

**ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt**  
Release Date: July 30, 2023

**ClinicalTrials.gov ID: NCT02004236**

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### Study Identification

Unique Protocol ID: Autism and tRNS

Brief Title: Transcranial Random Noise Stimulation (tRNS) Over Fronto-temporal Cortex Improves Verbal Fluency and Empathy in Autism Children ( tRNS25112013 )

Official Title: Transcranial Random Noise Noninvasive Brain Stimulation Applied to the Fronto-temporal Cortex Improves Verbal Fluency and Empathy in Children With Autistic Spectrum Disorder

Secondary IDs:

### Study Status

Record Verification: July 2023

Overall Status: Completed

Study Start: February 2014 [Actual]

Primary Completion: August 2014 [Actual]

Study Completion: September 2014 [Actual]

### Sponsor/Collaborators

Sponsor: Spanish Foundation for Neurometrics Development

Responsible Party: Sponsor

Collaborators:

### Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved  
Approval Number: TEAE23112013  
Board Name: Bioethics Committee of the General Hospital of Elche  
Board Affiliation: National Health Services of Spain  
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Data Monitoring: Yes

FDA Regulated Intervention: No

## Study Description

**Brief Summary:** Interventional, prospective, randomized, double-blind, placebo-controlled and parallel assignment study, in which patients with Autism Spectrum Disorder (ASD) are two types of intervention by transcranial random noise stimulation (tRNS), to improve verbal fluency and empathy.

**Detailed Description:** Interventional, prospective, randomized, double-blind, placebo-controlled and parallel assignment study, in which patients receive three types of intervention tRNS: one group received 35 sessions focused on the fronto-temporal cortex, another group received 35 sessions focused on the temporal fusiform cortex and last placebo group was operated with 35 sessions tRNS. After brain noninvasive stimulation sessions, a blind analysis of the improvement in verbal fluency and empathy in patients with autism spectrum disorder is made. For each patient included a follow up period of three months will be established.

## Conditions

Conditions: Autism  
ASD

Keywords: tRNS  
QEEG  
ERP  
ASD  
Autism  
verbal fluency  
empathy  
noninvasive brain stimulation

## Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 3

Masking: Double (Participant, Outcomes Assessor)

Allocation: Randomized

Enrollment: 225 [Actual]

## Arms and Interventions

| Arms   | Assigned Interventions   |
|--|--|
| Experimental: tRNS Fronto-temporal cortex<br>This group receive 35 sessions of tRNS over fronto-temporal cortex          | Device: tRNS Fronto-temporal cortex<br>This group receive 35 sessions of tRNS over fronto-temporal cortex          |
| Experimental: tRNS over fusiform temporal cortex<br>This group receive 35 sessions of tRNS over fusiform temporal cortex | Device: tRNS over fusiform temporal cortex<br>This group receive 35 sessions of tRNS over fusiform temporal cortex |
| Placebo Comparator: tRNS with sham<br>This group receive 35 sessions with sham   | Device: tRNS with sham<br>the subjects receive 35 session with sham  |

## Outcome Measures

[See Results Section.]

## Eligibility

Minimum Age: 5 Years

Maximum Age: 12 Years

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients between 5 and 12 years.
- Meet DSM-IV criteria for autism spectrum disorder.
- Patients who have been diagnosed at least 2 years before inclusion in the study.

Exclusion Criteria:

- Acute visual or hearing loss.
- Traumatic brain injury.
- Other neurological disorders: migraine, epilepsy, tuberous sclerosis ...
- Trauma at birth.
- Mental retardation.
- Pregnancy.

## Contacts/Locations

Central Contact Person: Fernando Vargas-Torcal, PhD  
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Central Contact Backup:

Study Officials:

Locations: **Spain**

General Elche Hospital  
Elche, Alicante, Spain, 03203  
Principal Investigator: Fernando Vargas-Torcal, PhD

## IPDSharing

Plan to Share IPD:

## References

Citations:

Links: URL: <http://www.dep20.san.gva.es/>  
Description General Elche Hospital

URL: <http://www.bigdata4brain.com>  
Description Bigdata4brain LTD

Available IPD/Information:

# Study Results

## Participant Flow

### Reporting Groups

|                                    | Description  |
|------------------------------------|--|
| tRNS Over Fronto-temporal Cortex   | This group receive 35 sessions of tRNS over fronto-temporal cortex<br>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex            |
| tRNS Over Fusiform Temporal Cortex | This group receive 35 sessions of tRNS over fusiform temporal cortex<br>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex |
| tRNS With Sham                     | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham  |

### Overall Study

|                  | tRNS Over Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham    |
|------------------|----------------------------------|------------------------------------|-------------------|
| Started          | 75                               | 75                                 | 75                |
| Completed        | 75                               | 75                                 | 59 <sup>[1]</sup> |
| Not Completed    | 0                                | 0                                  | 16                |
| Lack of Efficacy | 0                                | 0                                  | 16                |

[1] Leave the group because the parents doesn't find any clinical improvement.

## Baseline Characteristics

### Baseline Analysis Population Description

Clinically referred sample of young children between 5 and 12 years old with ASD

### Reporting Groups

|                                    | Description  |
|------------------------------------|--|
| tRNS Fronto-temporal Cortex        | This group receive 35 sessions of tRNS over fronto-temporal cortex<br>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex            |
| tRNS Over Fusiform Temporal Cortex | This group receive 35 sessions of tRNS over fusiform temporal cortex<br>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex |

|                | Description   |
|----------------|---|
| tRNS With Sham | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham |

Baseline Measures

|  |                         | tRNS Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham  | Total            |
|--|-------------------------|-----------------------------|------------------------------------|-----------------|------------------|
| Overall Number of Participants   |                         | 75                          | 75                                 | 59              | 209              |
| <b>Age, Continuous</b><br>Mean (Standard Deviation)<br>Unit of years<br>measure:                       | Number Analyzed         | 75 participants             | 75 participants                    | 59 participants | 209 participants |
|  |                         | 7.5 (1.98)                  | 6.9 (2.1)                          | 7.2 (2.3)       | 7.2 (2.12)       |
| <b>Age, Categorical</b><br>Measure Count of<br>Type: Participants<br>Unit of participants<br>measure:  | Number Analyzed         | 75 participants             | 75 participants                    | 59 participants | 209 participants |
|  | <=18 years              | 75 100%                     | 75 100%                            | 59 100%         | 209 100%         |
|  | Between 18 and 65 years | 0 0%                        | 0 0%                               | 0 0%            | 0 0%             |
|  | >=65 years              | 0 0%                        | 0 0%                               | 0 0%            | 0 0%             |
| <b>Age, Customized</b><br>Mean (Standard Deviation)<br>Unit of years<br>measure:                       | Number Analyzed         | 75 participants             | 75 participants                    | 59 participants | 209 participants |
|  | 4-6 years               | 5.1 (0.80)                  | 4.8 (1.17)                         | 5.3 (0.75)      | 5.06 (0.91)      |
|  | 7-9 years               | 7.2 (0.9)                   | 8.4 (0.73)                         | 7.8 (1.1)       | 7.8 (0.91)       |
|  | 10-12 years             | 11.2 (0.48)                 | 10.1 (0.69)                        | 10.8 (0.88)     | 10.7 (0.68)      |
|  |                         |                             |                                    |                 |                  |
| <b>Sex: Female, Male</b><br>Measure Count of<br>Type: Participants<br>Unit of participants<br>measure: | Number Analyzed         | 75 participants             | 75 participants                    | 59 participants | 209 participants |
|  | Female                  | 0 0%                        | 0 0%                               | 0 0%            | 0 0%             |
|  | Male                    | 75 100%                     | 75 100%                            | 59 100%         | 209 100%         |

|                                   |                        | tRNS Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham  | Total            |
|-----------------------------------|------------------------|-----------------------------|------------------------------------|-----------------|------------------|
| <b>Region of Enrollment</b>       | <b>Number Analyzed</b> | 75 participants             | 75 participants                    | 59 participants | 209 participants |
| Measure Type:<br>Unit of measure: | Number<br>participants |                             |                                    |                 |                  |
| Spain                             |                        | 75                          | 75                                 | 59              | 209              |

## Outcome Measures

### 1. Primary Outcome Measure:

|                     |  |
|---------------------|--|
| Measure Title       | Verbal Fluency   |
| Measure Description | <p>Goal: Improve in verbal fluency in ASD children between 5 and 12 years. We use D-KEFS (Delis-Kaplan Executive Function System Delis Kaplan Sorting Test), Verbal Fluency Subtest - Category Condition.</p> <p>Description: The verbal fluency Category test evaluates fluent productivity in the verbal domain by asking participants to generate exemplars belonging to the category animals, and subsequently, boys' names. Participants were given 60 s to do it.</p> <p>Values: Category scores were based on the average number of items generated in the two categories (animals and boys' names) during 60 s.</p> <p>Time Frame: Baseline (Before treatment) and 1 day Post-treatment (after completing 3 months of intensive speech therapy during tRNS sessions)</p> |
| Time Frame          | During 3 months of intensive speech therapy during tRNS sessions   |

#### Analysis Population Description

Time frame: Baseline Before treatment and after completing 3 months of intensive speech therapy during tRNS sessions.

#### Reporting Groups

|                                    | Description   |
|------------------------------------|---|
| tRNS Fronto-temporal Cortex        | <p>This group receive 35 sessions of tRNS over fronto-temporal cortex</p> <p>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex</p>            |
| tRNS Over Fusiform Temporal Cortex | <p>This group receive 35 sessions of tRNS over fusiform temporal cortex</p> <p>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex</p> |

|                | Description   |
|----------------|---|
| tRNS With Sham | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham |

#### Measured Values

|  | tRNS Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham |
|--|-----------------------------|------------------------------------|----------------|
| Overall Number of Participants Analyzed  | 75                          | 75                                 | 59             |
| Verbal Fluency<br>Mean (Standard Deviation)<br>Unit of measure: units on a scale |                             |                                    |                |
| before tRNS  | 9.3 (1.3)                   | 10.5 (1.6)                         | 9.9 (1.1)      |
| after tRNS   | 8.3 (1.2)                   | 10.4 (1.1)                         | 10 (0.9)       |

## 2. Primary Outcome Measure:

|                     |   |
|---------------------|---|
| Measure Title       | Sociability   |
| Measure Description | <p>Goal: Evaluate empathy with CARS scale in autism spectrum disorder children between 5 and 12 years after tRNS sessions.</p> <p>CARS (Childhood Autism Rating Scale) by Shopler &amp; Reichler (1971) in Spanish version EVAI (Escala de Valoración de Autismo Infantil) by Leal-Soto, F.; Aguirre, L.P. y Williams, E.E.</p> <p>Description: 15 items in the scale that evaluate: Relating to people, Imitative Behavior, Emotional Response, Body Use, Object Use, Adaptation to Change, Visual Response, Listening Response, Perceptive Response, Fear or Anxiety, Verbal Communication, Non-Verbal Communication, Activity level, Level and consistency of Intellective Relations and General Impressions.</p> <p>Values: The CARS scores range from 15 to 60, with lower scores indicating better outcome. It classifies the child as not autistic (below 30), moderately autistic (30-36.5) or severely autistic (above 36.5)</p> |
| Time Frame          | During 3 months of intensive speech therapy during tRNS sessions  |

#### Analysis Population Description

Time frame: Baseline Before treatment and after completing 3 months of intensive speech therapy during tRNS sessions.



### Reporting Groups

|                                    | Description  |
|------------------------------------|--|
| tRNS Fronto-temporal Cortex        | This group receive 35 sessions of tRNS over fronto-temporal cortex<br>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex            |
| tRNS Over Fusiform Temporal Cortex | This group receive 35 sessions of tRNS over fusiform temporal cortex<br>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex |
| tRNS With Sham                     | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham  |

### Measured Values

|   | tRNS Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham |
|---|-----------------------------|------------------------------------|----------------|
| Overall Number of Participants Analyzed                                       | 75                          | 75                                 | 59             |
| Sociability<br>Mean (Standard Deviation)<br>Unit of measure: units on a scale |                             |                                    |                |
| before tRNS   | 30.6 (1.9)                  | 32.1 (2.2)                         | 31.8 (3.4)     |
| after tRNS  | 19.4 (2.1)                  | 20.2 (1.8)                         | 30.1 (2.5)     |

### 3. Secondary Outcome Measure:

|                     |  |
|---------------------|--|
| Measure Title       | Ratio Theta/Beta Before tRNS   |
| Measure Description | The purpose of the present study was to determine if the theta/beta ratio, and theta and beta separately, correlate with behavioral parameters, and if these measures discriminate between children a with Autism Spectrum disorder (ASD) and normal gender- and age-matched controls before and after tRNS intervention in ASD children between 5 and 12 years old. |
| Time Frame          | During 3 months of intensive speech therapy during tRNS sessions   |

Analysis Population Description  
[Not Specified]

#### Reporting Groups

|                                    | Description  |
|------------------------------------|--|
| tRNS Fronto-temporal Cortex        | This group receive 35 sessions of tRNS over fronto-temporal cortex<br>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex            |
| tRNS Over Fusiform Temporal Cortex | This group receive 35 sessions of tRNS over fusiform temporal cortex<br>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex |
| tRNS With Sham                     | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham  |

#### Measured Values

|  | tRNS Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham |
|--|-----------------------------|------------------------------------|----------------|
| Overall Number of Participants Analyzed  | 75                          | 75                                 | 59             |
| Ratio Theta/Beta Before tRNS<br>Mean (Standard Deviation)<br>Unit of measure: Ratio theta/beta before tRNS | 25 (0.88)                   | 30 (1.1)                           | 26 (0.53)      |

#### 4. Secondary Outcome Measure:

|                     |  |
|---------------------|--|
| Measure Title       | Theta Amplitude in T5 Before tRNS  |
| Measure Description | The purpose of the present study was to determine if the theta/beta ratio, and theta and beta separately, correlate with behavioral parameters, and if these measures discriminate between children a with Autism Spectrum disorder (ASD) and normal gender- and age-matched controls before and after tRNS intervention in ASD children between 5 and 12 years old. |
| Time Frame          | During 3 months of intensive speech therapy during tRNS sessions   |

Analysis Population Description  
[Not Specified]

#### Reporting Groups

|                                  | Description   |
|----------------------------------|---|
| tRNS Over Fronto-temporal Cortex | This group receive 35 sessions of tRNS over fronto-temporal cortex<br>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex |

|                                    | Description  |
|------------------------------------|--|
| tRNS Over Fusiform Temporal Cortex | This group receive 35 sessions of tRNS over fusiform temporal cortex<br>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex |
| tRNS With Sham                     | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham  |

#### Measured Values

|   | tRNS Over Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham |
|---|----------------------------------|------------------------------------|----------------|
| Overall Number of Participants Analyzed   | 75                               | 75                                 | 59             |
| Theta Amplitude in T5 Before tRNS<br>Mean (Standard Deviation)<br>Unit of measure: MicroVolts | 3.2 (0.3)                        | 2.7 (0.11)                         | 3.5 (0.5)      |

#### 5. Secondary Outcome Measure:

|                     |  |
|---------------------|--|
| Measure Title       | Ratio Theta/Beta After tRNS  |
| Measure Description | The purpose of the present study was to determine if the theta/beta ratio, and theta and beta separately, correlate with behavioral parameters, and if these measures discriminate between children a with Autism Spectrum disorder (ASD) and normal gender- and age-matched controls before and after tRNS intervention in ASD children between 5 and 12 years old. |
| Time Frame          | During 3 months of intensive speech therapy during tRNS sessions   |

Analysis Population Description  
[Not Specified]

#### Reporting Groups

|                                    | Description  |
|------------------------------------|--|
| tRNS Over Fronto-temporal Cortex   | This group receive 35 sessions of tRNS over fronto-temporal cortex<br>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex            |
| tRNS Over Fusiform Temporal Cortex | This group receive 35 sessions of tRNS over fusiform temporal cortex<br>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex |

|                | Description   |
|----------------|---|
| tRNS With Sham | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham |

#### Measured Values

|  | tRNS Over Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham |
|--|----------------------------------|------------------------------------|----------------|
| Overall Number of Participants Analyzed  | 75                               | 75                                 | 59             |
| Ratio Theta/Beta After tRNS<br>Mean (Standard Deviation)<br>Unit of measure: Ratio theta/beta after tRNS | 12 (1.1)                         | 14 (0.52)                          | 25 (0.77)      |

#### 6. Secondary Outcome Measure:

|                     |  |
|---------------------|--|
| Measure Title       | Theta Amplitude in T5 After tRNS   |
| Measure Description | Evaluate QEEG (brainwave changes in frequency bandfs and amplitude) after tRNS intervention in ASD children between 5 and 12 years old |
| Time Frame          | During 3 months of intensive speech therapy during tRNS sessions   |

Analysis Population Description  
[Not Specified]

#### Reporting Groups

|                                    | Description  |
|------------------------------------|--|
| tRNS Over Fronto-temporal Cortex   | This group receive 35 sessions of tRNS over fronto-temporal cortex<br>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex            |
| tRNS Over Fusiform Temporal Cortex | This group receive 35 sessions of tRNS over fusiform temporal cortex<br>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex |
| tRNS With Sham                     | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham  |

Measured Values

|  | tRNS Over Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham |
|--|----------------------------------|------------------------------------|----------------|
| Overall Number of Participants Analyzed  | 75                               | 75                                 | 59             |
| Theta Amplitude in T5 After tRNS<br>Mean (Standard Deviation)<br>Unit of measure: MicroVolts | 2.2 (0.41)                       | 1.5 (0.36)                         | 3.3 (0.84)     |

**7. Secondary Outcome Measure:**

|                     |  |
|---------------------|--|
| Measure Title       | Reaction Time in ECPT Before tRNS                                |
| Measure Description | ERP & Behaviour changes in ASD children after tRNS               |
| Time Frame          | During 3 months of intensive speech therapy during tRNS sessions |

Analysis Population Description  
[Not Specified]

Reporting Groups

|                                    | Description  |
|------------------------------------|--|
| tRNS Over Fronto-temporal Cortex   | This group receive 35 sessions of tRNS over fronto-temporal cortex<br>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex            |
| tRNS Over Fusiform Temporal Cortex | This group receive 35 sessions of tRNS over fusiform temporal cortex<br>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex |
| tRNS With Sham                     | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham  |

Measured Values

|   | tRNS Over Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham |
|---|----------------------------------|------------------------------------|----------------|
| Overall Number of Participants Analyzed | 75                               | 75                                 | 59             |

|   | tRNS Over Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham |
|---|----------------------------------|------------------------------------|----------------|
| Reaction Time in ECPT Before tRNS<br>Mean (Standard Deviation)<br>Unit of measure: Milliseconds | 756 (23.5)                       | 698 (34.2)                         | 722 (18.9)     |

### 8. Secondary Outcome Measure:

|                     |  |
|---------------------|--|
| Measure Title       | Omission Errors Before tRNS                                      |
| Measure Description | ERP and behaviour changes in ASD children before tRNS            |
| Time Frame          | During 3 months of intensive speech therapy during tRNS sessions |

Analysis Population Description  
[Not Specified]

### Reporting Groups

|                                    | Description  |
|------------------------------------|--|
| tRNS Over Fronto-temporal Cortex   | This group receive 35 sessions of tRNS over fronto-temporal cortex<br>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex            |
| tRNS Over Fusiform Temporal Cortex | This group receive 35 sessions of tRNS over fusiform temporal cortex<br>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex |
| tRNS With Sham                     | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham  |

### Measured Values

|  | tRNS Over Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham |
|--|----------------------------------|------------------------------------|----------------|
| Overall Number of Participants Analyzed  | 75                               | 75                                 | 59             |
| Omission Errors Before tRNS<br>Mean (Standard Deviation)<br>Unit of measure: number of errors during ECPT task | 85 (5.2)                         | 91 (3.2)                           | 88 (4.6)       |

**9. Secondary Outcome Measure:**

|                     |  |
|---------------------|--|
| Measure Title       | Commission Errors Before tRNS                                    |
| Measure Description | ERP and Behaviour changes in ASD children before tRNS            |
| Time Frame          | During 3 months of intensive speech therapy during tRNS sessions |

Analysis Population Description  
[Not Specified]

Reporting Groups

|                                    | Description  |
|------------------------------------|--|
| tRNS Over Fronto-temporal Cortex   | This group receive 35 sessions of tRNS over fronto-temporal cortex<br>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex            |
| tRNS Over Fusiform Temporal Cortex | This group receive 35 sessions of tRNS over fusiform temporal cortex<br>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex |
| tRNS With Sham                     | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham  |

Measured Values

|  | tRNS Over Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham |
|--|----------------------------------|------------------------------------|----------------|
| Overall Number of Participants Analyzed  | 75                               | 75                                 | 59             |
| Commission Errors Before tRNS<br>Median (Standard Deviation)<br>Unit of measure: number of errors during ECPT task | 6 (0.2)                          | 8 (1.1)                            | 19 (0.9)       |

**10. Secondary Outcome Measure:**

|                     |  |
|---------------------|--|
| Measure Title       | P3b Wave Amplitude Before tRNS                                   |
| Measure Description | ERP and behaviour Changes in ASD children before tRNS            |
| Time Frame          | During 3 months of intensive speech therapy during tRNS sessions |

Analysis Population Description  
[Not Specified]

Reporting Groups

|                                    | Description  |
|------------------------------------|--|
| tRNS Over Fronto-temporal Cortex   | This group receive 35 sessions of tRNS over fronto-temporal cortex<br>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex            |
| tRNS Over Fusiform Temporal Cortex | This group receive 35 sessions of tRNS over fusiform temporal cortex<br>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex |
| tRNS With Sham                     | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham  |

Measured Values

|  | tRNS Over Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham |
|--|----------------------------------|------------------------------------|----------------|
| Overall Number of Participants Analyzed  | 75                               | 75                                 | 59             |
| P3b Wave Amplitude Before tRNS<br>Mean (Standard Deviation)<br>Unit of measure: MicroVolts | 0.5 (0.12)                       | 0.7 (0.4)                          | 0.3 (0.2)      |

**11. Secondary Outcome Measure:**

|                     |  |
|---------------------|--|
| Measure Title       | Reaction Time After tRNS   |
| Measure Description | ERP and behaviour Changes in ASD children after tRNS             |
| Time Frame          | During 3 months of intensive speech therapy during tRNS sessions |

Analysis Population Description  
[Not Specified]

Reporting Groups

|                                  | Description   |
|----------------------------------|---|
| tRNS Over Fronto-temporal Cortex | This group receive 35 sessions of tRNS over fronto-temporal cortex<br>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex |



|                                    | Description  |
|------------------------------------|--|
| tRNS Over Fusiform Temporal Cortex | This group receive 35 sessions of tRNS over fusiform temporal cortex<br>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex |
| tRNS With Sham                     | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham  |

#### Measured Values

|  | tRNS Over Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham |
|--|----------------------------------|------------------------------------|----------------|
| Overall Number of Participants Analyzed  | 75                               | 75                                 | 59             |
| Reaction Time After tRNS<br>Mean (Standard Deviation)<br>Unit of measure: Milliseconds | 690 (10.4)                       | 556 (7.4)                          | 714 (3.2)      |

#### 12. Secondary Outcome Measure:

|                     |  |
|---------------------|--|
| Measure Title       | Omission Errors After tRNS                                       |
| Measure Description | ERP and behaviour Changes in ASD children after tRNS             |
| Time Frame          | During 3 months of intensive speech therapy during tRNS sessions |

Analysis Population Description  
[Not Specified]

#### Reporting Groups

|                                    | Description  |
|------------------------------------|--|
| tRNS Over Fronto-temporal Cortex   | This group receive 35 sessions of tRNS over fronto-temporal cortex<br>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex            |
| tRNS Over Fusiform Temporal Cortex | This group receive 35 sessions of tRNS over fusiform temporal cortex<br>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex |
| tRNS With Sham                     | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham  |

Measured Values

|   | tRNS Over Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham |
|---|----------------------------------|------------------------------------|----------------|
| Overall Number of Participants Analyzed   | 75                               | 75                                 | 75             |
| Omission Errors After tRNS<br>Mean (Standard Deviation)<br>Unit of measure: units on a scale uV | 68 (2.3)                         | 57 (4.7)                           | 20 (1.8)       |

**13. Secondary Outcome Measure:**

|                     |  |
|---------------------|--|
| Measure Title       | Commission Errors After tRNS                                     |
| Measure Description | ERP and behaviour Changes in ASD children after tRNS             |
| Time Frame          | During 3 months of intensive speech therapy during tRNS sessions |

Analysis Population Description  
[Not Specified]

Reporting Groups

|                                    | Description  |
|------------------------------------|--|
| tRNS Over Fronto-temporal Cortex   | This group receive 35 sessions of tRNS over fronto-temporal cortex<br>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex            |
| tRNS Over Fusiform Temporal Cortex | This group receive 35 sessions of tRNS over fusiform temporal cortex<br>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex |
| tRNS With Sham                     | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham  |

Measured Values

|   | tRNS Over Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham |
|---|----------------------------------|------------------------------------|----------------|
| Overall Number of Participants Analyzed | 75                               | 75                                 | 59             |

|   | tRNS Over Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham |
|---|----------------------------------|------------------------------------|----------------|
| Commission Errors After tRNS<br>Mean (Standard Deviation)<br>Unit of measure: number of errors during ECPT task | 6 (0.2)                          | 8 (1.1)                            | 19 (0.9)       |

#### 14. Secondary Outcome Measure:

|                     |  |
|---------------------|--|
| Measure Title       | P3b Wave Amplitude After tRNS                                    |
| Measure Description | ERP and behaviour Changes in ASD children after tRNS             |
| Time Frame          | During 3 months of intensive speech therapy during tRNS sessions |

Analysis Population Description  
[Not Specified]

#### Reporting Groups

|                                    | Description  |
|------------------------------------|--|
| tRNS Over Fronto-temporal Cortex   | This group receive 35 sessions of tRNS over fronto-temporal cortex<br>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex            |
| tRNS Over Fusiform Temporal Cortex | This group receive 35 sessions of tRNS over fusiform temporal cortex<br>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex |
| tRNS With Sham                     | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham  |

#### Measured Values

|   | tRNS Over Fronto-temporal Cortex | tRNS Over Fusiform Temporal Cortex | tRNS With Sham |
|---|----------------------------------|------------------------------------|----------------|
| Overall Number of Participants Analyzed   | 75                               | 75                                 | 59             |
| P3b Wave Amplitude After tRNS<br>Mean (Standard Deviation)<br>Unit of measure: MicroVolts | 2.1 (0.25)                       | 1.8 (0.65)                         | 0.4 (0.32)     |

## Reported Adverse Events

|                                     |                 |
|-------------------------------------|-----------------|
| Time Frame                          | [Not specified] |
| Adverse Event Reporting Description | [Not specified] |

### Reporting Groups

|                                    | Description  |
|------------------------------------|--|
| tRNS Fronto-temporal Cortex        | This group receive 35 sessions of tRNS over fronto-temporal cortex<br>tRNS Fronto-temporal cortex: This group receive 35 sessions of tRNS over fronto-temporal cortex            |
| tRNS Over Fusiform Temporal Cortex | This group receive 35 sessions of tRNS over fusiform temporal cortex<br>tRNS over fusiform temporal cortex: This group receive 35 sessions of tRNS over fusiform temporal cortex |
| tRNS With Sham                     | This group receive 35 sessions with sham<br>tRNS with sham: the subjects receive 35 session with sham  |

### All-Cause Mortality

|                           | tRNS Fronto-temporal Cortex |          | tRNS Over Fusiform Temporal Cortex |          | tRNS With Sham           |          |
|---------------------------|-----------------------------|----------|------------------------------------|----------|--------------------------|----------|
|                           | Affected/<br>At Risk (%)    | # Events | Affected/<br>At Risk (%)           | # Events | Affected/<br>At Risk (%) | # Events |
| Total All-Cause Mortality | /                           |          | /                                  |          | /                        |          |

### Serious Adverse Events

|       | tRNS Fronto-temporal Cortex |          | tRNS Over Fusiform Temporal Cortex |          | tRNS With Sham           |          |
|-------|-----------------------------|----------|------------------------------------|----------|--------------------------|----------|
|       | Affected/<br>At Risk (%)    | # Events | Affected/<br>At Risk (%)           | # Events | Affected/<br>At Risk (%) | # Events |
| Total | 0/75 (0%)                   |          | 0/75 (0%)                          |          | 0/59 (0%)                |          |

## Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 2%

|                              | tRNS Fronto-temporal Cortex |          | tRNS Over Fusiform Temporal Cortex |          | tRNS With Sham        |          |
|------------------------------|-----------------------------|----------|------------------------------------|----------|-----------------------|----------|
|                              | Affected/ At Risk (%)       | # Events | Affected/ At Risk (%)              | # Events | Affected/ At Risk (%) | # Events |
| Total                        | 1/75 (1.33%)                |          | 2/75 (2.67%)                       |          | 0/59 (0%)             |          |
| Nervous system disorders     |                             |          |                                    |          |                       |          |
| Dizziness <sup>A [1] †</sup> | 1/75 (1.33%)                | 1        | 2/75 (2.67%)                       | 2        | 0/59 (0%)             | 0        |

† Indicates events were collected by systematic assessment.

A Term from vocabulary, Dizziness

[1] The children are disorientated in time and space at least during 1 or 2 hours after tRNS session

## Limitations and Caveats

[Not specified]

## More Information

### Certain Agreements:

All Principal Investigators ARE employed by the organization sponsoring the study.

### Results Point of Contact:

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