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Examining the ora-dental health of children with ADHD

Submission date
05/12/2017

Recruitment status
No longer recruiting

Registration date
08/12/2017

Overall study status
Completed

Last Edited
13/01/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Attention-Deficit Hyperactivity Disorder (ADHD) is a disorder that causes inattentiveness, hyperactivity and impulsiveness. Children with ADHD often experience additional problems including sleep and anxiety. ADHD is often treated with medications. There are only a few studies about ora-dental health of children with ADHD and these studies presented conflicting results. Children with ADHD might have higher dental fear and higher caries (cavities) risk, and associated oral and dental health variables might show differences when compared with the healthy children. Medicated children with ADHD might have higher dental fear and exhibit worse ora-dental health than the control group. The aim of this study is to determine the ora-dental health and its relation with medication and dental fear in a group of Turkish children with ADHD.

Who can participate?
Children aged 6-15 years old who are diagnosed with ADHD.

What does the study involve?
Participants are assessed for their overall dental health at the first appointment. Dental treatment needs are determined and treatment appointments are organised. According to the dental fear scale sores appropriate dental behaviour management is decided applicable during dental treatment. Oral hygiene practice and anticariogenic diet informations are given to each patient.

What are the possible benefits and risks of participating?
Participants may benefit from having detailed information about your ora-dental health, caries risk factors and preventive strategies. There are no any direct risks for the patients participating in the study.

Where is the study run from?
Istanbul University (Turkey)

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

Who is funding the study?
The Research Support Unit of Istanbul University (Turkey)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
project no. 2172.

Study information

Scientific Title
Examining the ora-dental health and its relation with medication and dental fear in a group of Turkish children with attention deficit hyperactivity disorder

Acronym
ADHD

Study objectives

The objective of this study is to determine the ora-dental health and its relation with medication and dental fear in a group of Turkish children with ADHD.

Hypothesis:
1. Children with ADHD might have higher dental fear and higher caries risk, and associated oral and dental health variables might show differences when compared with the healthy children.
2. The medicated children with ADHD might have higher dental fear and exhibit worse ora-dental health than the control group.

Null hypothesis:
The children with ADHD (medicated or not) didn't have dental fear and show similar ora-dental health like healthy children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Istanbul University Clinical Research Ethics Committee, 22/08/2014, ref: no: 1281

Study design
Observational cross-sectional comparative research

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
The objective of this study was to determine the ora-dental health and its relation with medication and dental fear in a group of Turkish children with ADHD.

Interventions
Participants are recruited from a clinical sample of children aged 6-15 years who are consecutively referred to an outpatient children and adolescents psychiatry clinic in Istanbul, Turkey - between 04/05/2015 and 30/03/2016 and diagnosed with ADHD. ADHD diagnosis is made according to DSM-V (American Psychiatric Association, 2013) (25) criteria and healthy children (who didn't have any systemic disorder, mental or any other psychological diorders) constituted as non-ADHD (control group).

Before initiation of the study, participant consent forms are received from children and their parents who accepted to participate in the study. A similar age and gender distribution is taken into account in the control group. The exclusion criteria were the presence of confounding medical history, a severe mental health or any other psychological disorders.

After psychological assessment, participants are referred to the Istanbul University Faculty of Dentistry, Department of Pedodontics for oral and dental examinations.

First, the levels of dental fear of children are determined with “The Dental Subscale of Childrens Fear Survey Schedule (CFSS-DS)” in the pediatric dental clinic. The CFSS-DS consists of 15 items, related to the different aspects of dental treatment. The possible item responses range from 1 (not afraid at all) to 5 (very afraid), giving a range of possible scores of 15–75. Points between 15-32 indicate low, 32-38 refer to moderate level of fear and >39 were defined as dentally anxious.

Additionally, several factors that could be related to the caries risk are questioned through a survey, including socioeconomical status, frequency of dental follow-up, frequency of sugary snacks intake, fluoride program, frequency of toothbrushing, medication and the persistence of parafunctional habits (bruxism, tumbsucking, pacifier sucking, nail biting etc). The questionnaire is replied with the parents/children by face to face interviewing.

After the surveys had been completed, stimulated saliva samples are collected and laboratory study and culture procedures were performed in Istanbul University, Faculty of Dentistry, Department of Microbiology. Salivary flow rate, buffering capacity, MS, LB, and yeasts were counted. The saliva sample was collected before the dental examination, and participants were asked to refrain from eating, drinking, tooth brushing, and rinsing their mouths for at least 1 h before saliva collection.

Oral and dental health evaluation were performed by an experienced pediatric dentist, using a dental mirror, dental explorer, and a World Health Organization (WHO) periodontal probe. df(t) /df(s); DMF(T)/DMF(S) index score, the presence of white spot lesions, periodontal status (Silness Löe plaque index, bleeding index, probing pocket depth) were recorded.

Plaque index was scored as (0= PI < 0.4, 1= PI =0.4-1, 2= PI =1.1-2.0, 3= PI > 2), saliva flow rate (SFR) as (0= SFR > 1.1 ml, 1=SFR=0.9-1.1ml, 2=SFR= 0.5-0.9 ml, 3= SFR < 0.5 ml), buffering capacity (BC) as (0=BC= pH < 6, 1=BC= 4.5-5.5, 2=BC= pH < 4), mutans streptococci(MS) as (0=MS= Low < 105 cfu/ml, 1= MS=Medium 105-106 cfu/ml, 2=MS= High > 106 cfu/ml), lactobacillus (LB) as (0=LB= Low < 104 cfu/ml, 1=LB= Medium 104-105 cfu/ml, 2=LB= High > 105 cfu/ml) and candida (C) as (0= C=Low < 103 cfu/ml, 1=C= Medium 103-104 cfu/ml, 2= C=High > 104 cfu/ml).

All data is entered into a computer-based program, the Cariogram, and caries risk profiles of all children were determined as previously described (27,28). The following five Cariogram categories were used: “very low risk” = 81-100% chance to avoid caries; “low risk” = 61-80% chance to avoid caries; “moderate risk” = 41-60% chance to avoid caries; “high risk” = 21-40% chance to avoid caries; and “very high risk” = 0-20% chance to avoid caries.

Ora-dental health variables are compared with the children with ADHD and without ADHD. The groups were also analyzed in accordance with dental fear and medication.

Intervention Type
Other

Primary outcome measure
1. Levels of dental fear are measured using the CFSS-DS at the first appoinment for dental examination.
2. Caries risk are measured using a questionnaire consisting several factors that could be related to the caries risk were questioned through a survey, including socioeconomical status, frequency of dental follow-up, frequency of sugary snacks intake, fluoride program, frequency of toothbrushing, medication and the persistence of parafunctional habits (bruxism, tumbsucking, pacifier sucking, nail biting etc) was replied with the parents/children by face to face interviewing at the first appoinment for dental examination
3. Plaque index values were measured using Silness Löe plaque index at the first appoinment for dental examination
4. Bleeding is measured using the modified Sulcus Bleeding index, probing pocket depth at the first appoinment for dental examination
5. Caries activity are measured using the DMF(T)/DMF(S) indexes (WHO), saliva flow rate, saliva buffering capacity, MS, LB, yeast counts) was applied at the first appoinment for dental examination
6. Caries risk profiles of all children are determined with a computer-based program, the Cariogram, at the first appoinment for dental examination

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
02/01/2015

Completion date
30/12/2016

Eligibility

Key inclusion criteria
1. Children aged 6-15 years who are consecutively referred to an outpatient children and adolescents psychiatry clinic in Istanbul, Turkey - between 04/05/2015 and 30/03/2016
2. Diagnosed with ADHD. ADHD diagnosis is made according to DSM-V (American Psychiatric Association, 2013) (25) criteria and healthy children (who didn’t have any systemic disorder, mental or any other psychological diorders) constituted as non-ADHD (control group)
3. Consent to participate from children and their parents

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
A total of 117 children was included in the study with 58 children aged between 6-15 years, diagnosed with ADHD and 59 healthy children who have no any psychiatric diagnosis and systemic disorders.

Key exclusion criteria
1. The presence of confounding medical history
2. A severe mental health or any other psychological disorders

Date of first enrolment
04/05/2015

Date of final enrolment
30/03/2016

Locations

Countries of recruitment
Sudan

Suriname

Türkiye

Study participating centre
Istanbul University
Faculty of Dentistry
Department of Pedodontics
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34093

Study participating centre
Bakirkoy Training and Research Hospital for Mental Health and Neurological Disorders
Department of Child and Adolescent Psychiatry
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Study participating centre
Yedikule Surp Pırgiç Armenian Hospital
Clinical Psychology Department

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Sponsor type
University/education

ROR
https://ror.org/03a5qrr21

Funder(s)

Funder type
University/education

Funder Name
The Research Support Unit of Istanbul University

Results and Publications

Publication and dissemination plan
Planned to submit to Nigerian Journal of Clinical Practice.

Intention to publish date
30/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Assoc. Prof. Arzu Pınar-Erdem aperdem@gmail.com.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/08/2018	13/01/2022	Yes	No