The iBerry study *Interventions for Behavioral and Emotional Risk Reduction in Youth*
Phase 2: Baseline datacollection on determinants of the transition from subclinical symptomatology to psychiatric disorders

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The iBerry Study, phase 2, has two related main study objectives:1) Describing the long-term prognosis of sub-threshold symptoms in terms of course (transition to several full-blown psychiatric disorders, chronicity, recurrence, comorbidity) and...

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

Summary

ID

NL-OMON46968

Source
ToetsingOnline

Brief title
The iBerry study

Condition

- Psychiatric disorders NEC

Synonym
(Child) 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,Antes;Yulius;BAVO Europoort;GGZ Breburg;GGZ WNB;GGZ Delfland

Intervention

Keyword: Adolescents, Epidemiology, Psychiatry, Transition

Outcome measures

Primary outcome

Behavioral and emotional problems of youngsters

Psychiatric disorders

Lifestyle and substance use

Family characteristics (parent-child interaction, conflict tactics, family

coherence and communication style)

Social support and bullying

Sensation-seeking and impulsivity

Genetics

Epigenetics

Hair cortisol

Thyroid function

Metabolic parameters

Life events

Secondary outcome

Parental psychopathology

Demographic characteristics

Cognitive abilities

Somatic symptoms

Use of health care facilities

Study description

Background summary

Psychiatric disorders are among the most burdensome of all classes of disease, because of their high prevalence, their chronicity and their resulting serious impairment in individuals, families and society as a whole. The vast majority of psychiatric morbidity which manifests during adult life emerges for the first time before the age of 25 years, either evolving from childhood emotional and behavioral disorder, or appearing de novo from early adolescence through the mid-twenties. Next to these early ages of onset, disorders are often preceded by non-specific symptomatology with, albeit frequently mild, functional impairments in school performance, peer relationships and family relations. There is a high need of knowledge concerning individual biological, psychological and social factors that predict vulnerability and resilience to develop more effective preventive interventions.

Study objective

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

Study design

The iBerry Study is designed as a prospective cohort study including adolescents with (non-)specific symptomatology screened in the community, in whom psychosocial and biological risk and vulnerability factors are repeatedly measured. Central outcomes including all possible psychiatric disorders are measured in detail at baseline and after two, four, six, eight and ten years of follow-up in a cohort of 1,000 high-risk and 350 low-risk adolescents.

Study burden and risks

Assessments in participating youngsters encomprise questionnaires (maximum twice a year, maximum 30 minutes per questionnaire), an interview (maximum 35 minutes), cognitive and behavioral assessment (maximum 50 minutes including resting period), global physical examination (maximum 10 minutes), venapuncture and collection of hair. Measurements are child friendly and supervised by behavioral specialists (psychologists, psychiatrists).
Assessments in parents encomprise questionnaires (maximum twice a year, maximum 30 minutes per questionnaire), an interview (maximum 60 minutes), cognitive assessment (maximum 30 minutes), global physical examination (maximum 10 minutes) and venapuncture.
Participating minors and their parents do not directly benefit from participation, although they will receive some presents at the end of the assessments at the research center. Participation may lead to early detection of a serious psychiatric condition, for which effective treatment is available. Once one of the participations is diagnosed with a serious psychiatric disorder with possible danger for oneselves or others, they and their parents will be informed and advised to be referred (by the GP) to mental health care institutions.
This type of research cannot be restricted to participants above 18 years of age, since many psychiatric disorders have their onset in adolescence.

Contacts

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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

- Screenpositive or -negative based on the SDQ-Y score: a score within the highest 15% or a random sample from the lowest 85%
- Age: 12 years or older
- Written informed consent of (both) parents or legal caregivers
- Written informed consent by the adolescent
- Adolescent is able to speak and understand Dutch

Exclusion criteria

Participation in the Generation R Study

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:	Recruitment stopped
Start date (anticipated):	19-08-2015
Enrollment:	4050
Type:	Actual

Ethics review

Approved WMO Date:	02-07-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-02-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-09-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-07-2018
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	NL47209.078.14