

# Examining the ora-dental health of children with ADHD

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<b>Registration date</b> 08/12/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/01/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 scores 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?  
Professor Arzu Pinar Erden (Scientific)  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
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 oral-dental health than the control group.

Null hypothesis:

The children with ADHD (medicated or not) didn't have dental fear and show similar oral-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

### **Study type(s)**

Diagnostic

### **Health condition(s) or problem(s) studied**

The objective of this study was to determine the oral-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 disorders) 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, tumbucking, 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 Loe 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(s)**

1. Levels of dental fear are measured using the CFSS-DS at the first appointment 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, tumbucking, pacifier sucking, nail biting etc) was replied with the parents/children by face to face interviewing at the first appointment for dental examination
3. Plaque index values were measured using Silness Loe plaque index at the first appointment for dental examination
4. Bleeding is measured using the modified Sulcus Bleeding index, probing pocket depth at the first appointment 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 appointment for dental examination

6. Caries risk profiles of all children are determined with a computer-based program, the Cariogram, at the first appointment for dental examination

**Key secondary outcome(s)**

There are no secondary outcome measures.

**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 disorders) constituted as non-ADHD (control group)
3. Consent to participate from children and their parents

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 years

**Upper age limit**

15 years

**Sex**

All

**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

Istanbul

Türkiye

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 Pırgıç Armenian Hospital**

Clinical Psychology Department

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## **Sponsor information**

**Organisation**

Istanbul University

**ROR**

<https://ror.org/03a5qrr21>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

The Research Support Unit of Istanbul University

## Results and Publications

**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 Pinar-Erdem [aperdem@gmail.com](mailto:aperdem@gmail.com).

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		30/08/2018	13/01/2022	Yes	No