

A woman with long, wavy blonde hair, wearing a bright red, sleeveless, tiered dress, is walking away from the camera on a wooden suspension bridge. The bridge is made of thick wooden planks and is supported by numerous ropes and cables. The background is a dense, lush green forest with sunlight filtering through the trees, creating a bright and airy atmosphere. The bridge appears to be made of natural materials, possibly bamboo or rope, and is set in a natural, outdoor environment.

# Improving the lives of people with neurological conditions

**Annual General Meeting**

Neurotech International Limited (ASX: NTI) | November 2017

**Neurotech**



# Neurotech Overview

- ✓ Medical device company, focussed on the development & commercialisation of **regulated medical solutions** for **diagnosis & treatment of neurological disorders**
- ✓ **Flagship device Mente Autism** provides home-based neurofeedback therapy to children on the autism spectrum
- ✓ **Significant distributor momentum** with five new agreements signed since IPO in November 2016, expanding the geographic reach of Mente Autism
- ✓ **Preliminary results** from the independent US Clinical Trial
- ✓ **Continued focus** on R&D, product improvement & increasing awareness
- ✓ **Substantial achievements in less than 12 months**, from first batch production at the end of 2016 to strong traction today
- ✓ **Strong leadership** with highly qualified board & senior management team

# Preliminary US Clinical Trial Outcomes

Trial record 2 of 15 for: Mente

Previous Study Return to List Next Study

## Neurofeedback Therapy for Children Diagnosed With Autism

This study is ongoing, but not recruiting participants.

Sponsor:  
Carrick Institute for Graduate Studies

ClinicalTrials.gov Identifier:  
NCT02773303  
First Posted: May 16, 2016  
Last Update Posted: March 28, 2017

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

Information provided by (Responsible Party):  
Carrick Institute for Graduate Studies

Full Text View Tabular View No Study Results Posted Disclaimer How to Read a Study Record

### Purpose

This project aims:

- to further explore the effectiveness of a novel sonified Neurofeedback management therapy for children diagnosed with Autism Spectrum Disorder (ASD)
- to determine if balance control is different before and after therapy

Condition	Intervention
Autism Spectrum Disorder	Device: Mente Autism™ Device: Sham

Study Type: Interventional  
Study Design: Allocation: Randomized  
Intervention Model: Parallel Assignment  
Masking: Double (Participant, Care Provider)  
Primary Purpose: Treatment

Official Title: Neurofeedback Therapy for Children Diagnosed With Autism



## Preliminary results from US clinical study

"...one of the most exciting investigations this year. The changes observed in autistic children after a 12-week clinical trial are outstanding with many of the children with autism scoring in a normal range after the treatment."

- Dr Ahmed Hankir, Senior Research Fellow with the Bedfordshire Centre for Mental Health Research (BCMHR) in association with the University of Cambridge

"The study is ongoing but half of the children in our study have completed it & we have observed major positive changes in the children in the active arm of the study & no statistical changes in the control group of children that did not receive the active treatment."

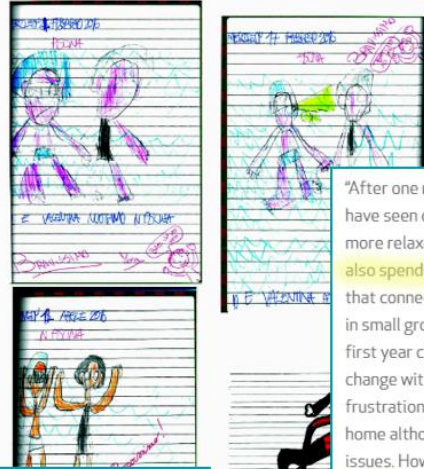
- Professor Carrick, Senior Research Fellow at BCMHR, principal clinical trial investigator

### Source:

- ClinicalTrials.gov, a service of the US National Institutes of Health (<https://clinicaltrials.gov/ct2/show/study?term=Mente&rank=2>).

# Parents' Testimonials

“ Since we started using Mente in February 2016, we have noticed a number of behavioural changes in our son. He accepted to use Mente with very few problems, so much so that after some time he started to ask for it when he woke up. This showed us that he sees the therapy as an integral part of his rigid daily routine. We noticed that he started to draw as a means of recreation and with greater attention to descriptive detail that he never showed before. His drawings are neater and less anxious. In general, the intensity and duration of repetitive actions and moments of estrangement from reality are reduced. He is also responding, in a very positive way, to stimuli that help him to return to normality from 'his world'. As for his behaviour, an improved attention span has enabled him to exit 'his world' in a shorter period of time. We have noticed changes in his sleeping habits, in that he is waking up fewer times during the night. Thank you for giving us the opportunity to try the Mente Autism system. The four drawings below are pre- and post- Mente Autism use.



## Fabio and Cristina

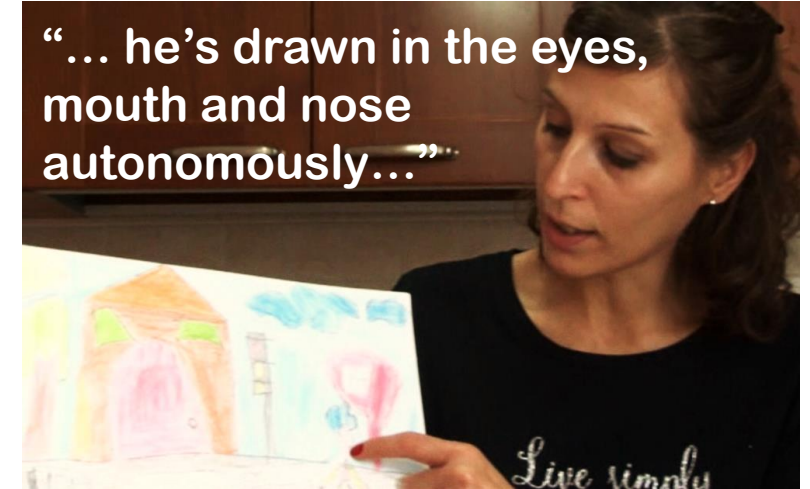
Parents of 11-year-old boy  
ASD  
Two-and-a-half months' usage of  
August 2016

“We started using Mente Autism six months ago and after only 45 sessions we were shocked that he started to make eye contact with us, to the extent that it became almost normal behaviour. This was something we had previously spent nearly two years trying to achieve. The success we achieved in such a short time encouraged us to keep the therapy going. We have noticed other behavioural changes in him. He has started to understand basic orders such as 'bring the water', 'close the door' and so on. My son not only recognises his name but he turns in the direction where the sound is coming from. This has been an amazing time for us and as a family we are once again hopeful. We are looking forward to using the next generation of Mente Autism and are firm believers in neurofeedback therapy.”

Asra Alhefazy, Parent of 8-year-old child/ ASD/ 45 days' usage/ Iraq/ August 2016

“After one month of use, our son, Manuel, has accepted the headband. We have seen considerable improvement, in that he is less hyperactive and more relaxed. At school, he often joins in and works with his classmates. He also spends more time in the classroom with them. (He has a small area that connects with the classroom where, apart from studying, he takes part in small group activities; a classmate and another student from the other first year class take it in turns to have lunch with him. He appears to accept change with less fear and he is easier to handle during those moments of frustration. In the past month, we have started to use the ABA method at home although we spend fewer hours than is necessary due to teacher issues. However, that said, after a month his carers noticed that it had become easier for him to accept the rules and 'punishments', such as taking the game away from him if he does not obey a rule. The carers also noticed that in a short period of time he is capable of formulating requests. He has started to copy pictures (a kite, cloud) and is better at colouring. During a school outing, his teacher was surprised and deeply touched when she saw him taking part in activities with his classmates. Birthday parties are still a challenge for him to interact with his friends; the attention paid to smart phones and other novelties still causes him to somewhat withdraw from the group.”

Cristina, Parent of 7-year-old boy ASD/ 45 days' usage/ Italy/ August 2016



More testimonials at: [www.mentetech.com/mente-autism/testimonials](http://www.mentetech.com/mente-autism/testimonials)

# Distribution

- The Mente Autism device is being distributed through a growing network of partners around the world
- Our initial focus in the European market, and have gained significant distributor momentum with five new agreements signed since our IPO in November 2016, predominately in this region
- These cover Germany, Switzerland, Austria, Greece and Cyprus, as well as Saudi Arabia and Turkey
- We also have a distribution agreement in Italy, and have recently re-negotiated the terms of this agreement with the distributor, Promosalute
- Our newest distribution agreement was signed with Australian partner Medilink, after we successfully registered Mente Autism with Australia's Therapeutic Goods Administration
- As a regulated medical device, market entry into each country is controlled in a deliberate manner, supported by a network of medical professionals. Our recent entry into the German market provides a useful case study

# Case Study: German Market Entry Strategy

- Distributor agreement signed in April 2017 with VDT Psychologie Medizinvertrieb
- Three-step approach to creating structure to develop a successful market in Germany:
  1. Appoint distribution partner ([done](#))
  2. Build medical professional network in collaboration with distribution partner ([ongoing](#))
  3. Create awareness about Mente Autism through participation at symposiums & congresses ([ongoing](#))
- Nine medical professionals have received training on Mente Autism – comprising medical doctors, psychiatrists, occupational therapists and neurologists
- Targeting community of 20 trained medical professionals by end of 2017
- Network will be expanded throughout 2018 as awareness of the product increases





# New Mente Autism Distribution Partners



- Marketing & distribution partner in Australia
- Supplies radiological imaging, radiotherapy products & a full range of medical imaging consumable products
- 20 years experience in bringing premium products, services & support to the Australian healthcare market
- Strong interest in the system following ASX announcement on preliminary clinical trial results



- Exclusive marketing & distribution partner in Saudi Arabia
- Jeddah based experienced medical device specialist with branches in Riyadh & other regions of Saudi Arabia
- Represents a wide range of high-tech medical equipment manufactured by companies in the USA & Europe



- Marketing & distribution partner in Germany & Switzerland
- Gottingen based provider of professional products for biofeedback, neurofeedback & other products for the healthcare & medicine market
- Provides equipment, systems & consumables from the world's leading manufacturers, with a focus on delivering independent, competent advice along with fast & uncomplicated service

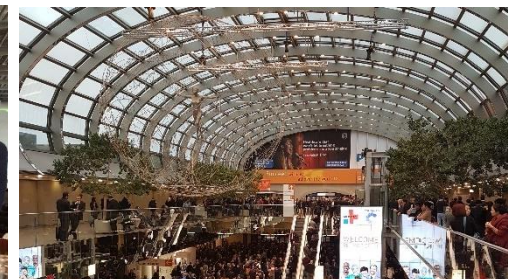


- Marketing & distribution partner in Greece & Cyprus
- Athens based distributor for high quality products & innovative technology
- Focus on products that add value to everyday life, & advance health & wellbeing for users



- Exclusive marketing & distribution partner in Austria
- Innsbruck based distributor for medical devices & consumables in the fields of urology, neurology & gynaecology
- Fastest growing neurotechnology distributor in Austria

L to R: at the Malta Research Facility, undertaking training in Italy, Greece, and the Medica International Trade Fair in Düsseldorf



# US Market and FDA approval

- The United States remains an important target market for the Mente Autism device
- We are starting to put the foundations in place to pursue approval from the US Food and Drug Administration (FDA) and our dealings with the FDA have so far been positive
- A pre-submission package was filed with the FDA in March 2017
- Based on feedback from the FDA, Neurotech will seek to market Mente Autism as a Class II regulated device in the US under the traditional 510(k) submission route
- Expect to make that final submission early 2018



# Key Achievements & Next Milestones

## Achievements

The Company has made substantial achievements in the space of less than 12 months:

- ✓ **Nov 2016:** A\$7 million ASX IPO
- ✓ **Dec 2016:** First shipments of Mente Autism & appointment of Scientific Advisory Board
- ✓ **Mar – Sep 2017:** Secured new Austrian, Greece, German & Swiss, Saudi & Australian distributors, renewed Turkey distributorship
- ✓ **Jun 2017:** Australian TGA registration received
- ✓ **Sep 2017:** Preliminary outcomes received from independent US clinical trial, with "...changes observed in autistic children...outstanding..."
- ✓ **Oct 2017:** Completed a well-over subscribed four-million-dollar placement to investors

## Looking Forward...

We are focussed on continuing to let science do the talking, and bringing Mente Autism to the parents and children who need it

- **Q1 2018:** New UK distributorship
- **Q1 2018:** Results of US clinical trial
- **Q1 2018:** US FDA submission
- **Q1 – 2 2018:** Mente Autism v 2.0 Improved usability and functionality
- **Q2 2018:** Publication of US trial results in peer-reviewed publications
- **2018:** US FDA determination
- **Ongoing:** additional distributorships and jurisdictions to drive revenue

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