

STUDY TITLE:

PREVENTION OF DEPRESSION AND BULLYING IN ADOLESCENTS BY MEANS OF AN
INTERVENTION BASED ON IMPLICIT THEORIES OF PERSONALITY

PROJECT NUMBER:

PSI2015-68426-R

(Ministry of the Economy and Competitiveness, Spanish Government)

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This consent form provides information about a research project that is being conducted at your child's school in collaboration with the University of Deusto and that aims to find new ways to help students reduce their stress, improve their daily mood, their physical and psychological health, and their academic performance. Below you will find all the relevant information about the project. Please complete the attached consent form on page 5 and give the document to your son/daughter to complete the student's consent form on page 6. Please return both forms via your child to the school within a maximum of **three days**.

Purpose of the project:

During secondary school, students may face potentially stressful events such as academic pressure, arguments with classmates, etc., which may affect their health and physical and psychological well-being as well as their academic performance. For this reason, the objective of this project is the evaluation of an educational intervention to prevent adolescents' stress and improve their well-being. The intervention has been very successful in other countries and now we have the opportunity to adapt it and use it in our culture. The intervention takes place in a single session of about 50 - 60 minutes. We employ two intervention formats to which the students are randomly assigned. The intervention consists of reading scientific texts about the functioning of the human mind and its possibilities of change, testimonials from students who have previously taken part in the intervention, as well as written reflections about the readings.

In order to assess the benefits of the intervention, measures will be collected through questionnaires, and three hormone levels indicative of stress responses will be examined by collecting students' saliva. Although this may seem unusual, it is actually a common research approach.

We believe that this study has a huge potential to reduce stress and for adolescents to learn how the human mind works. All the students in your child's class have received the invitation to participate, and it is estimated that the investigation will involve up to a total of **1000** students.

1. What will my child be asked to do?

If you allow your child to participate in this study, he/she will be asked to:

- Participate in the educational intervention. There are two versions of the intervention with similar activities, and students will be randomly assigned to one of the two versions, which will allow us to assess which one is more effective. The intervention will consist of reading scientific texts about the functioning of the human mind and its possibilities for change, testimonials from students who have previously taken part in the intervention, as well as reflections on the readings, and your child should respond in writing to questions about the readings. The duration is 50 minutes.
- Complete a questionnaire of about 40 minutes one week before the intervention, after the intervention, six months after the intervention, and one year after intervention in order to assess the beneficial effects of the intervention.
- Provide saliva samples at all four moments of evaluation. In the collected saliva, the following hormones will be analyzed: cortisol, dehydroepiandrosterone sulfate (DHEA-s) and testosterone. It should be noted that we shall *only* examine the three mentioned hormones, and that analyzing any other chemical substance is *not* allowed.

2. What will the fathers/mothers-guardian/ be asked to do?

If you allow your child to participate in this study, you will be invited to complete a brief questionnaire of about 20 minutes at three times (pre-intervention, 6-month follow-up, and 12-month follow-up). The questionnaire will be provided to the students in class in a sealed envelope. You can allow your child to participate in the study without having to complete these questionnaires.

3. How is the saliva collected?

Collection of saliva samples will be held at school (around 10 a.m.) on the day chosen by the researchers, which will be communicated in advance to the school and the students. The measurement of salivary hormones is painless and non-invasive. The evaluation will take place through the transfer of saliva (approximately 2 ml) from the mouth to a tube through a straw/sanitary straw.

The tubes will be tagged with highly random numeric codes that are not associated with any personally identifiable information about your child. Samples will be guarded by the researchers of the University of Deusto until they are sent to the *MEDIKOSTA Análisis Clínicos* laboratory for hormonal analysis.

A fact sheet on the saliva sample collection procedure is attached to the end of this document.

4. How will the researchers protect the participants' privacy?

The study was funded by the Ministry of Economy and Competitiveness and with the approval of the Committee of Ethics in Research at the University of Deusto. The researchers will protect the privacy of all the participants. No names or surnames are indicated in any place. The data will be crossed using a random code and another code known only to the participant.

5. How will the researchers share the results of the project?

Your child's school will receive a preliminary and final report that will reflect the results of the evaluation of the program in the entirety of the students who participated and it will be distributed to all the parents. As the data are anonymous, it is not possible to make individualized reports of any student.

6. Is there any risk or benefit for my child?

There are no foreseeable risks associated with participation in this project. The intervention and the questionnaires are regular school activities. The salivary hormone measurement is painless and non-invasive and does not present any risk. As has been shown in the United States, the intervention may be beneficial for a high percentage of students.

7. Does my child have to participate?

Consent is optional. Your decision to allow or to forbid your son/daughter to participate will not affect your child's current or future relationship with the University of Deusto, the school, or the teacher. If you choose to allow your child to participate, he/she will be asked if he/she agrees to participate, and if your child accepts, he/she will receive all necessary instructions. In addition, your child is free to stop participating at any time without any penalty or adverse consequence. You can also initially allow your child to participate in the study and then change your mind without any penalty.

This research study will take place during the normal activities of the classroom. However, if you do not want your child to participate, there will be a different activity available for him or her. Your child will be offered the possibility to use the time to read or do homework.

8. What happen will if my child does not want to participate?

In addition to your permission, your son/daughter must agree to participate in the study. If your child does not wish to participate, he/she will not be included in the

study and there will be no penalty. Although he/she initially agreed to participate in the study, your child can change his/her mind later without any penalty.

9. Is there any compensation?

There will be no compensation for participating. However, if your child brings the completed informed consent documents, regardless of the declared decision to participate, he/she will enter a raffle (one raffle per classroom) of a ticket for €20 to spend in a well known department store. In addition, those who DO participate in the study, as a thank-you for their effort, will enter a raffle (per classroom) for a second ticket for €40.

Also, the fathers and mothers who participate will receive a number for a raffle of a ticket gift of €100 (to redeem in a well known department store) each time their cooperation is requested: pre-test, 6-month follow up, and 12-month follow-up. The first raffle will take place on March 2017, and the award-winning number will be published on the website of the research team at the University of Deusto (<http://www.stress.deusto.es/>).

10. Who has reviewed the study?

This research study has been approved and funded by the Ministry of Economy and Competitiveness in the 2015 convocation of the State Program of I+D+i Oriented toward Challenges to Society. The project has also been reviewed by the Ethics Committee of the University of Deusto and by the director of your child's school. The school will not carry out the project activities. The study will be carried out by researchers from the University of Deusto.

11. Who can I contact if I have questions about the study?

Before, during, or after your participation, you can contact any of the following people:

- Nerea Cortazar:
 - Phone: 944139000 (ext. 2668); email: nerea.cortazar@deusto.es
- Liria Fernández:
 - Phone: 944 139 000 (ext. 2895); email: liria.fernandez@deusto.es
- Esther Calvete:
 - Phone: 94439000 (ext. 2847), email: esther.calvete@deusto.es



**Parents' consent form:
Study of Prevention of Stress in Adolescents**

You are making a decision about allowing your child to participate in this research study. Your signature indicates that you have read the information provided and have decided to **allow or not allow** your child to participate. Please return this form to your child's school within a maximum of **three days**.

I understand the conditions specified above and that I can withdraw my child from the project at any time; my son/daughter can choose not to answer any of the questions if he/she does not want to reply. I understand that my child's participation is completely voluntary.

- YES**, my child may participate in the research study.
- NO**, my child may not participate in the research study.

Name and surname of the Student

Signature of the Father/Mother or Guardian Date

The researcher's signature Date



**Student's consent form:
Study of Prevention of Stress in Adolescents**

I agree to take part in a study on stress in adolescents. This study was explained to my parents or guardians and they said that I could participate. All my answers to questionnaires will be confidential and I do not write my name anywhere.

In this study, I will be asked to provide saliva samples up to four times to control stress levels. The saliva collection will take about 10 minutes and I will provide sample through the transfer of saliva to a sample tube. The researchers will analyze the hormone cortisol and other chemicals in the saliva that can show how students react to stressful situations.

If I write my name on this page, it means I read it or it was read to me and I agree to be part of the study. I know what will happen. If I decide to leave the research, I just have to tell the person in charge. I can decide not to participate in the study and I can leave at any time. If there are any questions that I don't want to answer, I can choose not to answer them. I will not have any problems with my parents or my teacher if I do not agree to participate in this study.

Name and surname of the student

Signature of student

Date

The researcher's signature

Date

COLLECTION OF SALIVA FOR HORMONAL DETERMINATIONS

The saliva sample collection will be made in the morning (around 10 a.m.) at school, under the supervision of researchers from the University of Deusto. General Recommendations

- Fast for two hours before the saliva collection. Given that the collection will be held around 10 o'clock in the morning, it is possible to have breakfast until 8 o'clock in the morning. After that time, do not ingest any food or drink (except water).
- Brush your teeth and wash your mouth after breakfast but do not brush your teeth again in the 45 minutes prior to the sample collection.
- Do not go to the dentist in the 24 hours prior to collection of the sample.

Procedure to follow:

- Stimulate the secretion of saliva. This can be done imagining that we are eating our favorite food.
- Transfer the saliva accumulated in your mouth into the tube, approximately about 2 ml (half the tube) and close the tube with the press cap (not threaded).
- Deliver the sample to the researchers responsible for the collection, together with the following data that must be completed on a sheet that will be delivered to each student on the day of the pick up:

<i>Date of sample taking</i>		
<i>Sampling time</i>	<i>Hours</i>	<i>Minutes</i>
<i>Time spent in the sample collection</i>	<i>Minutes</i>	
<i>I fasted for two hours since breakfast</i>	<i>YES</i>	<i>NO</i>
<i>Presence of any illness or injury in the mouth</i>	<i>YES</i>	<i>NO</i>
<i>I have taken some medication.</i> <i>If the answer is Yes, indicate which medication:</i> <hr/>	<i>YES</i>	<i>NO</i>
<i>I use some ointment or shampoo with cortisone</i>	<i>YES</i>	<i>NO</i>

- The tubes will be tagged with random numeric codes that are not associated with any personally identifiable information of the participant. They will be guarded by researchers at the University of Deusto until they are sent for hormonal analysis to the Medikosta laboratory, which will exclusively receive the tubes with the assigned numeric code and the data of the participant's sex and age.