The iBerry Study 3.0 - Research on social, psychological and physical development in youth.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON52243

Source
ToetsingOnline

Brief title
The iBerry Study 3.0

Condition

- Psychiatric disorders NEC
- Age related factors

Synonym
Psychiatric disorders

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,ESPRI-instellingen:

Yulius;BAVO Europoort;Antes;GGZ Breburg;GGZ WNB;GGZ Delfland

Intervention

Keyword: Epidemiology, Psychiatry, Youth

Outcome measures

Primary outcome

The main outcomes and determinants of the study are:

- Behavioral and emotional problems (self-report and parent/caretaker-report)

- Psychiatric disorders

- Mental health care use

- Financial problems

- Lifestyle and drug use

- Family characteristics

- Social support and exclusion / bullying

- Life events and traumatic experiences

- Personality

- Sexuality

- Sleep and activity

- Cognitive functioning

- Psychomotor functioning

Secondary outcome

Not applicable.

Study description

Background summary

In August 2014, the iBerry Study started the first phase of a longitudinal study on the development of psychiatric disorders in cooperation with the Center for Youth and Families in the Rijnmond region (MEC-2014-416). In high school, adolescents aged 12-14 years were screened on emotional and behavioral problems as part of standard preventive youth health care. This has resulted in a selection of adolescents in which adolescents with a problem score in the top 15% scores of emotional and behavioral problems were overrepresented. In the second phase of the iBerry Study, selected adolescents were invited for their first visit at the research center as part of the iBerry Study baseline measurement (MEC-2015-007).
A total of 1022 adolescents enrolled in the study, of which 728 with the highest problem scores and 294 randomly selected from the other adolescents. This method generated sufficient power to investigate various biological, psychological and social factors that contribute to the transition to (adult) psychiatric disorders.

Selected adolescents and their parents were invited for a first visit, the baseline measurement, to the iBerry research center in the second phase of the study (MEC-2015-007). Data on emotional and behavioral problems, physical health, lifestyle, family functioning, genetic profiles, sociodemographic background, use of care and cognitive profile were collected by administering interviews, questionnaires, neuropsychological tasks and physical measurements. The baseline measurement was completed in 2019, resulting in a total cohort of 1022 adolescents.

The first follow-up measurement started in March 2019 (T1). Part of the instruments used at the baseline measurement are repeated and additional age-appropriate instruments were added. Study details are described in the study protocol, MEC-2018-14472.

The current research protocol concerns the second follow-up measurement in the second phase of the iBerry Study (T2). This measurement will take place two to three years after the first follow-up measurement. The objective is to further identify key factors in the course of (sub)clinical psychiatric symptoms. By accurately mapping and monitoring (sub)clinical psychiatric symptoms, the iBerry Study aims to provide significant insight in the background and course of psychiatric disorders and to contribute to the development of preventive interventions.

Study objective

The iBerry Study has two main study objectives:

1. Descibing long-term prognosis of subclinical symptoms in terms of course (transition to several psychiatric disorders, chronicity, recurrence, comorbidiy) and public health consequences (disability, costs)
2. Examining genetic, biological and psychosocial determinants of the transition from subclinical symtoms to psychiatric disorders.

Study design

The iBerry Study is a prospective observational study.

Study burden and risks

Assessments in participating young adults consist of measurements by questionnaires, interviews and physical measurements (e.g. length, weight, blood pressure, actigraphy). The total time load of the visit will take no more than 3,5 hours. The actigraphy has an additional time load of 1 hour, divided over 9 days.
Assessments in participating parents/caretakers consist of measurements by questionnaires, interviews and physical measurements (e.g. length, weight, blood pressure). The total time load of the visit will take no more than 3,5 hours.
All measurements are performed by trained researchers.

Participants do not directly benefit from participation in the iBerry Study 3.0, apart from gratification by gift vouchers. Participation may indirectly lead to early detection of serious psychiatric conditions, for which effective treatment is availlable. When participants are diagnosed with serious psychiatric conditions with possible danger for themselves or others, they will be informed and advised to visit their general practitioner and request referral to mental health care specialists.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Young adult:
Participation in the iBerry Study, phase 2, baseline.
Written informed consent for approach follow-up research.
Written informed consent for participation in the iBerry Study 3.0.
Sufficient command of the Dutch language.

Parents/primary caretaker:
Parent or primary caretaker of adolescent that participated in the iBerry Study, phase 2, baseline.
Written informed consent for participation in the iBerry Study 3.0.
Sufficient command of the Dutch language.

Other informant:
Knows the young adult.
Written informent consent for participation in the iBerry Study 3.0.
Sufficient command of the Dutch language.

Exclusion criteria

Young adult:
Temporarily or full withdrawal of participation in the iBerry Study
Decease of the participant

There are no exclusion criteria for the parent/primary caretaker or the other informant.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-08-2021
Enrollment:	1050
Type:	Actual

Ethics review

Approved WMO Date:	14-06-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-07-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL76715.078.21