

Intervention to reduce stressful emotions in children scheduled to undergo surgery

Submission date 29/12/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/01/2023	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/01/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

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

Study design

Prospective observational case-control study

Primary study design

Observational

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

