponsor details

Faculté de Médecine Saint-Antoine
27 rue de Chaligny
Paris
France
75012

Sponsor type

Research organisation

Website

www.iplesp.upmc.fr/eres

ROR

<https://ror.org/02qqh1125>

Funder(s)

Funder type

Government

Funder Name

Le Fond d'expérimentation pour la jeunesse

Results and Publications

Publication and dissemination plan

Plos One or BMC Public Health

Intention to publish date

01/01/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Pierre Chauvin (pierre.chauvin@inserm.fr). All data underlying the findings will be available without restriction. All relevant data will be deposited to Dryad as soon as the second article will be accepted in a peer reviewed journal. The consent form participants were asked by the research assistant at inclusion just before the randomisation. No comment on data anonymisation. No ethical or legal restriction was done by the CNIL (i.e. the French ethics committee).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/04/2019	08/04/2020	Yes	No
Dataset		01/05/2019	27/02/2023	No	No
Protocol article		26/04/2019	27/02/2023	Yes	No