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Research conducted

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A scientific single case study on speech, auditory processing and attentional strengthening with Forbrain®

SUMMARY REPORT

by Carles Escera, PhD, Professor
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Introduction

Forbrain® is a user-friendly device that uses bone conduction and a series of dynamic filters to give the user feedback of his/her own voice in a way that is proposed to optimize all components of the audio-vocal loop thus improving auditory perception. It has been suggested that the device can enhance speech, fluency, memory, focus, coordination and many other sensory functions, resulting in several improvements in the psychological (cognitive) / emotional domain.
The present single-case study is the first attempt to test the hypothesis that Forbrain® indeed induces plastic changes in the brain by at least two independent but related neural mechanisms:

1. by challenging the audio-vocal loop through the modified speech signal leading to a enriched acoustic environment resulting in auditory plasticity, and
2. by forcing the executive mechanisms of attention control to cope with the involuntary attention signals triggered by the mismatching speech inputs.

The final outcome of all these processes may be the reinforcement of the executive mechanisms of attentional control, resulting in better concentration, stronger resistance to distracters, improvements in working memory capacity and the feeling of being more focused.

Protocol

In this proof-of-concept research an individual case study (a 21-year old healthy female) was conducted to determine what mechanisms and changes could be detected following five fifteen minute sessions of Forbrain® use on consecutive days plus a follow-up day three days later. Specifically, the research was designed to look at the purported neural mechanism that challenged the audio-vocal loop through the modified speech signal leading to an enriched acoustic environment resulting in auditory plasticity. In addition, it researched whether focus could be improved by forcing the executive mechanisms of attentional control to cope with involuntary attention signals triggered by mismatching speech inputs.

Measurements were taken prior to use, during use and after use and included metrics on voice quality, emotional arousal as measured by skin conductance and heart rate, and attention which looked, among other things, the neurological response to distraction (ATT test).

The auditory discrimination of speech (AUD test) was measured by a test that looked at the acoustic (fundamental frequency and intensity) and phonological (vowel identity and duration) changes.

Procedure of evaluation

The procedure was as follows:

1. Baseline measurements were taken on four consecutive, alternating runs of the AUD and ATT tests, lasting a total of 80 minutes.
2. Baseline measurements of voice quality and emotional arousal parameters were obtained during reading for 7 minutes while wearing Forbrain® in off mode.
3. During a 15-minutes long session, voice quality and emotional arousal parameters were recording during reading with Forbrain® in on mode.
4. After using Forbrain®, new measurements of voice quality and emotional arousal parameters were obtained during reading for 7 additional minutes while wearing Forbrain® in off mode.
5. A full post-treatment (post-Forbrain® use) measurement session including four consecutive, alternating runs of the AUD and ATT tests lasting for 80 minutes was finally performed.

This very same schedule was repeated on five consecutive days, featuring a total of 75 minutes of Forbrain® use.

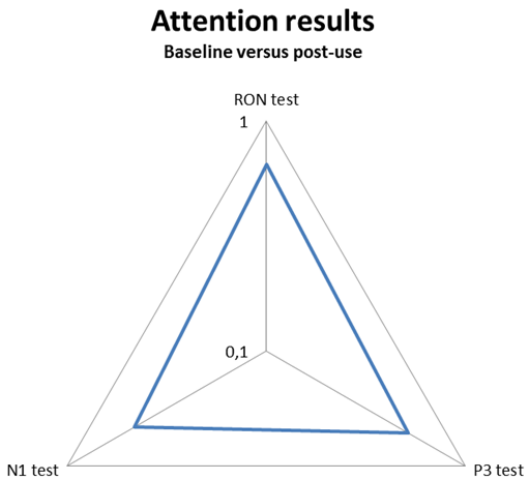
Results

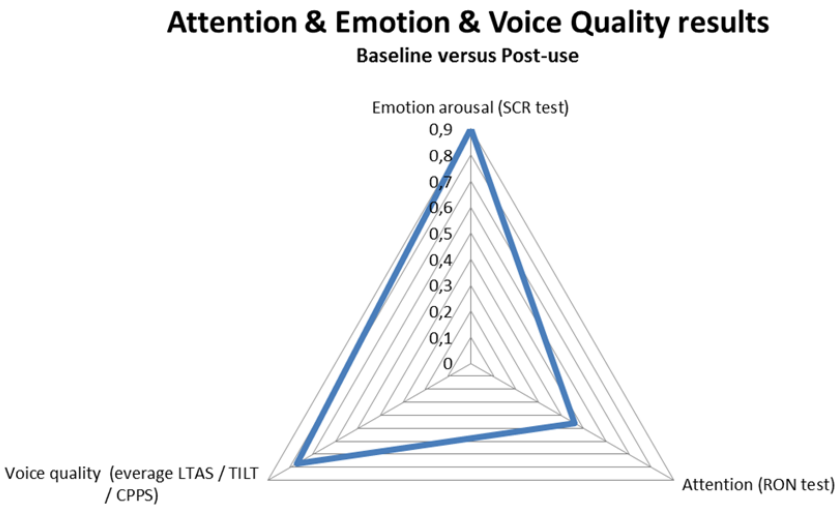
The present single-case study was designed to scientifically test whether the use of Forbrain® had any cognitive enhancement effects. To test for such effects, a sophisticated design was implemented that recorded behavioral, psychophysiological and brain responses before, during and after Forbrain® was used for 15 minutes on five consecutive days, plus a follow-up day. The data was analyzed by means of quantitative statistical methods suited for single-case studies (Manolov et al., 2014; Shadish et al., 2014a; Shadish et al., 2014b), and the results obtained revealed significant effects on all three levels of analysis: behavioral (voice quality), psychophysiological (emotional arousal), and neuronal (activation of the cerebral network of attention control). Specifically the results can be summarized as follows:

1. **After using Forbrain® for 15 minutes, the activation of the cerebral network of involuntary attention was dampened. This is supported by the attenuated amplitudes of all components of the distraction potential (N1-enhancement, novelty-P3, reorienting negativity) and indicates that Forbrain® can reinforce the mechanisms of executive control of attention and protect from distraction, resulting in better concentration, at least during the subsequent 80 minutes when the post-Forbrain® use measurements were taken.**
2. **During the use of Forbrain® there is an enhancement in ongoing emotional arousal. This is supported by the statistically significant differences in heart rate and skin conductance between measurements taken during reading without Forbrain compared to measurements taken during reading while using Forbrain®. Because there were no differences between measurements during reading while using Forbrain® and post-use ones, these effects, at least regarding the skin conductance response, remain for the short period of seven minutes of the post-use measurement.**
3. **During the use of Forbrain®, and at least during the seven-minute period afterwards, voice quality improves as a consequence of Forbrain® use.**

The research is, of course, subject to all the limitations of a single case design and has limited generalizability. However, as a first step in researching the effects of a limited use of Forbrain, the results suggest that there is a real basis for the claims that Forbrain can improve voice quality and the executive attentional mechanisms and memory.

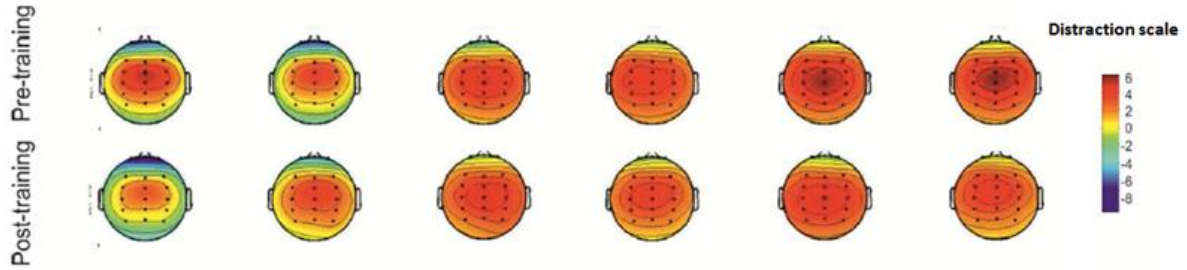
The results suggest that Forbrain® could be helpful in improving focus in those who have attention disorders such as ADHD, and those who have difficulties with speech production and auditory processing. Moreover, any improvement in attention, such as was demonstrated in this study, could have benefits to everyone on memory, focus and fluency.





Impact (>0.4 = significant)

Scalp pictures illustrate the temporal series of all 48 measurements of the N1-enhancement and the late novelty-P3, split by recording days and pre- and post treatment series with Forbrain. These measures show significant attenuation of distraction.



Further research should be undertaken to fully understand the scope and the pervasiveness of Forbrain® effects.
The full report of this research will be published in a Scientific Review.

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Forbrain®'s effect on the reading process

SUMMARY REPORT

Master Degree thesis by Beatriz Aguilar Guerrero

It has recently appeared on the market Forbrain, a device that promises to improve the cognitive abilities related to the reading process. This study tries to investigate the basis of its operation and quantify the possible real improvements that may occur to the reading processes in children at the second year of Public Primary School in Malaga. It is carried out an experimental study with control group, pretest and postest evaluation and a constant work with the device for ten minutes and ten days.

The evaluation will be carried out using the test PROLEC in its reduced version that will provide significant data on the following variables: NL-P, NL-V, LS-P, LS-V, EG-P, EG-V, CT and CT-P. After analyzing the results obtained by the students they all have achieved a significant improvement in all the subtests in comparison with the control group, leading to the conclusion that the use of Forbrain really improves cognitive skills involved in the reading process.

ESCOLA MEDITERRANI

Forbrain®'s effects on the reading speed and comprehension ability.

This Neurosensory stimulation program was used with 8 primary school students: 4 of them in first grade, 2 in second grade and 2 in sixth grade over a 2-month period, with 4 weekly sessions, giving a total of 20 Forbrain® sessions per child. To measure the students' progress and evaluate the program's benefit in the school, we used the standard reading speed test GALÍ in Catalonian. Forbrain® improved all of the participating student's reading skills. We also took into consideration that Forbrain has an important effect in other aspects of the child's development as well.

The average of progression based on the speed test GALI has been evaluated at 25%.

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Research in progress

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Determine if modifications in auditory amplitude using Forbrain can improve reading ability.

by Dr. Scott L. Decker, Assistant Professor
School Psychology Program, USC – University of South Carolina

The purpose of this study is to determine if modifications in auditory amplitude using the Forbrain can improve reading ability. Forbrain dynamic filter isolates the user's voice and changes the sound frequency to change auditory processing. Additionally, auditory processing has been found to be a significant deficit in children with developmental reading disorders. Therefore, training the auditory processing components for children has potential to improve reading ability. The current study aims to identify if using the forbrain device during reading instruction increases students' reading ability.

The University of South Carolina's Dr. Scott L. Decker, an Assistant Professor in the School Psychology program USC, is coordinating with Richland County's Tutor Eau Claire Dyslexia Center Director, Tracey Ely, in order to obtain the data for this study. Data collection will take place at the Tutor Eau Claire center by USC study staff. There are approximately 10 measures that will be administered, including tests from the Woodcock Johnson IV and AIMS Web. A standardized battery of all assessment measures will be determined for both clinical and research purposes.

The current study will have a control group that receives only the Orton Gillingham intervention, and the experimental group will receive the Orton Gillingham intervention as well as the Forbrain intervention. Each group will receive Orton Gillingham for 45 minutes, twice a week, until the last session on November 19th. The first session will be held on September 8th. On November 20th preliminary intervention data will be achieved.(…)

Research Consortium on Children and Families
www.sc.edu/research/childfamily

Scott L. Decker, PhD
https://sites.google.cHi om/site/acnlabatusc/

UNIVERSITY OF NORTH DAKOTA

Impact of Speech treatment and Auditory Feedback training with Forbrain for Children with Speech Sound Disorder.

by Alycia Cummings, Associate Professor, CCC-SLP.
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Five to eight percent of all children in the United States have a speech sound disorder (SSD). Children with SSD have difficulty producing sounds of their target language system. Some of these children also have difficulty perceiving and categorizing speech sounds. It is presently unknown what underlying mechanisms might account for the communication problems children with SSD encounter. One possible explanation is that children with SSD cannot produce speech sounds correctly because they have poorly specified phonological representations, which are the result of inaccurate speech sound perception. Thus, speech sound production errors may stem from imprecise speech perception and its resulting sparse phonological representations.

We propose to use electrophysiological measures (event-related potentials, ERPs) to examine how phonological representations and their associated auditory sensory responses change in conjunction with two traditional speech treatment approaches: one that does and one that does not involve auditory feedback with Forbrain®. A better understanding of phonological representations and the auditory sensory system in children with SSD will inform how speech evaluations and treatment are best conducted by speech-language pathologists.

Our major objective is to characterize how traditional speech treatment (with and without auditory feedback with Forbrain®) alters the auditory neural responses to sounds targeted in treatment. Since SSD has a relatively high incidence, a good understanding of its underlying nature can inform its clinical management, which could ultimately improve the lives of the affected children and their families. Specifically, children who receive treatment for their SSD have better long-term social, academic, and communicative prognoses than those who do not receive treatment. Here, we propose to use ERP measures to assess auditory sensory processing of speech syllables in children with SSD.

Aim: To assess how ERP auditory sensory responses evoked by English syllables change over time. This will allow for a better understanding of how the neural mechanisms associated with speech perception in SSD change after a period of traditional speech treatment, or intervention that combines traditional treatment and auditory feedback. It is predicted that the speech treatment program that includes auditory feedback with Forbrain® will enhance the phonological representations of children with SSD above and beyond what occurs with traditional treatment alone, resulting in ERP amplitude and latency waveform changes.

Treatment:

Speech sound treatment for children with SSD. Treatment will follow proven Evidence-Based Practice (EBP) methods of previous treatment studies of children with SSD (Cummings & Barlow, 2011; Gierut et al., 1996; Gierut & Morrisette, 2010; Morrisette & Gierut, 2002). A single-subject staggered multiple baseline design will be used in this treatment program, as it has been shown to be useful in the study of treatment of communicative disorders (Connell & Thompson, 1986; McReynolds & Kearns, 1983; McReynolds & Thompson, 1986). Following procedures for this design, the children with SSD will be randomly assigned to

one of two treatment conditions: traditional speech treatment alone (Tx) or traditional speech treatment with auditory feedback training via Forbrain® (AFTx). Every child will be evaluated in a baseline period in which no treatment was provided, followed by speech treatment.

Consistent with efficient and effective Evidence-Based Practice procedures used previously by the PI (Cummings & Barlow, 2011) and others (Gierut et al., 1996; Gierut & Morrisette, 2010; Gierut & Neumann, 1992; Gierut, 1992; Morrisette & Gierut, 2002), treatment will be delivered in two phases: Imitation and Spontaneous Production. Treatment will be provided two times weekly in 1-hour sessions, for up to 14 sessions. Each treatment sound will be targeted through the production of five words that will be initially introduced to the child using a storybook reading format. During the Imitation phase of treatment, each child will be shown a picture of the target word and will be asked to repeat the clinician's verbal model until achieving either a pre-established performance- or time-based criterion, whichever comes first. Specifically, imitation treatment will continue until a child maintains 75% accurate production of the treated phoneme over two consecutive sessions (i.e. performance-based criterion) or until seven consecutive sessions are completed (i.e. time-based criterion) (Gierut et al., 1996). During the Spontaneous Production phase, each child will produce the treated phoneme without a model. In other words, the words targeted in treatment will be elicited by having the children name pictures, label objects, retell stories, and so on. This phase of treatment will continue until the child maintains either a performance-based criterion of 90% accurate production of the treated phoneme over three consecutive sessions, or a time-based criterion of seven consecutive sessions, whichever comes first (Gierut et al., 1996). It is expected that children will spend approximately 3 months in treatment.

Auditory feedback training for children with SSD. Half of the children with SSD will receive auditory feedback via Forbrain® during their twice-weekly speech treatment sessions. Each child will wear the Forbrain® device for 20 minutes during each treatment session. Specifically, the child will put on the Forbrain® device immediately after the reading of the treatment story and then wear it continually for the subsequent 20 minutes of treatment. This selected period of time in treatment sessions typically involves the shaping/elicitation of the treatment sound in isolation, as well as the production of the treatment words in drill play activities. Once the Forbrain® wear-time is complete, the child will remove the device for the remainder of the treatment session.

Phasic boosting of attentional capabilities with a Forbrain® session.

by Carles Escera, PhD, Professor
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Objective. The purpose of this empirical study will be to replicate the effects of a single fifteen minute session of Forbrain® use on neuronal, physiological and behavioral measures in a group of healthy participants, as previously described in our proof of concept single case study (Forbrain N1).

Work. We will focus our testing only on the parameters that yielded significant results in our previous study: the ATTN test, heart rate, skin conductance, and voice variables. The design will be very similar to that used in the previous study, with the following changes: 1) instead of a single case design (N=1 participant) there now be 32 subjects (**N=32 participants)** and 2) **half (n=16) of the participants will be randomly assigned to a control ("placebo") group** in which the Forbrain® device will be kept off during the whole session. Because in our initial study robust effects appeared after one single session of use, we will have one single session per participant. However, before starting the actual experiment, we will collect some dummy data on all three measurements to allow for the participant to become acquainted with the laboratory procedures and thus avoid the undesired effects for heart rate we observed during session 1 in our previous experiment. The protocol for the study will be therefore as follows:

1. Accommodation to the laboratory procedures
2. ATTN test pre-use (2 runs of 10 minutes)
3. Physiological and voice recordings during reading (Forbrain **off**) – (7 minutes)
4. Physiological and voice recordings during reading (Forbrain **on**) – (15 minutes). Notice however that for the **control (placebo) group, Forbrain will be kept off** during the whole laboratory session.
5. Physiological and voice recordings during reading (Forbrain **off**) – (7 minutes)
6. ATTN test post-use (2 runs of 10 minutes)

Impact. The proposed design, a controlled-placebo, eventually double-blind study (at least, the participants won't be informed about which group they are in, and the researcher analyzing the data will ignore the group assignment until the conclusions are drawn), **will provide the strongest evidence in support of the phasic effects of Forbrain**. We expect to replicate our previous single case findings. If so, it is anticipated that a highly impactful scientific publication will result from this study.

Methodology
To test for attentional capabilities, concentration and the ability to cope with involuntary attention, the participants' performance on a task in which they have to cope with distracters, as well as the brain responses triggered by these distracters (the distraction potential --DP, including mismatch negativity –MMN, novelty-P3, and reorienting negativity –RON) will be used (see Escera et al., 1998; Escera and Corral, 2007). [**ATT test**].

In addition, the effects of Forbrain® on voice quality and on emotional arousal will be tested. The former will be checked by recording the participant's voice during reading; the latter will be checked by measuring electrodermal activity (EDA) and the electrocardiogram (EKG) to derive heart rate.

Subjects. A total of **N=32** participants will be enrolled. They will be healthy university students (age range 18-35 years; male or female) with no history of neurological or psychiatric disorders and normal hearing (hearing level will be determined through standard audiometry). Music expertise will be disregarded, as it has been shown to enhance the encoding of speech sound features and auditory discrimination.

The experiment will be conducted in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki). Before the experimental session, all the details of the research (except the hypotheses) will be explained to the participant, who will be informed also about the characteristics of the methods (EEG).

During the active speech protocol, the participant will be given a self-selected text and will be instructed to read aloud during a period of 15 consecutive minutes, while wearing the Forbrain® device.

Stimulus presentation and EEG recording. [**ATT test**] To measure involuntary attention control, a distraction paradigm will be used. In this paradigm, participants are instructed to discriminate visual stimuli (consonants and vowels) while ignoring the preceding auditory stimulus. The sound-letter pairs are presented every 1.2 seconds, and subjects are instructed to press the corresponding response button (consonant/vowel) as fast and as accurately as possible. Critically, most of the sounds consist of a repeated tone pip, which is occasionally replaced by a "distracting" novel sound. In addition, brain responses are recorded to the distracting sounds to isolate the neural signatures of the three stages of involuntary attention control: detecting the distracter (MMN), orienting of attention (novelty-P3), restoring attention to primary task performance (RON) (Escera and Corral, 2007).

The EEG will be recorded at the premises of the ***Brainlab***-Cognitive Neuroscience Research Group (www.ub.edu/brainlab), located in the Department of Psychiatry and Clinical Psychobiology, University of Barcelona, by means of a SynAmpsRT amplifier. Acquisition parameters will be set to: 20000 kHz sampling rate, filter settings: 0.5-2000 Hz, and recordings will be obtained from at least 7 scalp locations (FPz, Fz, Cz, F3, F4, C3, C4); larger set-ups may be considered to record the DP.

An independent component analysis (ICA) blind procedure will be used to scan all EEG epochs for artifacts, and those with artifacts will be excluded from the averages. Responses will be analyzed separately by individual and condition. The dependent variables will be: the harmonic amplitudes of the FFR elicited to the CV /da/ in the two contexts (silent and speech-in-noise); the amplitude and latency of the MMN elicited to F0, INT, voD, voI deviants; and the response time and hit rate to visual targets preceded by repeated and novel sounds as well as the amplitude of the MMN, novelty-P3 and RON responses elicited to the distracters. A statistical approach based on time series analysis will be applied to the data.

A single-case study of phasic boosting of attentional capabilities with Forbrain® on Stuttering

by Carles Escera, PhD, Professor
Institute for Brain, Cognition and Behavior (IR3C) and Department of Psychiatry and Clinical Psychobiology University of Barcelona

Objective. The purpose of this empirical study will be to replicate the findings of the previous single case Forbrain (N=1) study on a specific clinical population for whom the use of Forbrain could be specifically beneficial: adults suffering from persistent developmental stuttering. This is a clinical group who suffers from a speech disorder that can significantly alter the ability to communicate and thus socialize. Many of these people suffer from social isolation, anxiety and even depression. Because currently there is no cure or even standard treatment for persistent developmental stuttering, if Forbrain produced even small changes, these improvements could be clinically significant.

Work. The proposal is to replicate the study that was already conducted on a healthy participant but this time choose a subject who meets the clinical diagnostic criteria for persistent developmental stuttering. In addition to the original design, subjective measures of speech performance, anxiety while speaking aloud, and wellbeing, will be obtained. As before, six sessions of 15 minutes use will feature the following protocol:

1. Accommodation to the laboratory procedures
2. ATTN test pre-use (4 runs of 10 minutes)
3. Physiological and voice recordings during reading (Forbrain **off**) – (7 minutes)
4. Physiological and voice recordings during reading (Forbrain **on**) – (15 minutes)
5. Physiological and voice recordings during reading (Forbrain **off**) – (7 minutes)
6. ATTN test post-use (4 runs of 10 minutes)

Before starting the actual experiment, we will collect some dummy data on all three measurements to allow for the participant to become acquainted with the laboratory procedures and thus avoid the undesired effects for heart rate we observed during session 1 of our previous experiment.

This protocol will be repeated on five consecutive days, featuring a total of 75 minutes of Forbrain® use.

A follow-up session will be scheduled three days after the last training session, to check for longer-term effects and the stability of the findings.

Impact. The expected results will provide the first empirical evidence in support of the use of Forbrain in the treatment of a specific pathological condition.