Cohort study into Mood and Resilience in Offspring - the MARIO study

Published: 26-03-2019
Last updated: 07-03-2025

A longitudinal cohort of 550-600 children will be set up (10-25 years old, 450 children with and 100-150 children without a parent with mood disorders) on basis of already identified participants (parents) that are part of the NESDA, BiG, OPPER,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Mood disorders and disturbances NEC
Study type	Observational invasive

Summary

ID

NL-OMON54834

Source
ToetsingOnline

Brief title
MARIO cohort study

Condition

- Mood disorders and disturbances NEC

Synonym
Bipolar disorder, Depression

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Children of parents with mood disorders, Intergenerational transmission, Mood disorders, Resilience

Outcome measures

Primary outcome

- Depression diagnosis via the K-SADS (psychiatric interview) (Kaufman et al.,

1997)

- Symptoms of depression via the PHQ-9 (Kroenke et al., 2001)

Secondary outcome

- Diagnosis of other types of psychopathology via the K-SADS (Kaufman et al.,

1997)

- Mania symptoms derived from the screenings items of the K-SADS (Kaufman et

al., 1997) and the General Behavior Inventory (Depue et al., 1981)

- Dimensional psychopathology via the Adult/Youth Self report (Achenbach &

Rescorla, 2001)

- Functioning/Impairment based on the fatigue scale of PROMIS (Lai et al.,

2013)

Study description

Background summary

One of the most important risk factors for the development of depression is having a parent with a mood disorder (depression or bipolar disorder). In the Netherlands, there are approximately 400.000 children of parents with mood disorders between the age of 10 and 25 years. Of those, 50-65% develop a mood disorder before the age of 35, where daughters are two times more likely to suffer from a depression compared to sons. However, little is known about the intergenerational transmission of mood disorders. As preparation, we conducted

a systematic review to identify existing cohort studies. Results showed that existing cohortstudies have relatively small sample sizes, often do not measure the co-parent, often have no control group (that is, children of parents without mood disorders), rarely measure in a multidisciplinary fashion (that is, biological, psychological and social factors) and that there is little focus on resilience. The MARIO project will address those limitations to beter understand the development of depression in children of parents with mood disorders.

Study objective

A longitudinal cohort of 550-600 children will be set up (10-25 years old, 450 children with and 100-150 children without a parent with mood disorders) on basis of already identified participants (parents) that are part of the NESDA, BiG, OPPER, MOTAR, BINCO, NormQuest, IMAGE_AL, and BRIDGE studies.
Primary Objective: To investigate the risk and development of depression in children of parents with mood disorders compared to children of parents without mood disorders.
Secondary Objective(s): We have several secondary objectives. First, we want to study differences in biological and psychosocial risk and protective factors in children of parents with and without mood disorders. Second, we want to investigate mechanisms of the intergenerational transmission of depression from parents to children via biological and psychosocial risk and resilience factors. Lastly, given that depression has been shown to be more prevalent in girls with more chronicity compared to boys (Essau, Lewinsohn, Seeley, & Sasagawa, 2010), we also want to examine which factors contribute to the sex difference in the development of depression.

Study design

The study will be a longitudinal cohort study where children of parents with mood disorders (n=450) and children of parents without mood disorders (n=100-150) will be followed for 3 years. Both parents additionally report on psychopathology of the child. Moreover, the co-parent (partner of the index parents that participated in the NESDA, BiG, OPPER, MOTAR, BINCO, NormQuest, IMAGE_AL, or BRIDGE studies) will be assessed once to measure their level of psychopathology and care use.
All parents, if it are parents with or without mood disorders (i.e., at-risk versus control group) have exactly the same assessments. That means that co-parents always report over themselves and co- and index parents always report over the child, independent on whether they have a disorder (at-risk group) or not (control group).

Study burden and risks

Burden:

- Children will be invited twice (baseline and 3-year follow-up) for a measurement on-site where the following things will be administered: an interview about background, psychopathology and traumatic experiences, blood samples (if < 16 years: 16ml per assessment, so 32ml in total; if >= 16 years: 34ml at first assessment, 16 ml at second assessment, so 50 ml in total; this is to keep the burden for children under 16 years as low as possible), blood pressure, heart rate, BMI, Waist-to-Hip ratio, hair for for instance cortisol, and two sub-tasks of a cognitive test. Children will also fill in an evaluation form about the visit. This procedure will take about 4 hours.
- Children will fill in questionnaires at baseline and 1-3 year follow-up with questions about for instance psychopathology, negative life events, self image, and social support. This will take approximately 75 minutes (shorter in children under 12 years, as we deliberately only included half of the questionnaires for these children).
- Children will complete an ESM app at baseline and 1-3 year follow-up. This is a diary study in which children will fill in mini-questionnaires 5 times a day for 2 weeks (for example, where and with whom they are and what their mood is). This will take approximately 182 minutes. Children get to see their personal mood profile in the app for each time they participate in the ESM app. We will call participants after 2 days (5 min) to ask how they are completing the app and to inquire if they have any questions or encounter any problems. In addition, we also call participants who miss ten consecutive measurements to ask how the app is going (for example to find out if there are technical problems), if they have any questions and to motivate them to continue.
- Children are asked to download a passive app, Behapp at the 3-year follow-up assessment. This app measures social behavior such as calling, sending messages and moving from one location to another. This information is collected for 6 weeks with no identifiable data and is used to investigate the relationship between social behavior and mood symptoms.
- During the 3-year measurement, children will be asked to participate in an actigraphy measurement by means of wearing a geneactiv watch. This watch is worn day and night for 2 weeks to measure daily activity, movement and sleep.
- An interview will be conducted with the parents about psychopathology of the child. This will take approximately 60-120 minutes per child, based on the number of problems of the child. Parents will also fill in an evaluation form about the visit (baseline and 3-year follow-up)
- Parents fill in questionnaires about psychopathology (e.g., about depressive symptoms or autism) of the child. This takes approximately 30 minutes per child. (baseline and 1-3 year follow-up). At baseline parents will be asked to cooperate with DNA collection(10 min) when there is no DNA available from their previous participation in one of the cohort studies.
- The co-parent will fill in questions about his/her own psychopathology, pregnancy and delivery (if co-parent is a woman) and care use. This will take approximately 15 minutes (baseline)

Risks:
- During bloodcollection, participants can get bruises and can in rare cases

faint. Given that the bloodcollection will be performed by trained research assistants, this risk is relatively small.
- Questions about psychopathology and childhood trauma can be perceived as confronting. We however know from earlier research in our group (e.g. NESDA and BRIDGE) that this risk is relatively small. Moreover, answers can be discussed during the interview and general practitioners will be informed in case of suicidality or current abuse. We have a detailed protocol in case of worrying situations like suicidality or child abuse (see pages 40-41 in the protocol).

Contacts

Public
Vrije Universiteit Medisch Centrum

Oldenaller 1
Amsterdam 1081HJ
NL
Scientific
Vrije Universiteit Medisch Centrum

Oldenaller 1
Amsterdam 1081HJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

- Child is between the age of 10 - 25 years
- Children recruited from the BRIDGE study are between the age of 10-32 years
- Parent participated in one of the following four cohort studies: NESDA, BiG, OPPER, MOTAR,
BINCO or NormQuest. Or child has participated in cohort study BRIDGE or IMAGE_AL
- Written informed consent of child and parent (depending on the age of the child)
- Fluent in Dutch

Exclusion criteria

- Child is not biological child of the index parent
- Subjects with a cognitive impairment, sufficient to interfere with their ability to provide informed consent or complete study questionnaires (based on parent information; IQ < 70)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-11-2019
Enrollment:	1650
Type:	Actual

Ethics review

Approved WMO Date:	26-03-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-09-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-08-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-04-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-02-2025

Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL66596.029.18