ISRCTN97724780 https://doi.org/10.1186/ISRCTN97724780

Disruptive mood and emotional conflict resolution in adolescent children of parents with recurrent depression or bipolar disorder and healthy controls

Submission date
30/07/2015

Recruitment status
No longer recruiting

Registration date
20/08/2015

Overall study status
Completed

Last Edited
19/08/2015

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Mood disorders are psychological disorders which cause the elevation or lowering of a person's mood, the most common examples of which are depression (major depressive disorder or unipolar depression) and bipolar disorder. It has been widely shown that mood disorders in parents may have an effect on the mental health of their children, increasing the risk of developing mental disorders. Examples of such are Severe Mood Dysregulation Disorder (SMDD) and Disruptive Mood Dysregulation Disorder (DMDD), which are characterised as severe and persistent irritability.
It has also been suggested that these children would not perform as well as children of healthy parents in conflict resolution tasks.
This study aims to find whether adolescent children of parents suffering from unipolar or bipolar disorder are more likely to show signs of mental disorders (such as DMDD and SMDD) compared to adolescent children of healthy parents. Additionally, the study aims to test how adolescent children of parents suffering from unipolar or bipolar disorder perform at conflict resolution tests than adolescent children of healthy parents.

Who can participate?
Adolescent children of adults with depression or bipolar disorder and adolescent children of healthy adults (control group)

What does the study involve?
Parents complete a number of questionnaires in order to assess their mental state. The adolescent offspring of both healthy parents and parents with unipolar/bipolar disorder complete further questionnaires to find out how many are affected by SMDD and DMDD. They are then shown a series of pictures of faces showing different emotions, as well as shapes and letters in various colours. The time it takes for them to respond to these pictures and letters is then measured.

What are the possible benefits and risks of participating?
The main benefit of pariticipating for both parents and adolescents will be knowledge gained on disorders and their effects.There are no notable risks of participating.

Where is the study run from?
Abant Izzet Baysal University Medical Faculty, Department of Psychiatry (Turkey)

When is the study starting and how long is it expected to run for?
February 2015 to February 2016

Who is funding the study?
Abant Izzet Baysal University Medical Faculty (Turkey)

Who is the main contact?
1. Dr. Evran Tufan (scientific)
2. Dr. Zehra Topal (public)

Contact information

Type(s)
Public

Contact name
Dr Zehra Topal

Contact details
Ars. Gor. Dr. Zehra Topal, Abant Izzet Baysal Universitesi Tip Fakultesi
Izzet Baysal Ruh Sag. ve Hst. Egt. Ars. Hastanesi Cocuk Psikiyatri Poliklinigi
Agacli Mevkii
Bolu
Türkiye
14300

Type(s)
Scientific

Contact name
Dr Evren Tufan

ORCID ID
http://orcid.org/0000-0001-5207-6240

Contact details
Abant Izzet Baysal Universitesi Tip Fak.
Izzet Baysal Ruh Sag. ve Hst. Egt. ve Ars. Hst. Cocuk Psikiyatri Poliklinigi
Agacli Mevkii
Bolu
Türkiye
14300

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2015/ 48

Study information

Scientific Title
Rates of psychopathology including Disruptive Mood Dysregulation Disorder and emotional conflict resolution among adolescent children of parents with recurrent Major Depressive Disorder versus those with Bipolar Disorder and matched healthy controls

Study objectives
1.That Severe Mood Dysregulation Disorder (SMDD)/Disruptive Mood Dysregulation Disorder (DMDD) diagnoses would be significantly more common among adolescent offspring of parents with mood disorders as a group compared to healthy controls.
2. That Severe Mood Dysregulation Disorder (SMDD)/Disruptive Mood Dysregulation Disorder (DMDD) diagnoses would be related with emotional conflict resolution as reflected in response latencies and errors in an emotional stroop paradigm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Abant Izzet Baysal University Clinical Research Ethics Committee, 10/06/2015, ref: 2015/48.

Study design
Single-centre observational cross-sectional case-control study.

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Disruptive Mood Dysregulation Disorder

Interventions
Parents' psychological status is evaluated with Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I). All parents will then complete SCL-90R, State-Trait Anxiety Inventory- Trait Version, General Functioning Subtest of the Family Assessment Scale, and Childhood Trauma Questionnaire- 28.
The psychological status of adolescents are evaluated with the Kiddie-Sads-Present and Lifetime Version (K-SADS-PL). Additionally SMDD Module as well as DSM-5 criteria for DMDD will be screened. They also complete Children's Depression Inventory, State-Trait Anxiety Inventory- Trait Version, Childhood Trauma Questionnaire- 28. Neuropsychological evaluations are Stroop Color Word Test- TBAG Form and Emotional Stroop (word-face) paradigm. The visual component of the emotional stroop was formed from pictures in the NIMH Child Emotional Faces Picture Set (NIMH-ChEFS) and the verbal component from TUDADEN (Affective Norms of Turkish Words). Also, the pubertal status will be evaluated with self-report via Turkish translation of the Carskadon Puberty Scale.

Intervention Type
Behavioural

Primary outcome measure
Reaction speed of adolescents in three groups (unipolar offspring, bipolar offspring, healthy controls) in emotional stroop trials (in milliseconds)

Secondary outcome measures
1. Reaction speeds of adolescents in three groups (unipolar offspring, bipolar offspring, healthy controls) in Stroop Color Word Test - TBAG Form (in milliseconds)
2. Rates of psychopathologies (including DMDD) according to structured interviews (K-SADS-PL)

Overall study start date
26/02/2015

Completion date
26/02/2016

Eligibility

Key inclusion criteria
For parents (in unipolar/bipolar groups):
1. Aged between 30- 65 years
2. Recurrent Major Depressive Disorder or Bipolar I/ II diagnosis (ascertained via SCID- I),
3. Followed at the outpatient department of Psychiatry of Abant Izzet Baysal University Medical Faculty,
4. Are in remission (CGI-S ≤ 2, YMRS ≤ 5, HAM-D-17 ≤ 7)

For parents in control group:
1. Have brought their adolescent offspring for acute somatic symptoms to the pediatrics outpatient department of Abant Izzet Baysal University Medical Faculty within the study period
2. Are free of lifetime psychopathology (ascertained via SCID-I)

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
3 groups (unipolar offspring, bipolar offspring and healthy controls) with a total of 96 adolescents (32 each).

Key exclusion criteria
For parents (in unipolar/bipolar groups):
1. Active disorder (CGI-S > 2, YMRS > 5, HAM-D-17 > 7)
2. Epilepsy/chronic neurological disorders/mental retardation
3. Active psychotic symptoms
4. Illiteracy

For parents in control group:
1. Life time history of psychopathology
2. Epilepsy/chronic neurological disorders/mental retardation
3. Illiteracy

For adolescent offspring:
1. Epilepsy/chronic neurological disorders/mental retardation
2. Illiteracy

Date of first enrolment
27/07/2015

Date of final enrolment
02/11/2015

Locations

Countries of recruitment
Türkiye

Study participating centre
Abant Izzet Baysal University Medical Faculty, Department of Psychiatry
Abant Izzet Baysal Universitesi Tip Fakultesi Hastanesi
Psikiyatri AD Poliklinigi
Golkoy
Bolu
Türkiye
14280

Study participating centre
Abant Izzet Baysal Universitesi Tip Fakultesi
Izzet Baysal Ruh Sagligi ve Hast. Egt. Ars. Hastanesi
Cocuk Psikiyatri Poliklinigi, Agacli Mevkii
Bolu
Türkiye
14300

Sponsor information

Organisation
Abant Izzet Baysal University Medical Faculty

Sponsor details
Abant Izzet Baysal Universitesi Tip Fakultesi Dekanligi
Morfoloji Binasi
Golkoy
Bolu
Türkiye
14280
+90 3742534568
aibutipfakultesi@gmail.com

Sponsor type
University/education

Website
http://tip.ibu.edu.tr/

ROR
https://ror.org/01x1kqx83

Funder(s)

Funder type
University/education

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Dr. Topal will complete and defend her Dissertation in February 2016. Thereafter, a complete version of the Dissertation in Turkish will be stored in the Electronic Dissertation Database of Council of Higher Education of Turkey (https://tez.yok.gov.tr/UlusalTezMerkezi/ or https://tez.yok.gov.tr/UlusalTezMerkezi/giris.jsp (webpage in English)). We plan to present the results of primary and secondary analyses in 2016 as new research posters and to complete the final manuscript and submit it to a peer reviewed journal at the end of 2016 at the latest.
Post-hoc analyses will focus on the relationships between general psychopathology/ trait anxiety in family members, family functioning, traumatic experiences and DMDD symptoms in offspring. They will be conducted in 2016 and will be presented/disseminated in 2017. Please note that we will also define a priori hypotheses before undertaking any of the post-hoc analyses (e.g. trait anxiety in parents will be positively correlated with trait anxiety in offspring and negatively correlated with family functioning, traumatic experiences in parents will be positively correlated with threat bias in offspring etc.).

Intention to publish date

31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date