the iBerry Study 2.0 - Research in social, psychological and physical development in youth

Published: 29-11-2018
Last updated: 12-04-2024

The iBerry Study has two main study objectives:1. Describing long-term prognosis of sub-threshold symptoms in terms of course (transition to several psychiatric disorders, chronicity, recurrence, co-morbidity) and public health consequences (...

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

Summary

ID

NL-OMON55362

Source
ToetsingOnline

Brief title
the iBerry Study 2.0

Condition

- Psychiatric disorders NEC

Synonym
(Child) psychiatric disorders

Research involving
Human

Sponsors and support

Primary sponsor: Psychiatrie
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: Adolescents, Epidemiology, Psychiatry

Outcome measures

Primary outcome

- Behavioral and emotional problems in adolescents

- Psychiatric disorders

- Lifestyle and substance use

- Family characteristics (family coherence, parent-child interaction, conflict tactics, communication style)

- Social support and disclosure / bullying

- Genetics

- Epigenetics

- Haircortisol

- Life events

- Personality

- Sexuality

- Fysical characteristics (sleep and movement, quantitative sensory testing, advanced glycation end products)

Secondary outcome

N.A.

Study description

Background summary

In August 2014 the iBerry Study started the first phase of a longitudinal study in the development of psychiatric disorders, in cooperation with the Dutch Centre for Youth and Family in the Rijnmond region (MEC-2014-416). In high school, adolescents aged 12 to 14 years were screened on emotional and behavioral problems as part of standard preventive youth healthcare. In the second phase of the iBerry Study selected participants were invited for their first visit at the research center as part of the iBerry Study baseline measurement (MEC-2015-007). The current study is the first follow-up and takes place two to three years after baseline. The objective of the first follow-up is to further identify key factors in transition of sub-threshold symptoms to psychiatric disorders.

Study objective

The iBerry Study has two main study objectives:
1. Describing long-term prognosis of sub-threshold symptoms in terms of course (transition to several psychiatric disorders, chronicity, recurrence, co-morbidity) and public health consequences (disability, coststst)
2. Examining genetic, biological and psychosocial determinants of the transition from sub-threshold symptoms to psychiatric disorders

Study design

The iBerry Study is designed as a prospective observational study.

Study burden and risks

Assessments of participating adolescents consists of questionnaires, interviews, physical examination, respectively measurement of length, weight, skin fold, actigraphy, AGE-reader (advanced glycation end products), QST-measurement (quantitative sensory testing), venapuncture and collection of hair. All measurements are done child friendly under supervision of professionals. The total time load of the visit is no more than three hours. The actigraphy has an additional time load of 1,5 hour divided over 9 days (10 minutes per day)
Assessment in participating parents consists of questionnaires, interviews, physical examination, respectively measurement of length, weight, skin fold, AGE-reader (advanced glycation end products), QST-measurement (quantitative sensory testing), venapuncture and collection of hair. The total time load of the visit will take no more than three hours.
Participants in the iBerry Study 2.0 do not directly benefit from participation, apart from a small gratification (giftcard t.t.v.o. 35 euros in participation of all assessments). Participation may lead to early detection of serious psychiatric conditions, for which effective treatment is available. If a participant is diagnosed with a serious psychiatric condition with possible dangers for themselves or others, they will be informed and advised to see

their general practitioner and request referral for mental health care specialists.

Contacts

Public
Selecteer

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Selecteer

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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 2.0.

Exclusion criteria

Temporarily or full withdrawal of participation in the iBerry Study
Decease of the adolescent

Study design

Design

Study type:	Observational 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):	20-03-2019
Enrollment:	1120
Type:	Actual

Ethics review

Approved WMO Date:	29-11-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-04-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	25-02-2021
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	NL67275.078.18