RE-PAIR: the relation between parent-adolescent interactions and depressive symptoms in adolescents

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

Summary

ID

NL-OMON52729

Source
ToetsingOnline

Brief title
RE-PAIR

Condition

- Mood disorders and disturbances NEC
- Family issues

Synonym
Depression, Major Depressive Disorder (MDD)

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: NWO VICI grant

Intervention

Keyword: Adolescent, Depression, Parent-child interaction, Parents

Outcome measures

Primary outcome

We will study the quality of the parent-child interactions, primarily based on

the influence of parental criticism and empathy and the adolescent's mood.

We will also investigate the predictive value of the interactions on the course

of the complaints of the adolescents, controlled for possible treatment.

Secondary outcome

N.A.

Study description

Background summary

Depression rates sharply increase during adolescence. Negative parent-child interactions are proposed to be an important risk factor in the development and maintenance of depressive symptoms in youth. To date, details about the role of negative parent-child interactions in the development of youth*s depressive symptoms and the impact on the adolescent brain are lacking. This underlines the importance to study the potentially bi-directional interplay between adolescent depression and parent-child interactions. As indicators of negative parent-child interactions we will specifically focus on parental criticism, lack of empathy and support.

Study objective

The primary purpose of this study is to determine how excessive parental criticism and lack of empathy affects the emotional and neural development during adolescence and whether there are bidirectional influences between parent-child interactions and depressive symptoms in youth. The bidirectional relationship between negative parent-child interactions and adolescent depressive symptoms will be studied in adolescents with and without MDD and their parents, by using an intergenerational, multi-method approach. This approach will yield valuable new information on this topic and will be very

useful to identify key targets for interventions that will focus on the improvement of parent-child interactions and the diminishment of depressive symptoms in youth. In addition, we will study whether particular factors (i.e. parent-adolescent interactions, but also treatment) have a predictive value for the course of complaints and the depressive symptoms of the adolescents.

Study design

The present observational study will recruit adolescents and their both parents. The depressive adolescents will be recruited via practitioners in the clinical setting, via the GGD and via an interview in the local media. The healthy adolescents will be recruited via schools, public areas and social media. They will visit the lab for one day, during which they will participate in several interaction-tasks between adolescents and their parents. Additionally, participants will be asked to fill out electronic diaries for a period of 14 consecutive days about their mood and the quality of social interactions and a part of the adolescents and parents will be invited to undergo an MRI scan. After half a year, a year and two years participants will be approached to completed a few additional questionnaires.

Study burden and risks

After signing the informed consent, adolescents and both their parents will visit the lab for one day. Most of the tasks and questionnaires do not burden the participants at all and do not include any risks. The interaction-tasks between family members are often experienced as very positive, as well as the electronic diaries they have to fill out during the study. Parents and adolescents will be asked to fill out a short questionnaire for at least 4 times a day, during fourteen consecutive days. This will take them approximately 3 minutes per questionnaire. Besides, they will receive a lunch during the lab visit, travel funds and a financial compensation. Part of the adolescents and parents in the study will be invited to undergo an fMRI scan at the LUMC. The duration of the scan session will be approximately 3 hours. Although the loud noises of the scanner and the limited space in the scanner might be unpleasant for the participants, there are no health risks involved by this method. After half a year, a year and two years after the research day, participants will be asked to fill in a few questionnaires again via a link on their own computer. This component does not involve any risks.

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)

Inclusion criteria

Inclusion criteria:, Adolescents in depressive group:
• Aged between 11-17 years.
• Living with at least one primary caregiver
• At least one primary caregiver is willing to participate in the study
• Current depressive episode (having symptoms at least 2 months prior to the diagnostic interview)
• Major depressive disorder as primary diagnosis, Adolescents in control group:
• Aged between 11-17 years.
• Living with at least one primary caregiver
• At least one primary caregiver is willing to participate in the study

Exclusion criteria

Adolescents with major depressive disorder:
• Primary psychiatric disorder (Axis I), other than MDD.
• Comorbid eating disorders/mental retardation/psychoses/addictions (SUD)

• Use of antidepressants (i.e. SSRIs or TCAs), unless in a constant dosage.
• No good command of the Dutch language, Adolescents in the control group:
• Current psychiatric disorder
• History of psychiatric disorder in the past two years
• Lifetime depressive episode
• History of psychotherapy or other psychological treatment
• No good command of the Dutch language
• Use of medication for mental disorders or sleep medication, Additional fMRI exclusion criteria:
• Metal implants, clips, stents, or pacemakers
• Braces
• Current pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-06-2018
Enrollment:	480
Type:	Actual

Ethics review

Approved WMO

Date:	02-05-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	02-11-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	03-10-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	12-02-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	25-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	10-03-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL62502.058.17