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Autism Spectrum Disorder (ASD) Fever Effect Pilot Study Completed

Medical Device Improves Sleep Quality and Quantity



SAN DIEGO, CA – November 18, 2019 – AVACEN Medical, Inc. (AVACEN) announced that its sponsored and independently conducted 12-family double blinded, double placebo-controlled, multi-phase (6 weeks per phase) pilot study of ASD children ages 4-17* has been completed.

This extensive study which began 24 months ago, used the FDA-cleared, Class II, AVACEN 100 dry heat therapy device to simulate a low-grade fever by non-invasively infusing heat into the circulatory system.

The Fielding Graduate University IRB approved study is entitled: *“The Fever Effect: Do kids with autism do better when they use a device to warm their blood? Effects of a six-week AVACEN Treatment Method on Autism Spectrum Disorder”*. It examined improvements in the Childhood Autism Rating Scale and the Parental Stress Scale.

The study also evaluated changes in pragmatic language and behavior, parents stress levels, Autism symptom severity and reductions in sleep problems previously reported by parents of ASD children and adolescents using the AVACEN 100.

According to Frances Poteet, Graduate Researcher at Fielding Graduate University in Santa Barbara, California who acted as Principal Investigator: “We have seen exciting results relating to improved sleep quality and quantity without the use of medications. This is significant because sleep problems are among the most urgent concerns for families coping with ASD.”

Joshua Feder M.D., a board-certified family and child psychiatrist practicing in Solana Beach, California acted as Study Advisor. Dr. Feder, who researches ASD commented; “Although the size of this study is small, this study offers new insights in the evaluation of treatments by rating video samples of subjects before and after treatment.”

ASD Fever Effect

In 1980, when a viral infection swept through a therapeutic nursery for children with autism at Bellevue Psychiatric Hospital in New York, the hospital staff reported that the children were more social, alert, and talkative while feverish (Sullivan, 1980). When their fevers faded, so did those behavioral improvements. Unraveling the “fever effect” could lead to innovative ways to improve the lives of individuals affected by ASD.

The Autism Society estimates that 70 million people worldwide have ASD. Research on the costs associated with ASD conducted in the United States (e.g. Croen, et al. 2006) determined that the average cost for children with ASD were twice as high as other children for hospitalization, clinic visits, and prescription medications.

About Fielding Graduate University

Fielding Graduate University, a private university in Santa Barbara, California was founded in 1974 by Frederic M. Hudson, Hallock Hoffman, and Renata Tesch.

They designed Fielding as a graduate program for mid-career professionals who were not being served by traditional universities.

It offers postgraduate and doctoral studies mainly in psychology, education, and organizational studies.

About AVACEN Medical

AVACEN Medical www.AVACEN.com is dedicated to the innovation and design of safe, easy to use, noninvasive drug-free alternatives for the management of pain associated with numerous chronic and acute conditions including the temporary relief of minor muscle and joint pain and stiffness associated with arthritis and potentially other conditions that can cause joint pain, such as CRPS, Reynaud's, and Lyme Disease. Founded in 2009, AVACEN Medical is headquartered in San Diego. Contact: Thomas Muehlbauer, CEO at (888) 428-2236 x 701 or tmuehlbauer@AVACEN.com.

E.U. Approval: A heat therapy system indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains; the temporary relief of widespread pain associated with fibromyalgia; muscular relaxation; and the temporary increase of microcirculation.

U.S. FDA-Clearance: A heat therapy system indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains; muscular relaxation; and the temporary increase of local circulation where applied.

IMPORTANT: The AVACEN 100 is not for sale in the U.S. or E.U. for any non-cleared or non-approved indication mentioned in this document.

*AVACEN recommends parents contact a physician before using the AVACEN 100 on those under 18 years of age.

The Fever Effect:

Do kids with Autism do better when
they use a device to warm their
blood?

Effects of a 6-week AVACEN
Treatment Method on Autism
Spectrum Disorder



Pilot Study
by Frances Poteet

Method

Participants:

- Randomly selected from respondents to promotional flyers posted in Facebook Autism group, and Autism support group meetings.
- Thirteen children
- Between ages 4.5- 17 years old
- Male = 9 Female= 4
- All had diagnosis of Autism Spectrum Disorder.
- Residents of the San Diego area.
- Not participating in other research projects concurrently.
- Able to sit in one spot for 20 minutes at a time.
- Randomly assigned to 3 experimental conditions: one treatment or two placebo controls.

Materials:

- AVACEN 100 device
- CELF-5: Clinical Evaluation of Language Fundamentals 5th Edition- Pragmatics Subtest
- CARS-2: Childhood Autism Rating Scale 2nd Edition
- PSS: Parent Stress Scale

Design:

- Between groups design: treatment: 108heat/negative pressure vacuum (Exp); 108heat only/no vacuum (108H+/V-); and no added heat (body temperature) 98heat/no vacuum. (98H-/V-)
- Independent variables: temperature, negative pressure
- Dependent variables: behavior, sleep
- Additional variables: family dynamics, school, peers, health

Method

Procedure

Procedure:

- At three points in time of the study (pre-treatment, mid-treatment at 3 weeks, and post-treatment at 6 weeks), parents prepared 20 minute videos of their child interacting with others in a spontaneous scenario. Children were not to engage in use of electronic devices during that time.
- Three assessment tools (e.g. for pragmatics (social skills), autism severity, and parent stress), were completed by parent interview at three points in time of the study.
- Parents and children participated in an orientation about how to use the device, document and forward data. They received the device to take home for the study.
- Two daily sessions for 6 weeks: one in the morning and one in the afternoon.
- After turning on machine, once it calibrated, subject put on plastic glove and inserted hand in unit.
- Each session lasted 20 minutes.
- Parents/caregivers completed logs documenting sessions start and end time, score achieved, and ratings/comments about ability to fall asleep, length of sleep, quality of sleep, number of times woken up at night, any changes in appetite, energy and disposition during daytime.
- Parents/caregivers forwarded daily logs to researcher for data collection and transcription into Excel.
- At the end of Phase 1 parents mailed units back to AVACEN where the team retrieved stored scores.
- To confirm compliance, the scores were compared to daily logs documented on Excel sheets.
- Phase 2 was unblinded, as only subjects who were part of the control groups participated. They were aware that they had the experimental unit during Phase 2.
- Same protocol was followed for daily use, data collection protocols, and parent interviews.
- At the end of Phase 1, each video was randomly assigned to blind coders who had direct clinical experience with autism to review and score using the CARS-2 tool to determine the severity of autism.
- The procedure was repeated at the end of Phase 2.
- Via verbal interview, at initial, medial and final points in time of each Phase, the parents completed questionnaires about their child's pragmatic social skills (CELF-5), and their own level of stress (PSS).

Brief explanation for each test:

- **Pragmatics Subscale from the Clinical Evaluation of Language Fundamentals-5 (CELF-5)**

The CELF helps to identify verbal and nonverbal pragmatic deficits that may negatively influence social and academic communication. The skills that are evaluated are common, daily skills observed across ages, genders, and situations which are necessary for obtaining, responding to, and giving information. The Pragmatics subtest was completed based on parent interview/report.

- **Childhood Autism Rating Scale (CARS-2)**

The CARS was developed to help diagnose autism in children 2 years old or older. CARS works by rating the child's behaviour, characteristics, and abilities against the expected developmental growth of a typical child. The CARS-2 consists of 14 domains assessing behaviors associated with autism, with a 15th domain rating general impressions of autism. Each domain is scored on a scale ranging from one to four; higher scores are associated with a higher level of impairment. Total scores can range from a low of 15 to a high of 60; scores below 30 indicate that the individual is in the non-autistic range, scores between 30 and 36.5 indicate mild to moderate autism, and scores from 37 to 60 indicate severe autism.

- **Parent Stress Scale (PSS)**

The PSS is a self-report scale that contains 18 items representing pleasure or positive themes of parenthood (emotional benefits, self-enrichment, personal development) and negative components (demands on resources, opportunity costs and restrictions). Respondents are asked to agree or disagree with their child, and to rate each item on a five-point scale: strongly disagree (1), disagree (2), undecided (3), agree (4), and strongly agree (5). The 8 positive items are reverse scored so that possible scores on the scale can range between 18-90. Higher scores on the scale indicate greater stress. The scale is intended to be used for the assessment of parental stress for both mothers and fathers and for parents of children with and without clinical problems.

Phase 1: 3 Experimental Conditions

- Experimental Group received heat and negative vacuum
 - = (Exp)
- Control Heat Only received heat only
 - = (108H+/V-)
- Control Placebo remained at body temperature only
 - = (98H-/V-)

Language Statements



Phase 1

Language Statements	Exp	108H+/V-	98H-/V-
Reported increased vocabulary to express themselves	4	3	2
Produced lengthier responses	2	1	2
More willingness to engage in conversations	4	1	1
More willingness to use words to engage others (vs. quiet observer, or physical	4	2	3
Understanding others' non-verbal gestures	4	2	1
Responding to "why?" questions	3	1	2
Increased vocal cadence (e.g., softer, slower, inflection	3	1	3
Less tangents	4	2	2
Respond to cues for extending narratives	3	2	3
Reported increased receptiveness, expression and accuracy when communicating	4	2	3
Reported clarity of thought	3	2	1
Verbalizing disagreement and frustration	4	2	3

Phase 2

Language Statements	108H+/V-	98H-/V-
Increased (non-verbal) interpretation of others' facial expressions and body language	3	3
Producing more tone inflection and gestures	3	3
Engages during conversations	3	3
Producing longer conversational volleys per topic	3	3
Asked for clarification when something was unclear	2	3
Showed emerging ability to respond to "why" questions	3	2
Verbalized wants	3	3
Uttered thoughts in phrases and sentences	3	3
Discussed language with less prompts	2	3
Discussed a wider variety of topics	2	3
Made more observations	3	2
Expanded vocabulary	3	3
Initiated verbal exchanges	2	3

Sleep Statements



Phase 1

Sleep Statements	Exp	108H+/V-	98H-/V-
Reported longer and deeper sleep	4	3	3
Easier falling asleep	4	2	5
Reported feeling refreshed in the morning	4	3	4
Reported decreased frequency of waking up at night	4	3	5
Reported going back to sleep easily again after waking up in the middle of the night	4	2	4

Phase 2

Sleep Statements	108H+/V-	98H-/V-
Fall asleep with ease	4	4
Reported longer and deeper sleep	4	4
Increased sleeping through the night	4	4
Wakes up refreshed and alert in the morning	4	4
Reported going back to sleep easily again after waking up in the middle of the night	4	4



“The AVACEN 100 has been shown to increase the quality and quantity sleep, which as part of a healthy lifestyle, may help living well with ASD.”