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# Intervention to reduce stressful emotions in children scheduled to undergo surgery

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 29/12/2022 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 30/01/2023 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 30/01/2023 | Mental and Behavioural Disorders | [ ] Record updated in last year |

**Plain English summary of protocol**

Background and study aims

Children who undergo surgical and endoscopic procedures display high levels of stress, and various means are applied to reduce anxiety. Salivary cortisol is often used as a valid biomarker of stress. The aim of this study is to determine whether the application of the Theory of Planned Behavior (TPB) as an intervention to parents could ultimately reduce stress levels in children who undergo surgical or endoscopic procedures, as measured through salivary cortisol levels, and whether parents would be willing to allow their children to participate in the diagnostic procedure of saliva collection.

Who can participate?

Children scheduled to undergo surgical and endoscopic procedures and their parents

What does the study involve?

Participants were divided into two groups: Explained and Unexplained. The Explained Group comprised children and one of their parents who, after completion of the questionnaire, were provided with information concerning the entire procedure. After this training, parents communicated the given information to their children. The second, the Unexplained Group, included children and one of their parents who after completing the questionnaire received no explanation related to the surgical or endoscopic procedure. Three saliva samples were collected during the following hours: 7:00 a.m. – 9:00 a.m. in the clinic room; 9:00 a.m. – 12:00 a. m. just before anesthesia administration; and 5:00 p.m. – 7:00 p.m.

What are the possible benefits and risks of participating?

Providing proper education and information for parents may have a positive effect on reducing children's stress levels. Changing parental attitudes towards saliva collection plays the most important role, since a positive attitude can influence intention and ultimately participation in these procedures.

Where is the study run from?

University General Hospital Attikon (Greece)

When is the study starting and how long is it expected to run for?
January 2020 to January 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Nikolaos Zavras, nzavras@med.uoa.gr

# Contact information

### Type(s)
Principal investigator

### Contact name
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# Additional identifiers

### Protocol serial number
456

# Study information

### Scientific Title
The planned behavioral theory as an interventional tool to reduce stress in children undergoing surgical and endoscopic procedures as proved by salivary cortisol

### Acronym
PBT

### Study objectives
To investigate the Planned Behavioral Theory as a tool to reduce stress levels in children who are undergoing surgical or endoscopic procedures, as measured through salivary cortisol levels, and whether parents would be willing to allow their children to participate in the diagnostic procedure of saliva collection

### Ethics approval required

Old ethics approval format

## Ethics approval(s)
Approved 18/02/2020, Scientific Board of the Attiko University General Hospital (1 Rimini Str, Haidari, Athens, 12462, Greece; +30 (0)2105831000; politis@attikonhospital.gr), ref: EBΔ753/12-12-2019

## Primary study design
Observational

## Study design
Prospective observational case-control study

## Study type(s)
Quality of life

## Health condition(s) or problem(s) studied
Stress reduction

## Interventions
Consecutive children scheduled to undergo a surgical operation or endoscopy (gastroscopy or coloscopy, or both) were recruited. The patients were divided into two groups: Explained and Unexplained. The Explained Group comprised children and one of their parents who, after completion of the questionnaire, were provided with information concerning the entire procedure. After this training, parents communicated the given information to their children. The second, the Unexplained Group, included children and one of their parents who after completing the questionnaire received no explanation related to the surgical or endoscopic procedure.

Three saliva samples were collected during the following hours: 7:00 a.m. – 9:00 a.m. in the clinic room; 9:00 a.m. – 12:00 a.m. just before anesthesia administration; and 5:00 p.m. – 7:00 p.m.

## Intervention Type
Behavioural

## Primary outcome(s)
Salivary cortisol concentration in children measured using commercially available kits. Three saliva samples were collected during the following hours: 7:00 a.m. – 9:00 a.m. in the clinic room; 9:00 a.m. – 12:00 a.m. just before anesthesia administration; and 5:00 p.m. – 7:00 p.m.

## Key secondary outcome(s)
Parental intention measured at 7.00-9.00 am (on admission) using 18 items divided into the following sub-scales:
1. Intention: the assessment of parental intention towards saliva collection included three items based on a seven-point Likert scale, with 1 as unlikely and 7 likely. Higher mean scores indicated parental intention
2. Attitude: this subscale concerns parental attitudes towards saliva collection with eight items, four of which focus on salivary biomarkers, and four on whether saliva sampling affects general health. All items were based on a seven-point Likert scale. 1: unpleasant/stressful. ...7: pleasant /significant
3. Subjective norms: included items regarding parental perception of subjective norms, which

regard agreement or disagreement with the advice and prescriptive norms about saliva collection
4. Perceived behavioural control: Three items assessed parental perception regarding their ability to control saliva collection. More specifically, they evaluated perceived behavioural control as self-efficacy assessing the extent that adults perceive themselves as capable of showing behaviour, as graded on a seven-point Likert scale, of how at ease they felt regarding their children's participation in the collection of saliva. The answers ranged from 1: extremely difficult to 7: extremely high sense of control

### Completion date
01/01/2022

## Eligibility

### Key inclusion criteria
1. Children scheduled to undergo surgical and endoscopic procedures and their parents
2. Ability to understand and participate in the research procedures

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Child

### Sex
All

### Total final enrolment
60

### Key exclusion criteria
1. Children with a history of previous surgery or endoscopy, liver, renal, cardiac, pulmonary, neurological, and psychological diseases
2. Children who received steroids

### Date of first enrolment
01/03/2020

### Date of final enrolment
01/01/2022

## Locations

### Countries of recruitment
Greece

**Study participating centre**
**University General Hospital Attikon**
1 Rimini Str
Haidari
Greece
12462

# Sponsor information

**Organisation**
University General Hospital Attikon

**ROR**
https://ror.org/03gb7n667

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated and/or analysed during the current study are/will be available upon request from Zavras Nikolaos (nzavras@med.uoa.gr).
Type of data: all data gathered during the processes of the study
Dates of availability: Data will be available upon request within a reasonable timeframe
Consent was obtained from all participants
No ethical or legal restrictions arose

**IPD sharing plan summary**
Available on request