(food selectivity and sensitivity); whereas Differential Reinforcement of Alternative Behaviour only addresses behaviour-based. However, further research is required in the field of SOS to improve its evidence base.

Recent RCT's by Marshall [37, 38] have attempted to increase the evidence base of sensory techniques for feeding difficulties and compared operant conditioning to sensory desensitisation.

There were:

4) No differences in efficacy of both interventions
5) No differences observed between etiological groups or intensity (weekly vs intensive intervention)
6) 3 month follow up showed continued improvements

6. Ethical Concerns with Applied Behavioural Analysis for Autism Spectrum Disorder

Autism advocates have raised concerns about the use of ABA for many years, citing bioethical concerns about the rights of autistic children and their parents which are regularly infringed upon [40]. The question of the ethicality of ABA is of critical societal importance especially as it is often referred to as the "gold standard" of care for ASD [40].

ABA is a form of behaviour modification that relies heavily on external reinforcement, both positive and negative (operant conditioning) [41]. ABA is intended to modify or diminish behaviours, as well as increase language, communication, social skills, attention, etc., in children with ASD [41]. While operant conditioning may be effective for teaching specific tasks in certain situations, in nearly all other circumstances it is not typically used to the extreme extent that it has been applied with for the treatment of many children with ASD [41].

ABA therapy has been viewed as the gold standard for treating children with ASD because various meta-analyses have found it to be very efficacious [41]. However, research indicates

efficacy only with those who have a measurable Intelligence Quotient (IQ), typically at 70 or above [41]. Much of the research has excluded children who are non-verbal, particularly those who are "lower functioning' and 'untestable' [41]. Unsurprisingly, this is the population that tends to receive continuous ABA therapy over a longer period of time due to their reduced ability to meet the criteria needed to master a task [41].

ABA has been described as *"an encroachment on the autonomy of children forced to receive it. Even granting that parents have the* ***authority*** *to decide in favour of ABA, doing so runs two very serious risks. First, it can alter children's identities by preventing them from forming and pursuing their own passions. Second— and more problematically—it can teach them that there is something wrong with who they are, teaching them how to blend in rather than exercise their own unique capacities." [40]*

A lifetime or punishment and reward without an understanding of the task that is being asked, can create individuals who are compliant and conditioned to obey others, independent of a task. Research [42] has indicated numerous problems with the underlying theory of ABA, specifically unintended consequences such as; (1) compliance, (2) low intrinsic motivation, (3) prompt dependency (4) low self-confidence, or self-esteem to successfully engage in any task and (5) lack of independent functioning—the latter of which is the presumed goal of ABA therapy in the first place.

Sandoval-Norton et al. 2019 [41] stated that *"being punished for certain movements, and being forced to engage in eye contact despite the physiological pain and discomfort of doing so, is psychological and physical abuse. A lifetime of being forced to sit still with no regard for actual cognitive abilities can create further emotional and psychological harm."*

ABA neglects current research and data on children with Autism. Some of this research would include the autistic brain, access to MRI studies, or comorbid psychopathology associated with autism such as;

1) Anxiety
2) Attention-Deficit/Hyperactivity Disorder (ADHD)
3) Obsessive Compulsive Disorder

This knowledge is neglected by ABA therapists who implement behaviourist principles that are inappropriate to treat these comorbid disorders. Sandoval-Norton et al. 2019 [41] notes that ABA therapists *"...are essentially practicing out of their scope and without a license, with the hopes that ABA will somehow address both maladaptive behaviours and comorbid disorders....ABA is never prescribed to rid someone of anxiety but it can in fact create more anxiety along with a myriad of other issues previously discussed."*

It should also be noted that most ABA practitioners are unregulated and unlicensed paraprofessionals and care givers, with neither the discipline of psychology nor related fields nor government establishing any real oversight or review procedures [43].

- ABA is not regulated in Australia.
- Griffith University and Monash University are the only two institutions that offer a BCBA qualification.

A recent online survey by Kupferstein (2018) [44] investigated what percentage of individuals exposed to ABA met criteria for PTSD based on responses from both caregivers and adults with ASD. This survey was further analysed using qualitative techniques [45]. The findings of this survey are summarised in Table 7. This is the only study to date which has investigated this interaction.

Table 7: Research into Post Traumatic Stress Disorder caused by ABA

Author (year) and country	Study aim	Methodology and sample	Data collection	Results/Outcome
Kupferstein (2018) [44]	(a) To investigate whether autistic individuals exposed to ABA intervention would meet the PTSD criteria. (b) Test for correlations between the severity of PTSS and the length of time exposed to the intervention.	**Online survey** Professional diagnosis of ASD Age over 18 (autistic adults and caregivers) Recruited via social media, support	-Basic demographics -Type of ASD intervention received as a child -Length of intervention -26 questions relating to PTSD using Likert Scale	-46% of ABA exposed respondents met the threshold for PTSD -Within that group, 47% recorded extreme levels of severity -Adults and children without ABA exposure had a 72% chance of reporting no PTSS

		groups, email contact		-Increased exposure was linked to greater PTSD severity
Kupferstein (2019) [45]	To explore why autistic people and their caregivers choose interventions other than ABA, and how their decision impacts them over their lifespan.	**Online survey** Thematic analysis of comments section of previous survey by Kupferstein. Secondary analysis of initial survey responses	As above	Communication-based intervention group experienced less PTSS (30%) than their ABA-exposed peers (42%). Only 17% of those with no treatment met the criteria for PTSD ($p < 0.001$) **Qualitative analysis** -Those exposed to ABA more likely to use psychologically abnormal language that were indicative of desensitisation -Those who opted out of the survey did so around the questions pertaining to self-harm and injurious behaviour -Those who abandoned the survey were less likely to have been exposed to ABA

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Research Request – Magnetic EEG/EKG Guided-Resonance Therapy (MeRT)

Brief	• Please provide a summary rating the quality of evidence cited and provided by applicant • Please provide any further research evidence of the use of MeRT as an intervention for a child (10 years) with ASD. • Is MeRT considered a clinical intervention and therefore not appropriately funded through the NDIS
Date	11/11/20
Requester	s47F - personal privacy (Senior Technical Advisor TAB)
Researcher	s47F - personal privacy (Research Team Leader)

Contents

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters

Summary

- The evidence provided by the participant is generally of low quality
    - Mainly consists of evidence for the use of MeRT for those with a diagnosis of PTSD
- No peer reviewed literature could be sourced on the use or efficacy of MeRT in people with an ASD diagnosis
- There is some early evidence in favour of transcranial magnetic stimulation (TMS) (MeRT is a variant of TMS) for ASD, however, published literature is of low quality and must be regarded as preliminary and insufficient to support offering TMS to treat ASD.
- MeRT/TMS are clinical interventions which must be administered by a trained and accredited medical/health professional. It is not covered by Medicare or Private Health Insurance

Magnetic EEG/EKG Guided-Resonance Therapy (MeRT)

Magnetic EEG guided Resonant Treatment or Magnetic e-Resonance Therapy (MeRT) is a variation of Transcranial Magnetic Stimulation (TMS) where personalized treatment frequencies and output intensities are derived from patient's EEG data and resting heart rate.

Transcranial Magnetic Stimulation

Refer to NED20/281579 for an overview of repetitive TMS which is approved for use in Australia and recommended by the Royal Australian and New Zealand College of Psychiatrists (RANZCP) as treatment for treatment resistant major depressive disorders.

TMS has been around for more than two decades and has data confirming its low risk profile, and excellent tolerability. While adult trials show promise in using TMS as a novel, non-invasive, non-pharmacologic diagnostic and therapeutic tool in a variety of nervous system disorders, its use in children is only just emerging.

Multiple systematic reviews investigating the use of TMS' in children and adolescents with ASD have been published [1-4]. All reviews concluded that:

1) Treatment led to improvements in relation to repetitive behaviours, stereotypes behaviours, social behaviours and executive function tasks.
2) Long term gains/stability were not well reported
3) Studies are of low methodological quality (case studies, non-randomised trials), included cohorts with significant heterogeneity and lacked any control of confounding factors

Therefore, there is urgent need for randomised controlled trials of high quality with adequate follow up periods to test the efficacy of TMS for ASD. Currently available evidence must be regarded as preliminary and insufficient to support offering TMS to treat ASD.

Is TMS a clinical intervention?

TMS is a clinical intervention and should only be administered by a professional who has undertaken training and is credentialed in the procedure. This is commonly a psychiatrist, however, psychiatry trainees and psychiatric nurses can perform the treatment under supervision.

In Australian clinical practice TMS should only be administered for an illness where there is adequate evidence of clinical indication and effectiveness. This includes depression, schizophrenia and obsessive compulsive disorder. It should be considered as a therapeutic option alongside other treatments after detailed psychiatric assessment.

Clinical settings for TMS

- TMS treatment can be conducted safely as an outpatient procedure and is predominantly provided in this context internationally.
- TMS treatment does not require sedation or general anaesthesia.
- All services providing TMS should have in place appropriate protocols, training and equipment to allow for the safe and effective administration of treatment. This should include protocols for patient assessment, monitoring during treatment, monitoring of the quality of the provision of treatment, protocols for response to adverse events and monitoring of outcomes
- Where TMS is conducted as an outpatient the outpatient TMS clinic should be suitably accredited by an accepted accreditation agency such as International Standards Organisation (ISO) or Australian Council of Healthcare Standards (ACHS)
- Devices used for TMS should be approved by the Therapeutic Goods Administration (TGA) for use in Australia or the New Zealand Medicines and Medical Devices Safety Authority for use in New Zealand. A service using a specific TMS device should check the intended use that has been formally approved by these organisations, as these can differ between devices.

Cost

In Australia, TMS is not covered by Medicare or Private Health Insurance.

Scientific Evidence provided by the Brain Treatment Centre

The evidence provided by the Brain Treatment Centre (Table 1) consists of:

1) Narrative review which summarises the results of systematic reviews investigating the efficacy of TMS for major depressive disorder. This paper is of **moderate** quality and shows that TMS is a useful tool to treat **major depressive disorders** but provides no scientific information of MeRT.
2) Cross sectional study which shows that peak alpha frequency (PAF) measures from EEG correlates with non-verbal cognitive function in children with ASD. This measure is being claimed to have the potential to act as a biomarker in the future, to help study whether an autism treatment is effective in restoring peak alpha frequency to normal levels. This paper is of **medium** quality, however, provides little value in the argument for MeRT. All it shows is

a difference in brain waves/oscillations between normally developing children and those with ASD, not whether MeRT is appropriate or useful as a treatment for ASD.

3) A conference presentation is the only evidence provided for the use of MeRT in children with ASD. Although results show improvements in autism behaviours the quality of the evidence is rated as **very low** as it is not peer reviewed, retrospective data collection and there were high dropout rates. This information should not be used as evidence for the effectiveness of the treatment.
4) The two remaining papers include a retrospective chart review **(low quality)** and an unpublished randomised controlled trial **(very low quality)**. These two papers investigate the use of MeRT in **veterans with PTSD**. Both show positive results but must be assessed with caution due to their low methodological quality, lack of peer review and potential for bias as the studies were not performed by an independent research group (co-creators of MeRT conducted studies).

Table 1. Literature provided by the Brain Treatment Centre

Author (year) and country	Study aim	Methods/participant characteristics/outcome measures	Outcome/summary	Quality of evidence High/Medium/Low/Very Low
Janicak and Dokucu [5]	Considers the developmental history of TMS as a treatment strategy, its basic principles, purported mechanism(s) of action, and the results of clinical trials for acute and maintenance management of **major depression**	**Narrative Review** Previous systematic reviews of TMS for **major depressive disorder** are summarised. No methods section included. Unclear how literature was identified. 1) TMS vs Sham treatment 2) TMS vs Electroconvulsive therapy	• Significantly better response rate for TMS compared to sham • Significantly higher remission rates for TMS • TMS averaged more than a 4-point greater decrease in Hamilton Depression Rating Scale (HDRS) scores compared with sham procedure • ECT superior to high-frequency TMS both in terms of response (P<0.03) and remission (P<0.006) • TMS effect size 1.33 and ECT 2.14	**Medium** This type of article ranks low on the evidence hierarchy (narrative review), however, it summarises the most up to date systematic reviews on TMS for treatment resistant major depressive disorders. This evidence can be used to show that TMS is a promising novel treatment with a good safety profile for a particular diagnosis **(treatment-resistant or treatment-intolerant depressed patients)**
Dickinson, DiStefano [6] This is the publication referred to in the 'media release'	To investigate alpha oscillations as a potential biomarker of cognitive function in ASD using EEG.	**Cross sectional study** Children aged 2-11 59 children with ASD 38 age matched typically developing (TD) children	PAF (a number reflecting the frequency of certain brain waves) was decreased in children with ASD. Moreover, in ASD, PAF correlated strongly with non-verbal cognitive function, but not with chronological age.	**Low** Single cross-sectional study. Of little value to argue the use of TMS in children with ASD. Only shows that there are differences in PAF between ASD and normally

provided by the Brain Treatment Centre		Exclusion criteria included other neurological abnormalities (including active epilepsy), birth-related complications and uncorrected vision or hearing impairment. • Cognitive and language assessments • electroencephalography (EEG) recording to measure peak alpha frequency (PAF)	PAF may be used as a biomarker in the future, to help study whether an autism treatment is effective in restoring peak alpha frequency to normal levels, for instance.	developing aged matched children. Furthermore, the study didn't measure ASD symptoms so cannot infer how this may change across severity levels.
Kim and Taghva [7]	Hypothesize behavioural improvements in autism behaviours via TMS with customized frequency modulation.	**Conference presentation** Retrospective chart review 141 patients underwent TMS with customized frequency modulation. Serial EEGs were used to modify frequency delivered using resting alpha frequency combined with resting heart rate. **35 patients were excluded at 1 week due to lack of improvement on Child Autism Score (CARS).** 1 patient was excluded at first week for seizure (0.7%). 44 (41.5%) made it to the 24-month follow up period.	At 24 month follow up, 26 of 44 (59%) patients showed statistically-significant improvements of -11.7 +/- 6.2 S.D. Ten patients' CARS fell below 26 (38%) consistent with minimization of autism behaviours. Most improvements were made in Taste, Smell, and Touch Response and Use, Fear and Nervousness, and Verbal Communication	**Very Low** Non peer reviewed, retrospective, high dropout rates. This literature should not be used to make a clinical treatment decision.

		Age, sex, race, other treatments, number of treatments, CARS scores were sub-stratified.		
Taghva, Silvetz [8]	To determine if magnetic brain stimulation can induce normalization of EEG abnormalities and improve clinical symptoms in **PTSD** in a preliminary, open-label evaluation	**Retrospective Chart Review** 21 veterans consecutively-treated for **PTSD**. Magnetic resonance therapy (MRT) was administered for two weeks at treatment frequencies based on frequency-domain analysis of each patient's dominant alpha-band EEG frequencies and resting heart rate. Patients were evaluated on the PTSD checklist (PCL-M) and pre- and post-treatment EEGs before and after MRT.	Of the 21 patients who initiated therapy, 16 (76%) completed treatment. Clinical improvements on the PCL-M were seen in these 16 patients, with an average pre-treatment score of 54.9 and post-treatment score of 31.8 ($P < 0.001$). In addition, relative global EEG alpha band (8 - 13 Hz) power increased from 32.0 to 38.5 percent ($P = 0.013$), and EEG delta-band (1 - 4 Hz) power decreased from 32.3 percent to 26.8 percent ($P = 0.028$)	**Low** Small sample, no control group, lack of long term follow up data. The study suggests that non-invasive neuro-modulation magnetic resonance therapy may lead to clinical improvements, however, further large scale, high quality studies are required
Taghva, Jin [9]	To determine if MeRT can improve clinical symptoms in **PTSD** in a double-blind, sham controlled, randomized trial.	**Randomised Controlled Trial** 86 veterans (ages 20-56, mean 37.8; 9 female, 77 male) with prior diagnosis of **PTSD** (moderate to severe, PCL-M> 50) were randomized to receive MeRT versus sham stimulation for two weeks, followed by open-label active treatment of both groups for two weeks. MeRT was administered with pulse intensity at 80% of patient motor	Characteristics for the randomized groups were similar, with pre-treatment average PCL-M scores of 65.7 and 65.4 in the MeRT and sham stimulation groups respectively. 74 completed. 12 (14%) dropped out of study Two-week post-treatment PCL-M in the control arm was 51.4 (28.9% improvement), and in the treatment arm was 42.6 (47.4% improvement, $F1,71 = 7.4$, $P < 0.01$)	**Very Low** Unpublished/non-peer reviewed, no power or sample size calculations, no information on how participants were recruited/selected (selection bias)

		threshold and stimulation frequency based on analysis of each patient's EEG and resting heart rhythm. Patients were evaluated on the PTSD Check List – Military (PCL-M), at pre-treatment, weeks 2 and 4 of treatment, and three-month follow up (eight weeks post treatment). Exclusion criteria included history of seizure disorder, history of intracranial lesion, and history of intracranial implant, prior transcranial magnetic therapy, and inability to adhere to the treatment schedule.	No adverse events (seizures, neurologic deficit, worsening of pre-treatment condition) were reported.	

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