

Participant information sheet for adults.

Protocol: **autismoEEG2020**

Title: "Participant information sheet for adults. Analysis of physical acoustic correlates of emotional prosodies."

Study center	Instituto Tecnológico y de Estudios Superiores de Monterrey, Campus Monterrey
Principal researcher:	M.S.C. Mathilde Marie Duville
Ethic Committee: Contact: Address: Phone number:	Comité de Ética en Investigación de la Escuela de Medicina del Instituto Tecnológico y de Estudios Superiores de Monterrey. Dr. Federico Ramos Ruiz Presidente del Comité de Ética en Investigación Dr. Carlos Jerjes Sánchez Díaz Presidente del Comité de Investigación Av. Ignacio Morones Prieto 3000 Pte. Col. Los Doctores CP: 64710 Monterrey, Nuevo León México Dr. Victor Javier Lara Diaz: 81 88 88 21 07

Introduction

With this document, we want to invite you to voluntary participate to a research study.

This study has the objective to create a database composed of emotional utterances in order to further analyze its acoustic characteristics.

Before that you accept to participate, we ask you to read the present document, that has the objective of telling you the possible risks and benefits, so that you can take an informed decision. You can share it with whoever you want (a friend, a family member, etc). If you have doubts, you can ask directly the researchers involved in the study in order them to answer your questions.

Once you will know more about the study, we will ask you to sign this document in order to participate. Your decision is voluntary, meaning that you are entirely free to decide if you participate or not. You can withdraw your agreement

Purpose of the study

This study is the first one of 3 research studies. Its aim is to record voice emotional utterances with the objective of establishing a database composed of words and its acoustic characteristics. These recordings will also be used for the second study which goal is to record the brain's activity related to emotional processing in autistic children. Your recording will be edited in order to create synthesized voices for the 2nd study. 4 adults will participate to this study. Your participation will last approximatively 1 hour.

After signing this agreement, inclusion and exclusion criteria will be checked:

- Aged between 19 and 35-year-old
- Have been grown-up in Mexico
- Not having any pathology that affects emotional behaviours, audition or speech. Not being sick the day of the session.

Study procedure

You will have to read a list of words in a microphone with specific emotional intonations, which can be : neutral, disgust, anger, happiness, sadness or fear. You will have all the time you need to read beforehand the set of words.

Because of the current pandemic issues, you will have to use a mask when you will interact with me. I will also give you antibacterial gel that you will have to use at the beginning and the end of the session. I will stay at least at 1.5meters from you during the entire session. Finally, I disinfected the microphone before you would use it.

Participant's responsibilities

You have the responsibility to:

- Give us the the appropriate required information
- Follow the instructions related to the experiment's procedure

Risks

You will not take any risk for participating to this study.

Benefits

With your help, we will know more about acoustic features of voices when they trigger emotional information. Furthermore, your recording will further be used to know how the autistic brain process emotional intentions.

Participating is voluntary?

Your participation is voluntary and can be withdrawn at any moment without any consequence. Participating to this study is your decision. You can freely choose not to participate or change your mind.

The researcher can decide to withdraw your participation without your agreement if:

- You do not follow the instructions
- The experiment is interrupted by the Independent Ethics Committee (CEI) or the Council of Institution Revision (CRI), a group of people that revised the investigation to protect your right, or a regulatory agency.

Participation cost

There is no cost to participate to this study.

Will I be paid to participate?

You will not receive any payment for participating.

If I participate, how will my privacy be protected?**Confidentiality**

Once you will sign this document, the CEI, CRI and regulatory authorities will have access to the original document to check the study's procedure and data, without violating your confidentiality up to what is allowed by the law and applicable regulations.

- Your recordings will be identified and will be kept confidential, and up to what is allowed by the law and applicable regulations, there will not have public knowledge of it. If the study results will be published, your identity will be kept confidential.

Your recordings and the one of your health status will strictly be kept confidential at any moment. However, there will have to be accessible for the Independent Ethics Committee (CEI) and the Medical Regulatory Authorities.

By signing this document, you allow the access for the present study and any other posterior investigation which will you this information. However, the researcher of the study will take the measures needed to protect your information and will not include your name in any future form, publication or dissemination. If you withdraw from the study, we will not obtain more information about you, but we will keep using the information obtained so far.

You will not be identified in any report, publication that will result from this study.

Who can I contact if I have questions?

Before signing this document, you should ask about any doubt. The research team will answer all your questions before, during and after the study. If you think that a question has not been

answered or if you did not understand the answer, please keep asking.

Do not sign this document if you did not have the opportunity to ask all your questions and to be entirely pleased with their answers.

**YOUR RIGHTS ARE NOT AFFECTED BY ANY
INFORMATION PROTECTION LAW**

Who can I contact if I have questions about my rights?

This agreement form has been revised the Ethics Committee of the Ethical Committee of the School of Medicine of Tecnológico de Monterrey.

If you have any question about your rights as participant, you can call the following number:
(01) 81 88882107.



Signatures:

Mark with X if you agree with the sentence.

☐ I have been informed about the study and I have had my first conversation with the researcher (Date)_____and hour (if necessary) _____

☐ I read and understood the information given in the present document.

☐ I could ask all what I wanted, and all my doubts have been answered correctly.

☐ I agree to participate in this study, and I do not renounce any of my legal rights for signing this agreement.

I understand that I will receive a signed and dated copy of this document

Name of the participant

Signature of the participant

Date

Hour

Name of legal representant

Parentage

Signature of legal representant

Signature

Hour

Impartial witnesses

Name of impartial witness 1

Address impartial witness 1

Parentage

Signature of impartial witness 1 Date (dd-mm-yy) Hour

Name of impartial witness 2

Address impartial witness 2

Parentage

Signature of impartial witness 1 Date (dd-mm-yy) Hour

Person who obtains the agreement

Name

Signature Date Hour

- I certify that I received a copy of the present agreement and I gave a copy of my official identification.

Signature of legal representant

Participant information sheet for children (from 6 to 11-year-old)

Protocol: autismoEEG2020

Title: "Participant information sheet for children. Analysis of physical acoustic correlates of emotional prosodies."

Study center	Instituto Tecnológico y de Estudios Superiores de Monterrey, Campus Monterrey
Principal researcher:	M.S.C. Mathilde Marie Duville
Ethic Committee:	Comité de Ética en Investigación de la Escuela de Medicina del Instituto Tecnológico y de Estudios Superiores de Monterrey.
Contact:	Dr. Federico Ramos Ruiz Presidente del Comité de Ética en Investigación Dr. Carlos Jerjes Sánchez Díaz Presidente del Comité de Investigación
Address:	Av. Ignacio Morones Prieto 3000 Pte. Col. Los Doctores CP: 64710 Monterrey, Nuevo León México
Phone number:	Dr. Victor Javier Lara Diaz: 81 88 88 21 07

Introduction

With this document, we want to invite you to voluntary participate to a research study. You can take all the time you need to read this document. You can ask all the questions you want.

This study has the objective to create a database composed of emotional utterances in order to further analyze its acoustic characteristics. You will have to read a list of words in a microphone with specific emotional intonations, which can be: neutral, disgust, anger, happiness, sadness or fear. You will have all the time you need to read beforehand the set of words.

Because of the current pandemic issues, you will have to use a mask when you will interact with me. I will also give you antibacterial gel that you will have to use at the beginning and the end of

the session. I will stay at least at 1.5 meters from you during the entire session. Finally, I disinfected the microphone before you would use it.

¿What could happen?

This study is of minor risks. It means that there is no risk for you to participate.

Benefits

With your help, we will know more about acoustic features of voices when they trigger emotional information. Furthermore, your recording will further be used to know how the autistic brain process emotional intentions.

Participation and withdrawal

Your participation is voluntary. If you do not want to participate, nobody will force you, nor will be mad at you. You can ask to be withdrawn from the experiment at any moment. If you have question, you can ask your parents to write to the PhD student Mathilde Marie Duville at: A00829725@itesm.mx

Confidentiality and management of the information

We will not publish your name. Only the researchers in charge will be able to see your information and will not tell it to anyone that is not working on this study.

Identification of the researchers

If you want to talk more about the study or if you have any question, you ask your parents to call or write to the Dr. David Ibarra Zarate (correo electrónico: david.ibarra@tec.mx) or Dr. Luz María Alonso Valerdi (correo electrónico: lm.aloval@tec.mx), or PhD student Mathilde Marie Duville (A00829725@itesm.mx).



Declaration sheet

Please answer the following questions



- | | Yes | No |
|--|--------------------------|--------------------------|
| a. Did you read or did someone read you this document and do you want to participate? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Did you ask and did we answer all your doubts? | <input type="checkbox"/> | <input type="checkbox"/> |
| c. Did you understand that your participation is voluntary and that you can ask us if you want to be withdrawn from the study at any moment? | <input type="checkbox"/> | <input type="checkbox"/> |
| d. Did you understand that we cannot give money to your parents for your participation? | <input type="checkbox"/> | <input type="checkbox"/> |
| e. Did you understand that if you do not want to participate, we will still be attending you as always? | <input type="checkbox"/> | <input type="checkbox"/> |

Participant declaration

I, _____ declare that I agree to participate to the study. My participation is voluntary. I have been explained that I can ask to be withdrawn from the study at any moment without anything bad happening.

Participant name and signature

Date

Choose the happy smiley 😊 if you want to participate, or the sad one 😞 if you do

not want:

☐☐

Yes I want to participate

No I don't want to participate

Name and signatures of the
Legal representant

Parentage

Date

Impartial witnesses

Name and signature of witeness 1

Parentage

Date

Address of witeness 1

Name and signature of witeness 2

Parentage

Date

Address of witeness 2

Person who obtain the consent

- Name and signature

Date

Participant information sheet for legal tutors of children participants.

Protocolo: autismoEEG2020

Title: "Participant information sheet for legal tutors of children participants. Analysis of physical acoustic correlates of emotional prosodies."

Study center	Instituto Tecnológico y de Estudios Superiores de Monterrey, Campus Monterrey
Principal researcher:	M.S.C. Mathilde Marie Duville
Ethic Committee:	Comité de Ética en Investigación de la Escuela de Medicina del Instituto Tecnológico y de Estudios Superiores de Monterrey.
Contact:	Dr. Federico Ramos Ruiz Presidente del Comité de Ética en Investigación Dr. Carlos Jerjes Sánchez Díaz Presidente del Comité de Investigación
Address:	Av. Ignacio Morones Prieto 3000 Pte. Col. Los Doctores CP: 64710 Monterrey, Nuevo León México
Phone number:	Dr. Victor Javier Lara Diaz: 81 88 88 21 07

Introduction

With this document we want to invite your child to voluntary participate to a research study that has the objective to create a database composed of emotional expressions in order to further analyze its acoustic characteristics.

Before that you accept your child's participation, we ask you to read the present document, that has the objective of telling you the possible risks and benefits, so that you can take an informed decision. You can share it with whoever you want (a friend, a family member, etc). If you have doubts, you can ask directly the researchers involved in the study in order them to answer your questions.

Once you will know more about the study, we will ask you to sign this document in order your child to participate. Your decision is voluntary, meaning that you are entirely free to decide if your child participate or not. You can withdraw your agreement at any moment without having to justify yourself, without affecting the attention we have for you.

Purpose of the study

This study is the first one of 3 research studies. Its aim is to record voice emotional utterances with the objective of establishing a database composed of words and its acoustic characteristics. These recordings will also be used for the second study which goal is to record the brain's activity related to emotional processing in autistic children. Your recording will be edited in order to create synthesized voices for the 2nd study. 4 children will participate to this study. Your child's participation will last approximatively 40 minutes.

After signing this agreement, inclusion and exclusion criteria will be checked:

- Aged between 9 and 11-year-old
- Have been grown-up in Mexico
- Not having any pathology that affects emotional behaviours, audition or speech. Not being sick the day of the session.

Study procedure

Your child will have to read a list of words in a microphone with specific emotional intonations, which can be: neutral, disgust, anger, happiness, sadness or fear. He/she will have all the time she/he needs to read beforehand the set of words.

Because of the current pandemic issues, your child will have to use a mask when he/she will interact with me. I will also give him/her antibacterial gel that he/she will have to use at the beginning and the end of the session. I will stay at least at 1.5 meters from him/her during the entire session. Finally, I disinfected the microphone before he/she would use it.

Participant's responsibilities

You have the responsibility to:

- Give us the required information about you child
- Follow the instructions related to the experiment's procedure

Risks

Your child does not take any risk for participating to this study.

Benefits

With your help, we will know more about acoustic features of voices when they trigger emotional

information. Furthermore, your recording will further be used to know how the autistic brain process emotional intentions.

Participating is voluntary?

Your child's participation is voluntary and can be withdrawn at any moment without any consequence. Participating to this study is your decision and the one of your child. You and your child can choose not to participate or change your mind.

The researcher can decide to withdraw your child's participation without your agreement if:

- You do not follow the instructions
- The experiment is interrupted by the Independent Ethics Committee (CEI) or the Council of Institution Revision (CRI), a group of people that revised the investigation to protect your right, or a regulatory agency.

Participation cost

There is no cost to participate to this study.

Will I be paid to participate?

You will not receive any payment for participating.

If I participate, how will my privacy be protected?

Confidentiality

The name of your child will not be used at any moment. Your child information will not be used for any study that is not related to the present one. No information will be shared without your authorization, except if it is asked by the law. The Ethics Committee of the Regional Maternal Infantile Hospital of High Specialty and the Instituto Tecnológico y de Estudios Superiores de Monterrey approved the realization of this study. These committees approve and supervise human research studies. The scientific data obtained as part of this study could be used in scientific publications or presentations.

YOUR RIGHTS ARE NOT AFFECTED BY ANY INFORMATION PROTECTION LAW

Who can I contact if I have questions about my rights?

Before signing this document, you should ask about any doubt. The research team will answer all your questions before, during and after the study. If you think that a question has not been answered or if you did not understand the answer, please keep asking.

Do not sign this document if you did not have the opportunity to ask all your questions and to be entirely pleased with their answers.

This agreement form has been revised the Ethics Committee of the Ethical Committee of the School of Medicine of Tecnológico de Monterrey.

If you have any question about your rights as participant, you can call the following number:
(01) 81 88882107.



Signatures:

Mark with X if you agree with the sentence.

☐ I have been informed about the study and I have had my first conversation with the researcher (Date)_____and hour (if necessary) _____

☐ I read and understood the information given in the present document.

☐ I could ask all what I wanted, and all my doubts have been answered correctly.

☐ I agree to participate in this study, and I do not renounce any of my legal rights for signing this agreement.

I understand that I will receive a signed and dated copy of this document

Name of the participant

Signature of the participant

Date

Hour

Name of legal representant

Parentage

Signature of legal representant

Signature

Hour

Impartial witnesses

Name of impartial witness 1

Address impartial witness 1

Parentage

Signature of impartial witness 1 Date (dd-mm-yy) Hour

Name of impartial witness 2

Address impartial witness 2

Parentage

Signature of impartial witness 1 Date (dd-mm-yy) Hour

Person who obtains the agreement

Name

Signature Date Hour

- I certify that I received a copy of the present agreement and I gave a copy of my official identification.

Signature of legal representant

Participant information sheet for children (from 6 to 11-year-old)

Protocol: autismoEEG2020

Title: "Participant information sheet for children participants. Analysis of electroencephalographic correlate of Mexican Spanish emotional prosody processing in children with high functioning autism: synthetic versus human voices."

Study center	Instituto Tecnológico y de Estudios Superiores de Monterrey, Campus Monterrey
Principal researcher:	M.S.C. Mathilde Marie Duville
Ethic Committee:	Comité de Ética en Investigación de la Escuela de Medicina del Instituto Tecnológico y de Estudios Superiores de Monterrey.
Contact:	Dr. Federico Ramos Ruiz Presidente del Comité de Ética en Investigación Dr. Carlos Jerjes Sánchez Díaz Presidente del Comité de Investigación
Address:	Av. Ignacio Morones Prieto 3000 Pte. Col. Los Doctores CP: 64710 Monterrey, Nuevo León México
Phone number:	Dr. Victor Javier Lara Diaz: 81 88 88 21 07

Introduction

With this document, we want to invite you to voluntary participate to a research study. You can take all the time you need to read this document. You can ask all the questions you want. This study has the objective to record your brain's activity related to emotional processing. For this purpose, a headset will be collocated on your head before starting the experiment and will be removed at the end of the session.

You will have to listen to words uttered with emotional intonations, which can be: neutral, disgust, fear, anger, happiness and sadness. After each word, you will have to choose on the computer screen which Emoji match best the emotion conveyed by the word's intonation. While

performing the task, your brain activity will be monitored.

Because of the current pandemic issues, you will have to use a mask when you will interact with me. I will also give you antibacterial gel that you will have to use at the beginning and the end of the session. I will stay at least at 1.5 meters from him/her during the entire session.

¿What could happen?

This study is of minor risks. It means that there is no risk for you to participate.

Benefits

With your help, we will know more about the autistic brain signature of emotional prosody processing. Furthermore, your recordings will help to develop an intervention which aim will be to improve emotional discrimination abilities in autistic children.

Participation and withdrawal

Your participation is voluntary. If you do not want to participate, nobody will force you, nor will be mad at you. You can ask to be withdrawn from the experiment at any moment. If you have question, you can ask your parents to write to the PhD student Mathilde Marie Duville at: A00829725@itesm.mx

Confidentiality and management of the information

We will not publish your name. Only the researchers in charge will be able to see your information and will not tell it to anyone that is not working on this study.

Identification of the researchers

If you want to talk more about the study or if you have any question, you ask your parents to call or write to the Dr. David Ibarra Zarate (correo electrónico: david.ibarra@tec.mx) or Dr. Luz María Alonso Valerdi (correo electrónico: lm.aloval@tec.mx), or PhD student Mathilde Marie Duville (A00829725@itesm.mx).



Declaration sheet

Please answer the following questions



- | | Yes | No |
|--|--------------------------|--------------------------|
| a. Did you read or did someone read you this document and do you want to participate? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Did you ask and did we answer all your doubts? | <input type="checkbox"/> | <input type="checkbox"/> |
| c. Did you understand that your participation is voluntary and that you can ask us if you want to be withdrawn from the study at any moment? | <input type="checkbox"/> | <input type="checkbox"/> |
| d. Did you understand that we cannot give money to your parents for your participation? | <input type="checkbox"/> | <input type="checkbox"/> |
| e. Did you understand that if you do not want to participate, we will still be attending you as always? | <input type="checkbox"/> | <input type="checkbox"/> |

Participant declaration

I, _____ declare that I agree to participate to the study. My participation is voluntary. I have been explained that I can ask to be withdrawn from the study at any moment without anything bad happening.

Participant name and signature

Date

Choose the happy smiley 😊 if you want to participate, or the sad one 😞 if you do

not want:

☐☐

Yes, I want to participate

No I don't want to participate

Name and signatures of the
Legal representant

Parentage

Date

Impartial witnesses

Name and signature of witeness 1

Parentage

Date

Address of witeness 1

Name and signature of witeness 2

Parentage

Date

Address of witeness 2

Person who obtain the consent

- Name and signature

Date

Participant information sheet for legal tutors of autistic children participants.

Protocol: autismoEEG2020

Titulado: "Participant information sheet for legal tutors of autistic children participants. Experimental group. Analysis of electroencephalographic correlate of Mexican Spanish emotional prosody processing in children with high functioning autism: synthetic versus human voices."

Study center	Instituto Tecnológico y de Estudios Superiores de Monterrey, Campus Monterrey
Principal researcher:	M.S.C. Mathilde Marie Duville
Ethic Committee: Contact:	Comité de Ética en Investigación de la Escuela de Medicina del Instituto Tecnológico y de Estudios Superiores de Monterrey. Dr. Federico Ramos Ruiz President of Ethics Committee Dr. Carlos Jerjes Sánchez Díaz President of Investigation Committee
Address:	Av. Ignacio Morones Prieto 3000 Pte. Col. Los Doctores CP: 64710 Monterrey, Nuevo León México
Phone number:	Dr. Victor Javier Lara Diaz: 81 88 88 21 07

Introduction

With this document we want to invite your child to voluntary participate to a research study that has the objective to record and analyze neuronal correlates of emotion processing through human and synthesized voices in high functioning autistic children and their corresponding typically-developed controls.



Before that you accept your child's participation, we ask you to read the present document, that has the objective of telling you the possible risks and benefits, so that you can take an informed decision. You can share it with whoever you want (a friend, a family member, etc). If you have doubts, you can ask directly the researchers involved in the study in order them to answer your questions.

Once you will know more about the study, we will ask you to sign this document in order your child to participate. Your decision is voluntary, meaning that you are entirely free to decide if your child participate or not. You can withdraw your agreement at any moment without having to justify yourself, without affecting the attention we have for you.

Purpose of the study

This study is the second one of 3 research studies. Its aim is to record and analyze the electroencephalographic activity correlated to emotional prosody uttered by human and synthesized voices. The objective of this analysis is to determine which voice leads to the nearest approximation to non-pathological neuronal processing in high-functioning autistic children. This voice will be selected and used in a future intervention study focused on the training of emotional prosodies discrimination for autistic children.

About 40 persons will participate to this study. Your child's participation will last approximatively 35 minutes.

After signing this agreement, inclusion and exclusion criteria will be checked:

- Aged between 9 and 11-year-old
 - A T-score greater than 60 (slightly elevated to very elevated scores for autistic behaviors) on Social/Communication, DSM-IV-TR (Text Revision), Peer and Adult Socialization and Social/Emotional Reciprocity of the Autism Spectrum Rating Scale.
 - Have been diagnosed with high-functioning autism spectrum disorders by using the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, Fourth) or on el ICD-10 (International Classification of Diseases and Related Health Problems – Tenth Edition).
 - Without intellectual disability
 - Not being under any medical treatment acting on the nervous system
-

- Not having auditive deficits or any pathology affecting the nervous system other than autism

Study procedure

Your child will have to listen to words uttered with emotional intonations, which can be: neutral, disgust, fear, anger, happiness and sadness. After each word, he/she will have to choose on the computer screen which Emoji match best the emotion conveyed by the word's prosody. While performing the task, his/her brain activity will be monitored. For this purpose, an electroencephalographic headset will be collocated on his/her head before starting the experiment and will be removed at the end of the session.

Because of the current pandemic issues, your child will have to use a mask when he/she will interact with me. I will also give him/her antibacterial gel that he/she will have to use at the beginning and the end of the session. I will stay at least at 1.5meters from him/her during the entire session.

Participant's responsibilities

You have the responsibility to:

- Give us the required information about you child
- Follow the instructions related to the experiment's procedure

Risks

Your child does not take any risk for participating to this study.

Benefits

With your help, we will know more about the autistic brain signature of emotional prosody processing. Furthermore, your recordings will help to develop an intervention which aim will be to improve emotional discrimination abilities in autistic children.

Participating is voluntary?

Your child's participation is voluntary and can be withdrawn at any moment without any consequence. Participating to this study is your decision and the one of your child. You and your child can choose not to participate or change your mind.

The researcher can decide to withdraw your child's participation without your agreement if:

- You do not follow the instructions
- The experiment is interrupted by the Independent Ethics Committee (CEI) or the Council of Institution Revision (CRI), a group of people that revised the investigation to protect your right, or a regulatory agency.

Participation cost

There is no cost to participate to this study.



Will I be paid to participate?

You will not receive any payment for participating.

If I participate, how will my privacy be protected?**Confidentiality**

The name of your child will not be used at any moment. Your child information will not be used for any study that is not related to the present one. No information will be shared without your authorization, except if it is asked by the law. The Ethics Committee of the Regional Maternal Infantile Hospital of High Specialty and the Instituto Tecnológico y de Estudios Superiores de Monterrey approved the realization of this study. These committees approve and supervise human research studies. The scientific data obtained as part of this study could be used in scientific publications or presentations.

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INFORMATION PROTECTION LAW****Who can I contact if I have questions about my rights?**

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If you have any question about your rights as participant, you can call the following number:
(01) 81 88882107.

Signatures:

Mark with X if you agree with the sentence.

☐ I have been informed about the study and I have had my first conversation with the researcher (Date)_____and hour (if necessary) _____

☐ I read and understood the information given in the present document.

☐ I could ask all what I wanted, and all my doubts have been answered correctly.

☐ I agree to participate in this study, and I do not renounce any of my legal rights for signing this agreement.

I understand that I will receive a signed and dated copy of this document

Name of the participant

Signature of the participant

Date

Hour

Name of legal representant

Parentage

Signature of legal representant

Signature

Hour

Impartial witnesses

Name of impartial witness 1

Address impartial witness 1

Parentage

Signature of impartial witness 1 Date (dd-mm-yy) Hour

Name of impartial witness 2

Address impartial witness 2

Parentage

Signature of impartial witness 1 Date (dd-mm-yy) Hour

Person who obtains the agreement

Name

Signature Date Hour

- **I certify that I received a copy of the present agreement and I gave a copy of my official identification.**

Signature of legal representant



Participant information sheet for legal tutors of autistic children participants.

Protocol: autismoEEG2020

Titulado: "Participant information sheet for legal tutors of typically-developed children participants. Control group. Analysis of electroencephalographic correlate of Mexican Spanish emotional prosody processing in children with high functioning autism: synthetic versus human voices."

Study center	Instituto Tecnológico y de Estudios Superiores de Monterrey, Campus Monterrey
Principal researcher:	M.S.C. Mathilde Marie Duville
Ethic Committee: Contact:	Comité de Ética en Investigación de la Escuela de Medicina del Instituto Tecnológico y de Estudios Superiores de Monterrey. Dr. Federico Ramos Ruiz President of Ethics Committee Dr. Carlos Jerjes Sánchez Díaz President of Investigation Committee
Address:	Av. Ignacio Morones Prieto 3000 Pte. Col. Los Doctores CP: 64710 Monterrey, Nuevo León México
Phone number:	Dr. Víctor Javier Lara Díaz: 81 88 88 21 07

Introduction

With this document we want to invite your child to voluntary participate to a research study that has the objective to record and analyze neuronal correlates of emotion processing through human and synthesized voices in high functioning autistic children and their corresponding typically-developed controls.

Before that you accept your child's participation, we ask you to read the present document, that has the objective of telling you the possible risks and benefits, so that you can take an informed decision. You can share it with whoever you want (a friend, a family member, etc). If you have doubts, you can ask directly the researchers involved in the study in order them to answer your questions.

Once you will know more about the study, we will ask you to sign this document in order your child to participate. Your decision is voluntary, meaning that you are entirely free to decide if your child participate or not. You can withdraw your agreement at any moment without having to justify yourself, without affecting the attention we have for you.

Purpose of the study

This study is the second one of 3 research studies. Its aim is to record and analyze the electroencephalographic activity correlated to emotional prosody uttered by human and synthesized voices. The objective of this analysis is to determine which voice leads to the nearest approximation to non-pathological neuronal processing in high-functioning autistic children. This voice will be selected and used in a future intervention study focused on the training of emotional prosodies discrimination for autistic children.

About 40 persons will participate to this study. Your child's participation will last approximatively 35 minutes.

After signing this agreement, inclusion and exclusion criteria will be checked:

- Aged between 9 and 11-year-old
- A T-score lower than 60 on the Autism Spectrum Rating Scales
- Without intellectual disability
- Not being under any medical treatment acting on the nervous system
- Not having auditive deficits or any pathology affecting the nervous system

Study procedure

Your child will have to listen to words uttered with emotional intonations, which can be: neutral, disgust, fear, anger, happiness and sadness. After each word, he/she will have to choose on the computer screen which Emoji match best the emotion conveyed by the word's prosody. While performing the task, his/her brain activity will be monitored. For this purpose, an

electroencephalographic headset will be collocated on his/her head before starting the experiment and will be removed at the end of the session.

Because of the current pandemic issues, your child will have to use a mask when he/she will interact with me. I will also give him/her antibacterial gel that he/she will have to use at the beginning and the end of the session. I will stay at least at 1.5 meters from him/her during the entire session. Finally, I disinfected the microphone before he/she would use it.

Participant's responsibilities

You have the responsibility to:

- Give us the required information about your child
- Follow the instructions related to the experiment's procedure

Risks

Your child does not take any risk for participating to this study.

Benefits

With your help, we will know more about the autistic brain signature of emotional prosody processing.

Participating is voluntary?

Your child's participation is voluntary and can be withdrawn at any moment without any consequence. Participating to this study is your decision and the one of your child. You and your child can choose not to participate or change your mind.

The researcher can decide to withdraw your child's participation without your agreement if:

- You do not follow the instructions
- The experiment is interrupted by the Independent Ethics Committee (CEI) or the Council of Institution Revision (CRI), a group of people that revised the investigation to protect your right, or a regulatory agency.

Participation cost

There is no cost to participate to this study.

Will I be paid to participate?

You will not receive any payment for participating.

If I participate, how will my privacy be protected?

Confidentiality

The name of your child will not be used at any moment. Your child information will not be used for any study that is not related to the present one. No information will be shared without your

authorization, expect if it is asked by the law. The Ethics Committee of the Regional Maternal Infantile Hospital of High Specialty and the Instituto Tecnológico y de Estudios Superiores de Monterrey approved the realization of this study. These committees approve and supervise human research studies. The scientific data obtained as part of this study could be used in scientific publications o presentations.

**YOUR RIGHTS ARE NOT AFFECTED BY ANY
INFORMATION PROTECTION LAW**

Who can I contact if I have questions about my rights?

Before signing this document, you should ask about any doubt. The research team will answer all your questions before, during and after the study. If you think that a question has not been answered or if you did not understand the answer, please keep asking.

Do not sign this document if you did not have the opportunity to ask all your questions and to be entirely pleased with their answers.

This agreement form has been revised the Ethics Committee of the Ethical Committee of the School of Medicine of Tecnológico de Monterrey.

If you have any question about your rights as participant, you can call the following number:
(01) 81 88882107.



Signatures:

Mark with X if you agree with the sentence.

☐ I have been informed about the study and I have had my first conversation with the researcher (Date)_____and hour (if necessary) _____

☐ I read and understood the information given in the present document.

☐ I could ask all what I wanted, and all my doubts have been answered correctly.

☐ I agree to participate in this study, and I do not renounce any of my legal rights for signing this agreement.

I understand that I will receive a signed and dated copy of this document

Name of the participant _____

Signature of the participant _____

Date _____

Hour _____

Name of legal representant _____

Parentage _____

Signature of legal representant _____

Signature _____

Hour _____

Impartial witnesses

Name of impartial witness 1

Address impartial witness 1

Parentage

Signature of impartial witness 1 Date (dd-mm-yy) Hour

Name of impartial witness 2

Address impartial witness 2

Parentage

Signature of impartial witness 1 Date (dd-mm-yy) Hour

Person who obtains the agreement

Name

Signature Date Hour

- **I certify that I received a copy of the present agreement and I gave a copy of my official identification.**

Signature of legal representant



Participant information sheet for children (from 6 to 11-year-old)

Protocol: autismoEEG2020

Title: “Participant information sheet for children participants. Intervention groups. Development of a Social Story™ and robot-based intervention to improve emotional prosody discrimination in autistic children.”

Study center	Instituto Tecnológico y de Estudios Superiores de Monterrey, Campus Monterrey
Principal researcher:	M.S.C. Mathilde Marie Duville
Ethic Committee: Contact:	Comité de Ética en Investigación de la Escuela de Medicina del Instituto Tecnológico y de Estudios Superiores de Monterrey. Dr. Federico Ramos Ruiz Presidente del Comité de Ética en Investigación Dr. Carlos Jerjes Sánchez Díaz Presidente del Comité de Investigación
Address:	Av. Ignacio Morones Prieto 3000 Pte. Col. Los Doctores CP: 64710 Monterrey, Nuevo León México
Phone number:	Dr. Victor Javier Lara Diaz: 81 88 88 21 07

Introduction

With this document, we want to invite you to voluntary participate to a research study. You can take all the time you need to read this document. You can ask all the questions you want. This study has the objective to develop a drug-free intervention based on the use of synthesized voices, social stories™ and NAO social robot for improving emotion discrimination abilities of autistic children.

Because of the current pandemic issues, you will have to use a mask when you will interact with me. I will also give you antibacterial gel that you will have to use at the beginning and the end of the session. I will stay at least at 1.5meters from him/her during the entire session.

You will have to come and see me for 15 sessions. This is the first one: you will have to listen to words uttered with emotional intonations, which can be: neutral, disgust, fear, anger, happiness, and sadness. After each word, you will have to choose on the computer screen which Emoji match best the emotion

conveyed by the word's intonation. While performing the task, your brain activity will be monitored. You will repeat this task at sessions 7, 13, 14 and 15. Sessions 2 to 13 will consist of interactions with a robot that will tell you stories. You will have to listen to him and to answer its questions. He will tell you two 5-min stories.

What could happen?

This study is of minor risks. It means that there is no risk for you to participate.

Benefits

With your help, we will know more about the efficacy of a robot and Social Story™-based intervention on neuronal and behavioural abilities to discriminate emotional prosodies in autistic children.

Participation and withdrawal

Your participation is voluntary. If you do not want to participate, nobody will force you, nor will be mad at you. You can ask to be withdrawn from the experiment at any moment. If you have question, you can ask your parents to write to the PhD student Mathilde Marie Duville at: A00829725@itesm.mx

Confidentiality and management of the information

We will not publish you name. Only the researchers in charge will be able to see your information and will not tell it to anyone that is not working on this study.

Identification of the researchers

If you want to talk more about the study or if you have any question, you ask your parents to call or write to the Dr. David Ibarra Zarate (correo electrónico: david.ibarra@tec.mx) or Dr. Luz María Alonso Valerdi (correo electrónico: lm.aloval@tec.mx), or PhD student Mathilde Marie Duville (A00829725@itesm.mx).



Declaration sheet

Please answer the following questions



	Yes	No
a. Did you read or did someone read you this document and do you want to participate?	<input type="checkbox"/>	<input type="checkbox"/>
b. Did you ask and did we answer all your doubts?	<input type="checkbox"/>	<input type="checkbox"/>
c. Did you understand that your participation is voluntary and that you can ask us if you want to be withdrawn from the study at any moment?	<input type="checkbox"/>	<input type="checkbox"/>
d. Did you understand that we cannot give money to your parents for your participation?	<input type="checkbox"/>	<input type="checkbox"/>
e. Did you understand that if you do not want to participate, we will still be attending you as always?	<input type="checkbox"/>	<input type="checkbox"/>

Participant declaration

I, _____ declare that I agree to participate to the study. My participation is voluntary. I have been explained that I can ask to be withdrawn from the study at any moment without anything bad happening.

Participant name and signature

Date

Choose the happy smiley 😊 if you want to participate, or the sad one 😞 if you do not

want:

☐☐

Yes, I want to participate

No I don't want to participate

Name and signatures of the
Legal representant

Parentage

Date

Impartial witnesses

Name and signature of witness 1

Parentage

Date

Address of witness 1

Name and signature of witness 2

Parentage

Date

Address of witness 2

Person who obtain the consent

-

Name and signature

Date

Participant information sheet for children (from 6 to 11-year-old)

Protocol: autismoEEG2020

Title: “Participant information sheet for children participants. Control groups. Development of a Social Story™ and robot-based intervention to improve emotional prosody discrimination in autistic children.”

Study center	Instituto Tecnológico y de Estudios Superiores de Monterrey, Campus Monterrey
Principal researcher:	M.S.C. Mathilde Marie Duville
Ethic Committee: Contact:	Comité de Ética en Investigación de la Escuela de Medicina del Instituto Tecnológico y de Estudios Superiores de Monterrey. Dr. Federico Ramos Ruiz Presidente del Comité de Ética en Investigación Dr. Carlos Jerjes Sánchez Díaz Presidente del Comité de Investigación
Address:	Av. Ignacio Morones Prieto 3000 Pte. Col. Los Doctores CP: 64710 Monterrey, Nuevo León México
Phone number:	Dr. Victor Javier Lara Diaz: 81 88 88 21 07

Introduction

With this document, we want to invite you to voluntary participate to a research study. You can take all the time you need to read this document. You can ask all the questions you want. This study has the objective to develop a drug-free intervention based on the use of synthesized voices, social stories™ and NAO social robot for improving emotion discrimination abilities of autistic children.

Because of the current pandemic issues, you will have to use a mask when you will interact with me. I will also give you antibacterial gel that you will have to use at the beginning and the end of the session. I will stay at least at 1.5meters from him/her during the entire session.

You will have to come and see me for 5 sessions. This is the first one: you will have to listen to words uttered

with emotional intonations, which can be: neutral, disgust, fear, anger, happiness, and sadness. After each word, you will have to choose on the computer screen which Emoji match best the emotion conveyed by the word's intonation. While performing the task, your brain activity will be monitored. You will repeat this task at sessions 2, 3, 4 and 5.

What could happen?

This study is of minor risks. It means that there is no risk for you to participate.

Benefits

With your help, we will know more about the efficacy of a robot and social storyTM-based intervention on neuronal and behavioural abilities to discriminate emotional prosodies in autistic children.

Participation and withdrawal

Your participation is voluntary. If you do not want to participate, nobody will force you, nor will be mad at you. You can ask to be withdrawn from the experiment at any moment. If you have question, you can ask your parents to write to the PhD student Mathilde Marie Duville at: A00829725@itesm.mx

Confidentiality and management of the information

We will not publish your name. Only the researchers in charge will be able to see your information and will not tell it to anyone that is not working on this study.

Identification of the researchers

If you want to talk more about the study or if you have any question, you ask your parents to call or write to the Dr. David Ibarra Zarate (correo electrónico: david.ibarra@tec.mx) or Dr. Luz María Alonso Valerdi (correo electrónico: lm.aloval@tec.mx), or PhD student Mathilde Marie Duville (A00829725@itesm.mx).



Declaration sheet

Please answer the following questions



	Yes	No
a. Did you read or did someone read you this document and do you want to participate?	<input type="checkbox"/>	<input type="checkbox"/>
b. Did you ask and did we answer all your doubts?	<input type="checkbox"/>	<input type="checkbox"/>
c. Did you understand that your participation is voluntary and that you can ask us if you want to be withdrawn from the study at any moment?	<input type="checkbox"/>	<input type="checkbox"/>
d. Did you understand that we cannot give money to your parents for your participation?	<input type="checkbox"/>	<input type="checkbox"/>
e. Did you understand that if you do not want to participate, we will still be attending you as always?	<input type="checkbox"/>	<input type="checkbox"/>

Participant declaration

I, _____ declare that I agree to participate to the study. My participation is voluntary. I have been explained that I can ask to be withdrawn from the study at any moment without anything bad happening.

Participant name and signature

Date

Choose the happy smiley 😊 if you want to participate, or the sad one 😞 if you do not

want:

☐☐

Yes, I want to participate

No I don't want to participate

Name and signatures of the
Legal representant

Parentage

Date

Impartial witnesses

Name and signature of witness 1

Parentage

Date

Address of witness 1

Name and signature of witness 2

Parentage

Date

Address of witness 2

Person who obtain the consent

-

Name and signature

Date

Participant information sheet for legal tutors of autistic children participants.

Protocol: autismoEEG2020

Title: "Participant information sheet for legal tutors of children participants. Intervention group1. Development of a Social Story™ and robot-based intervention to improve emotional prosody discrimination in autistic children."



Study center	Instituto Tecnológico y de Estudios Superiores de Monterrey, Campus Monterrey
Principal researcher:	M.S.C. Mathilde Marie Duville
Ethic Committee: Contact:	Comité de Ética en Investigación de la Escuela de Medicina del Instituto Tecnológico y de Estudios Superiores de Monterrey. Dr. Federico Ramos Ruiz President of Ethics Committee Dr. Carlos Jerjes Sánchez Díaz President of Investigation Committee
Address:	Av. Ignacio Morones Prieto 3000 Pte. Col. Los Doctores CP: 64710 Monterrey, Nuevo León México
Phone number:	Dr. Victor Javier Lara Diaz: 81 88 88 21 07

Introduction

With this document we want to invite your child to voluntary participate to a research study that has the objective to develop a drug-free intervention based on the use of synthesized voices, social stories™ and NAO social robot for improving emotion discrimination abilities of autistic children.

Before that you accept your child's participation, we ask you to read the present document, that has the objective of telling you the possible risks and benefits, so that you can take an informed decision. You can share it with whoever you want (a friend, a family member, etc). If you have doubts, you can ask directly the researchers involved in the study in order them to answer your questions.

Once you will know more about the study, we will ask you to sign this document in order your child to participate. Your decision is voluntary, meaning that you are entirely free to decide if your child participate or not. You can withdraw your agreement at any moment without having to justify yourself, without affecting the attention we have for you.



Purpose of the study

This study is the third one of 3 research studies. Its aim is to develop a drug-free intervention based on the use of synthesized voices, NAO social robot and Social Stories™ for helping autistic children to discriminate emotional prosodies. NAO is 57cm-high and can be programmed to talk and interact with humans on didactic and simple ways. It is generally well accepted by autistic children. There is no risk for your child.

The participants of this study are allocated to 4 different groups. Group 1 (5 participants) is composed of autistic children that will receive the intervention based on the use of NAO robot, synthesized and human voices. Group 2 (5 participants) is composed of autistic children that will receive the intervention based on the use of NAO robot and human voices. Group 3 (5 participants) is composed of autistic children that will not receive the intervention. Group 4 (5 participants) is composed of typically-developed children that will not receive the intervention. Your child belongs to group 1.

Your child's participation will last approximatively 35 minutes at sessions 1, 14 and 15, 10 minutes at sessions 2 to 6 and 14 and 45 minutes at sessions 7 and 13. You will have to answer the Autism Spectrum Rating Scales at sessions 1, 14 and 15 (20 minutes).

After signing this agreement, inclusion and exclusion criteria will be checked:

- Aged between 9 and 11-year-old
- A T-score greater than 60 (slightly elevated to very elevated scores for autistic behaviors) on Social/Communication, DSM-IV-TR (Text Revision), Peer and Adult Socialization and Social/Emotional Reciprocity of the Autism Spectrum Rating Scale.
- Have been diagnosed with high-functioning autism spectrum disorders by using the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, Fourth) or the ICD-10 (International Classification of Diseases and Related Health Problems – Tenth Edition)
- Without intellectual disability
- Not being under any medical treatment acting on the nervous system
- Not having auditive deficits or any pathology affecting the nervous system other than autism

Study procedure

Pretest phase

During the first session, you will have to answer the Autism Spectrum Rating Scales, which is a 71-question form in which you can answer in a 4-point scale. It aims to evaluate your child's autistic symptomatology. It will last approximatively 20 minutes. Your child will have to listen to words uttered with emotional intonations, which can be: neutral, disgust, fear, anger, happiness and sadness. After each word, he/she will have to choose on the computer screen which Emoji match

best the emotion conveyed by the word's prosody. While performing the task, his/her brain activity will be monitored. For this purpose, an electroencephalographic headset will be collocated on his/her head before starting the experiment and will be removed at the end of the session.

Intervention

Sessions 2 to 13 will consist of the intervention. Your child will have to listen to Social Stories™ told by NAO robot which have the objective of teaching your child to focus on appropriate cues to foster emotional intonations discrimination. Each story will last 5 minutes and will include interactive questions for your child to answer. Each story is personalized to your child according to the information that you sent before the 1st session. In sessions 7 and 13, your child will have to answer the same experimental procedure as the one he/she answered in session 1.

Posttest phase.

Sessions 14 and 15 will consist of the repetition of session 1 as follow-up assessments.

Because of the current pandemic issues, your child will have to use a mask when he/she will interact with me. I will also give him/her antibacterial gel that he/she will have to use at the beginning and the end of the session. I will stay at least at 1.5meters from him/her during the entire session.

Participant's responsibilities

You have the responsibility to:

- Give us the required information about you child
- Follow the instructions related to the experiment's procedure

Risks

Your child does not take any risk for participating to this study.

Benefits

With your help, we will know more about the efficacy of a robot and Social Story™-based intervention on neuronal and behavioural abilities to discriminate emotional prosodies in autistic children.

Participating is voluntary?

Your child's participation is voluntary and can be withdrawn at any moment without any consequence. Participating to this study is your decision and the one of your child. You and your child can choose not to participate or change your mind.

The researcher can decide to withdraw your child's participation without your agreement if:

- You do not follow the instructions

- The experiment is interrupted by the Independent Ethics Committee (CEI) or the Council of Institution Revision (CRI), a group of people that revised the investigation to protect your right, or a regulatory agency.

Participation cost

There is no cost to participate to this study.

Will I be paid to participate?

You will not receive any payment for participating.

If I participate, how will my privacy be protected?**Confidentiality**

The name of your child will not be used at any moment. Your child information will not be used for any study that is not related to the present one. No information will be shared without your authorization, except if it is asked by the law. The Ethics Committee of the Regional Maternal Infantile Hospital of High Specialty and the Instituto Tecnológico y de Estudios Superiores de Monterrey approved the realization of this study. These committees approve and supervise human research studies. The scientific data obtained as part of this study could be used in scientific publications or presentations.

**YOUR RIGHTS ARE NOT AFFECTED BY
ANY INFORMATION PROTECTION LAW**

Who can I contact if I have questions about my rights?

Before signing this document, you should ask about any doubt. The research team will answer all your questions before, during and after the study. If you think that a question has not been answered or if you did not understand the answer, please keep asking.

Do not sign this document if you did not have the opportunity to ask all your questions and to be entirely pleased with their answers.

This agreement form has been revised the Ethics Committee of the Ethical Committee of the School of Medicine of Tecnológico de Monterrey.

If you have any question about your rights as participant, you can call the following number:
(01) 81 88882107.

Signatures:

Mark with X if you agree with the sentence.

☐ I have been informed about the study and I have had my first conversation with the researcher (Date)_____and hour (if necessary) _____

☐ I read and understood the information given in the present document.

☐ I could ask all what I wanted, and all my doubts have been answered correctly.

☐ I agree to participate in this study, and I do not renounce any of my legal rights for signing this agreement.

I understand that I will receive a signed and dated copy of this document

Name of the participant

Signature of the participant

Date

Hour

Name of legal representant

Parentage

Signature of legal representant

Signature

Hour

=====

Impartial witnesses

Name of impartial witness 1

Address impartial witness 1

Parentage

Signature of impartial witness 1 Date (dd-mm-yy) Hour

Name of impartial witness 2

Address impartial witness 2

Parentage

Signature of impartial witness 1 Date (dd-mm-yy) Hour

Person who obtains the agreement

Name

Signature Date Hour

- **I certify that I received a copy of the present agreement and I gave a copy of my official identification.**
-
-

Signature of legal representant



Participant information sheet for legal tutors of autistic children participants.

Protocol: autismoEEG2020

Title: "Participant information sheet for legal tutors of children participants. Intervention group2. Development of a Social Story™ and robot-based intervention to improve emotional prosody discrimination in autistic children."



Study center	Instituto Tecnológico y de Estudios Superiores de Monterrey, Campus Monterrey
Principal researcher:	M.S.C. Mathilde Marie Duville
Ethic Committee: Contact:	Comité de Ética en Investigación de la Escuela de Medicina del Instituto Tecnológico y de Estudios Superiores de Monterrey. Dr. Federico Ramos Ruiz President of Ethics Committee Dr. Carlos Jerjes Sánchez Díaz President of Investigation Committee
Address:	Av. Ignacio Morones Prieto 3000 Pte. Col. Los Doctores CP: 64710 Monterrey, Nuevo León México
Phone number:	Dr. Victor Javier Lara Diaz: 81 88 88 21 07

Introduction

With this document we want to invite your child to voluntary participate to a research study that has the objective to develop a drug-free intervention based on the use of synthesized voices, social stories™ and NAO social robot for improving emotion discrimination abilities of autistic children.

Before that you accept your child's participation, we ask you to read the present document, that has the objective of telling you the possible risks and benefits, so that you can take an informed decision. You can share it with whoever you want (a friend, a family member, etc). If you have doubts, you can ask directly the researchers involved in the study in order them to answer your questions.

Once you will know more about the study, we will ask you to sign this document in order your child to participate. Your decision is voluntary, meaning that you are entirely free to decide if your child participate or not. You can withdraw your agreement at any moment without having to justify yourself, without affecting the attention we have for you.



Purpose of the study

This study is the third one of 3 research studies. Its aim is to develop a drug-free intervention based on the use of synthesized voices, NAO social robot and Social Stories™ for helping autistic children to discriminate emotional prosodies. NAO is 57cm-high and can be programmed to talk and interact with humans on didactic and simple ways. It is generally well accepted by autistic children. There is no risk for your child.

The participants of this study are allocated to 4 different groups. Group 1 (5 participants) is composed of autistic children that will receive the intervention based on the use of NAO robot, synthesized and human voices. Group 2 (5 participants) is composed of autistic children that will receive the intervention based on the use of NAO robot and human voices. Group 3 (5 participants) is composed of autistic children that will not receive the intervention. Group 4 (5 participants) is composed of typically-developed children that will not receive the intervention. Your child belongs to group 2.

Your child's participation will last approximatively 35 minutes at sessions 1, 14 and 15, 10 minutes at sessions 2 to 6 and 14 and 45 minutes at sessions 7 and 13. You will have to answer the Autism Spectrum Rating Scales at sessions 1, 14 and 15 (20 minutes).

After signing this agreement, inclusion and exclusion criteria will be checked:

- Aged between 9 and 11-year-old
- A T-score greater than 60 (slightly elevated to very elevated scores for autistic behaviors) on Social/Communication, DSM-IV-TR (Text Revision), Peer and Adult Socialization and Social/Emotional Reciprocity of the Autism Spectrum Rating Scale.
- Have been diagnosed with high-functioning autism spectrum disorders by using the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, Fourth) or the ICD-10 (International Classification of Diseases and Related Health Problems – Tenth Edition).
- Without intellectual disability
- Not being under any medical treatment acting on the nervous system
- Not having auditive deficits or any pathology affecting the nervous system other than autism

Study procedure

Pretest phase

During the first session, you will have to answer the Autism Spectrum Rating Scales, which is a 71-question form in which you can answer in a 4-point scale. It aims to evaluate your child's autistic symptomatology. It will last approximatively 20 minutes. Your child will have to listen to words uttered with emotional intonations, which can be: neutral, disgust, fear, anger, happiness and sadness. After each word, he/she will have to choose on the computer screen which Emoji match

best the emotion conveyed by the word's prosody. While performing the task, his/her brain activity will be monitored. For this purpose, an electroencephalographic headset will be collocated on his/her head before starting the experiment and will be removed at the end of the session.

Intervention

Sessions 2 to 13 will consist of the intervention. Your child will have to listen to Social Stories™ told by NAO robot which have the objective of teaching your child to focus on appropriate cues to foster emotional intonations discrimination. Each story will last 5 minutes and will include interactive questions for your child to answer. Each story is personalized to your child according to the information that you sent before the 1st session. In sessions 7 and 13, your child will have to answer the same experimental procedure as the one he/she answered in session 1.

Posttest phase.

Sessions 14 and 15 will consist of the repetition of session 1 as follow-up assessments.

Because of the current pandemic issues, your child will have to use a mask when he/she will interact with me. I will also give him/her antibacterial gel that he/she will have to use at the beginning and the end of the session. I will stay at least at 1.5meters from him/her during the entire session.

Participant's responsibilities

You have the responsibility to:

- Give us the required information about you child
- Follow the instructions related to the experiment's procedure

Risks

Your child does not take any risk for participating to this study.

Benefits

With your help, we will know more about the efficacy of a robot and Social Story™-based intervention on neuronal and behavioural abilities to discriminate emotional prosodies in autistic children.

Participating is voluntary?

Your child's participation is voluntary and can be withdrawn at any moment without any consequence. Participating to this study is your decision and the one of your child. You and your child can choose not to participate or change your mind.

The researcher can decide to withdraw your child's participation without your agreement if:

- You do not follow the instructions

- The experiment is interrupted by the Independent Ethics Committee (CEI) or the Council of Institution Revision (CRI), a group of people that revised the investigation to protect your right, or a regulatory agency.

Participation cost

There is no cost to participate to this study.

Will I be paid to participate?

You will not receive any payment for participating.

If I participate, how will my privacy be protected?**Confidentiality**

The name of your child will not be used at any moment. Your child information will not be used for any study that is not related to the present one. No information will be shared without your authorization, except if it is asked by the law. The Ethics Committee of the Regional Maternal Infantile Hospital of High Specialty and the Instituto Tecnológico y de Estudios Superiores de Monterrey approved the realization of this study. These committees approve and supervise human research studies. The scientific data obtained as part of this study could be used in scientific publications or presentations.

**YOUR RIGHTS ARE NOT AFFECTED BY
ANY INFORMATION PROTECTION LAW**

Who can I contact if I have questions about my rights?

Before signing this document, you should ask about any doubt. The research team will answer all your questions before, during and after the study. If you think that a question has not been answered or if you did not understand the answer, please keep asking.

Do not sign this document if you did not have the opportunity to ask all your questions and to be entirely pleased with their answers.

This agreement form has been revised the Ethics Committee of the Ethical Committee of the School of Medicine of Tecnológico de Monterrey.

If you have any question about your rights as participant, you can call the following number:
(01) 81 8882107.

Signatures:

Mark with X if you agree with the sentence.

☐ I have been informed about the study and I have had my first conversation with the researcher (Date)_____and hour (if necessary)

☐ I read and understood the information given in the present document.

☐ I could ask all what I wanted, and all my doubts have been answered correctly.

☐ I agree to participate in this study, and I do not renounce any of my legal rights for signing this agreement.

I understand that I will receive a signed and dated copy of this document

Name of the participant

Signature of the participant

Date

Hour

Name of legal representant

Parentage

Signature of legal representant

Signature

Hour

=====

Impartial witnesses

Name of impartial witness 1

Address impartial witness 1

Parentage

Signature of impartial witness 1 Date (dd-mm-yy) Hour

Name of impartial witness 2

Address impartial witness 2

Parentage

Signature of impartial witness 1 Date (dd-mm-yy) Hour

Person who obtains the agreement

Name

Signature Date Hour

- **I certify that I received a copy of the present agreement and I gave a copy of my official identification.**
-
-

Signature of legal representant



Participant information sheet for legal tutors of autistic children participants.

Protocol: autismoEEG2020

Title: "Participant information sheet for legal tutors of children participants. Control : group3. Development of a Social Story™ and robot-based intervention to improve emotional prosody discrimination in autistic children."



Study center	Instituto Tecnológico y de Estudios Superiores de Monterrey, Campus Monterrey
Principal researcher:	M.S.C. Mathilde Marie Duville
Ethic Committee: Contact:	Comité de Ética en Investigación de la Escuela de Medicina del Instituto Tecnológico y de Estudios Superiores de Monterrey. Dr. Federico Ramos Ruiz President of Ethics Committee Dr. Carlos Jerjes Sánchez Díaz President of Investigation Committee
Address:	Av. Ignacio Morones Prieto 3000 Pte. Col. Los Doctores CP: 64710 Monterrey, Nuevo León México
Phone number:	Dr. Victor Javier Lara Diaz: 81 88 88 21 07

Introduction

With this document we want to invite your child to voluntary participate to a research study that has the objective to develop a drug-free intervention based on the use of synthesized voices, social stories™ and NAO social robot for improving emotion discrimination abilities of autistic children.

Before that you accept your child's participation, we ask you to read the present document, that has the objective of telling you the possible risks and benefits, so that you can take an informed decision. You can share it with whoever you want (a friend, a family member, etc). If you have doubts, you can ask directly the researchers involved in the study in order them to answer your questions.

Once you will know more about the study, we will ask you to sign this document in order your child to participate. Your decision is voluntary, meaning that you are entirely free to decide if your child participate or not. You can withdraw your agreement at any moment without having to justify yourself, without affecting the attention we have for you.



Purpose of the study

This study is the third one of 3 research studies. Its aim is to develop a drug-free intervention based on the use of synthesized voices, NAO social robot and Social Stories™ for helping autistic children to discriminate emotional prosodies. NAO is 57cm-high and can be programmed to talk and interact with humans on didactic and simple ways. It is generally well accepted by autistic children. There is no risk for your child.

The participants of this study are allocated to 4 different groups. Group 1 (5 participants) is composed of autistic children that will receive the intervention based on the use of NAO robot, synthesized and human voices. Group 2 (5 participants) is composed of autistic children that will receive the intervention based on the use of NAO robot and human voices. Group 3 (5 participants) is composed of autistic children that will not receive the intervention. Group 4 (5 participants) is composed of typically-developed children that will not receive the intervention. Your child belongs to group 3.

Your child's participation will last approximatively 35 minutes at each session (1, 7, 13, 14 and 15). You will have to answer the Autism Spectrum Rating Scales at sessions 1, 14 and 15.

After signing this agreement, inclusion and exclusion criteria will be checked:

- Aged between 9 and 11-year-old
- A T-score greater than 60 (slightly elevated to very elevated scores for autistic behaviors) on Social/Communication, DSM-IV-TR (Text Revision), Peer and Adult Socialization and Social/Emotional Reciprocity of the Autism Spectrum Rating Scale.
- Have been diagnosed with high-functioning autism spectrum disorders by using the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, Fourth) or the ICD-10 (International Classification of Diseases and Related Health Problems – Tenth Edition).
- Without intellectual disability
- Not being under any medical treatment acting on the nervous system
- Not having auditive deficits or any pathology affecting the nervous system other than autism

Study procedure

Pretest phase

During the first session, you will have to answer the Autism Spectrum Rating Scales, which is a 71-question form in which you can answer in a 4-point scale. It aims to evaluate your child's autistic symptomatology. It will last approximatively 20 minutes. Your child will have to listen to words uttered with emotional intonations, which can be: neutral, disgust, fear, anger, happiness and sadness. After each word, he/she will have to choose on the computer screen which Emoji match best the emotion conveyed by the word's prosody. While performing the task, his/her brain activity

will be monitored. For this purpose, an electroencephalographic headset will be collocated on his/her head before starting the experiment and will be removed at the end of the session.

Intervention

Sessions 2 to 13 will consist of the intervention. Your child will have to listen to Social Stories™ told by NAO robot which have the objective of teaching your child to focus on appropriate cues to foster emotional intonations discrimination. Each story will last 5 minutes and will include interactive questions for your child to answer. Each story is personalized to your child according to the information that you sent before the 1st session. In sessions 7 and 13, your child will have to answer the same experimental procedure as the one he/she answered in session 1.

Posttest phase.

Sessions 14 and 15 will consist of the repetition of session 1 as follow-up assessments.

Because of the current pandemic issues, your child will have to use a mask when he/she will interact with me. I will also give him/her antibacterial gel that he/she will have to use at the beginning and the end of the session. I will stay at least at 1.5meters from him/her during the entire session.

Participant's responsibilities

You have the responsibility to:

- Give us the required information about you child
- Follow the instructions related to the experiment's procedure

Risks

Your child does not take any risk for participating to this study.

Benefits

With your help, we will know more about the efficacy of a robot and Social Story™-based intervention on neuronal and behavioural abilities to discriminate emotional prosodies in autistic children.

Participating is voluntary?

Your child's participation is voluntary and can be withdrawn at any moment without any consequence. Participating to this study is your decision and the one of your child. You and your child can choose not to participate or change your mind.

The researcher can decide to withdraw your child's participation without your agreement if:

- You do not follow the instructions



- The experiment is interrupted by the Independent Ethics Committee (CEI) or the Council of Institution Revision (CRI), a group of people that revised the investigation to protect your right, or a regulatory agency.

Participation cost

There is no cost to participate to this study.

Will I be paid to participate?

You will not receive any payment for participating.

If I participate, how will my privacy be protected?**Confidentiality**

The name of your child will not be used at any moment. Your child information will not be used for any study that is not related to the present one. No information will be shared without your authorization, except if it is asked by the law. The Ethics Committee of the Regional Maternal Infantile Hospital of High Specialty and the Instituto Tecnológico y de Estudios Superiores de Monterrey approved the realization of this study. These committees approve and supervise human research studies. The scientific data obtained as part of this study could be used in scientific publications or presentations.

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Who can I contact if I have questions about my rights?

Before signing this document, you should ask about any doubt. The research team will answer all your questions before, during and after the study. If you think that a question has not been answered or if you did not understand the answer, please keep asking.

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This agreement form has been revised the Ethics Committee of the Ethical Committee of the School of Medicine of Tecnológico de Monterrey.

If you have any question about your rights as participant, you can call the following number:
(01) 81 8882107.

Signatures:

Mark with X if you agree with the sentence.

☐ I have been informed about the study and I have had my first conversation with the researcher (Date)_____and hour (if necessary) _____

☐ I read and understood the information given in the present document.

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☐ I agree to participate in this study, and I do not renounce any of my legal rights for signing this agreement.

I understand that I will receive a signed and dated copy of this document

Name of the participant

Signature of the participant

Date

Hour

Name of legal representant

Parentage

Signature of legal representant

Signature

Hour

Impartial witnesses

Name of impartial witness 1

Address impartial witness 1

Parentage

Signature of impartial witness 1 Date (dd-mm-yy) Hour

Name of impartial witness 2

Address impartial witness 2

Parentage

Signature of impartial witness 1 Date (dd-mm-yy) Hour

Person who obtains the agreement

Name

Signature Date Hour

- **I certify that I received a copy of the present agreement and I gave a copy of my official identification.**
-
-

Signature of legal representant



Participant information sheet for legal tutors of autistic children participants.

Protocol: autismoEEG2020

Title: "Participant information sheet for legal tutors of children participants. Control : group
4. Development of a Social Story™ and robot-based intervention to improve emotional
prosody discrimination in autistic children."



Study center	Instituto Tecnológico y de Estudios Superiores de Monterrey, Campus Monterrey
Principal researcher:	M.S.C. Mathilde Marie Duville
Ethic Committee: Contact:	Comité de Ética en Investigación de la Escuela de Medicina del Instituto Tecnológico y de Estudios Superiores de Monterrey. Dr. Federico Ramos Ruiz President of Ethics Committee Dr. Carlos Jerjes Sánchez Díaz President of Investigation Committee
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Name of the participant

Signature of the participant

Date

Hour

Name of legal representant

Parentage

Signature of legal representant

Signature

Hour

Impartial witnesses

Name of impartial witness 1

Address impartial witness 1

Parentage

Signature of impartial witness 1 Date (dd-mm-yy) Hour

Name of impartial witness 2

Address impartial witness 2

Parentage

Signature of impartial witness 1 Date (dd-mm-yy) Hour

Person who obtains the agreement

Name

Signature Date Hour

- **I certify that I received a copy of the present agreement and I gave a copy of my official identification.**
-
-

Signature of legal representant
