**PARTICIPANT INFORMATION STATEMENT**

Decreasing Defensive Responses: The Safe & Sound Protocol a Neurophysiological and Pro-Social Behaviour Investigation with Children with Autism.

An intervention study of emotional regulation, social engagement, auditory processing, and motor skills.

Chief Investigator: Joanne McIntyre, PhD Candidate, School of Psychology and Public Health. College of Science, Health and Engineering, La Trobe University. Mobile: 0413 738 958, email: J.McIntyre@latrobe.edu.au

Supervisor: Darren Hocking (Senior Research Fellow, School of Psychology and Public Health. College of Science, Health and Engineering, La Trobe University. Tel: (03) 9479 5462, email: D.Hocking@latrobe.edu.au)

Dear Parents,

We are writing to invite you to have your child participate in a controlled clinical trial study that we hope will shed new light on how the above named intervention impacts the underlying nervous system that supports emotional regulation, social engagement and motor abilities. Growing evidence relates poor physiological state regulation with many of the behavioural, social and motor problems experienced by children with autism.

The Safe & Sound Protocol (SSP) was developed by Dr Stephen Porges from the University of North Carolina at Chapel Hill. Preliminary findings with nearly 300 children with ASD have been published, with results indicating improved behaviour regulation, social engagement and decreased auditory hypersensitivities. The SSP is currently registered in 4 clinical trials. This research project will be the fifth. Clinicians implementing the SSP report improvements in emotional regulation, anxiety, attention, speech and language and social engagement. This project will investigate underlying mechanisms in the brain and body informing this intervention.

We are seeking children to participate and have outlined specific inclusion criteria below.

**What are the aims of the study?**

The aim of this study is to investigate both neurophysiological and behavioural mechanisms impacted by the SSP intervention in children with autism. This study will measure brain activity, stress in the nervous system as well as social and motor skills.

**Description:**

Participation would involve attending testing sessions and an intervention week. Please see below for description of intervention and baseline measure sessions. The clinical trial involves allocation to one of two conditions: 1. Experimental: Filtered Music. 2. Experimental: Nonfiltered Music

Intervention: The intervention involves listening to filtered/modified music through headphones one hour per day for 5 consecutive days. You will be asked to attend La Trobe University at a set time for 5 consecutive days. The intervention will take place in a safe comfortable room with the researcher present. Your child will be able to interact with puzzles/manipulatives/colour while listening. They will ave their own sketch book for drawing that will remain with researcher. You will be asked to remain and provide support as the protocol aims at triggering engagement processes.

Baseline Sessions: You will be asked to attend 3 sessions over the course of the study. The first, one week prior to the intervention; the second one-week post intervention and the last, 2 months later. During this time, your child would participate in a number of social and behavioural activities and complete a brain map assessment. Parents would complete 3 checklists asking questions about sensory processing and social skills and auditory sensitivities.

**Will I receive any benefits for participating in the study?**

The preliminary date informing the SSP indicate improvements in emotional regulation, social engagement and auditory processing in children with ASD. Such data has prompted additional clinical trials in populations beyond ASD such as ADHD, Learning challenged and Prada- Willi Syndrome. Clinicians implementing the protocol report improvements in emotional regulation and social engagement. The SSP differs from traditional behavioural based interventions and aims to target the underlying nervous system supporting function. Participation in this study may result in improvements as noted above.

Additionally, you will be provided with a pre-post intervention brain map of your child.

If the study results are found significant, the active intervention will be made available.

**Who is conducting this study?**

This study is being conducted by Dr Darren Hocking (Supervisor), and Joanne McIntyre, PhD Candidate. Joanne McIntyre’s (Chief Investigator) contact details are listed above.

**Who is funding this study?**

University and self-funded study.

**What does this study involve?**

If you contact us by phone or email we will make a time to meet or talk over the phone to discuss the study further. We will happily answer any questions you may have. A link to online information will be emailed that includes study description, checklist and consent forms. If you are willing to have your child participate, we will ask you to complete written consent forms and the online information form asking questions such as name, age, or past therapy.

**Who is eligible to participate?**

To be eligible to participate your child must be aged between 8 and 14 years and have a confirmed diagnosis of Autism.

In addition to age and diagnosis we are looking for children with an IQ > 80, no history of seizures, head injuries, cardiac problems or hearing impairment/device. Both parent and child need to speak English.

Please also consider if you think you child would be OK with the brain map procedure of wearing a snug cap for about 25 min and having gel applied to areas on his/her head. Additionally, consider if your child would be OK with wearing headphones for 60 minutes.

If you would like to proceed, you will be asked to complete an online checklist in addition to some forms asking about age, gender grade and consent forms. The score on this checklist will also determine eligibility.

H**ow will the information be used?**

Once the data has been analysed, the results may be published in a journal article, book or presented at conferences and professional meetings. The results will be included within a doctoral thesis. If you are interested in the findings arising from this study, please contact Joanne McIntyre, PhD Candidate (details below). The data from this study may be used in other, similar research projects, however will be non-identifiable.

\_\_\_\_\_\_\_\_\_ check if you would like a summary of group findings sent at completion of study.

**How will my identity be protected?**

To protect the identity of participants, at no stage in reporting the results will we reveal any identifying information about you or your child. Only the researchers involved in this study and listed above will have access to the data. All information and data collected during this study will be stored in a locked office and/or password protected computer at the Developmental Neuromotor and Cognition Lab, La Trobe University. Data will be stored securely for five (5) years before being archived. Confidentiality of participants may be broken where authorised or required by law, or where the investigators believe that disclosure is necessary to lessen or prevent a serious threat to public health or public safety.

**Are there any risks associated with participating in the study?**

There is minimal risk involved in this study, however there is a small chance that completing these questionnaires may bring up feelings of discomfort or distress. If you feel distressed, please do not hesitate to contact Joanne McIntyre, PhD Candidate 0413 738 958, J.McIntyre@latrobe.edu.au) who will be able to refer you to relevant psychological services within the La Trobe University Psychology Clinic.

**What are your rights?**

Participation in this study is completely voluntary. You have the right to withdraw from active participation at any time during the testing session. You are also able to withdraw your consent for the use of data arising from your and your child’s participation up to 3 months post the completion of testing:

Please sign that you understand your rights:

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I understand that my child will compete and sign their own age appropriate Consent form

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Yes \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ No

 There are no disadvantages, penalties or adverse consequences for not participating or for withdrawing prematurely from the project.

**How do you accept this invitation to participate?**

If you would like to participate please send Joanne McIntyre an email at J.McIntyre@latrobe.edu.au (preferred) or phone 0413 738 958.

Please also see the link below to online description of the study and forms to be completed to be eligible.

ONLINE LINK

**How do you ask a question about this study or make a complaint?**

If you have any comments or concerns regarding this project, please contact the chief investigator (Joanne McIntyre, PhD Candidate, 0413 738 958, J.McIntyre@latrobe.edu.au) or Supervising Investigator (Dr Darren Hocking, (03) 9479 5462, D.Hocking@latrobe.edu.au). If you have any complaints or concerns about your participation in the study that the researcher has not been able to answer to your satisfaction, you may contact the Senior Human Ethics Officer, Ethics and Integrity, Research Office, La Trobe University, Victoria, 3086 (P: 03 9479 1443, E: humanethics@latrobe.edu.au). Please quote the application reference number ().

**Disclosure**

Joanne McIntyre, PhD Candidate has a working relationship with Integrated Listening Systems who in collaboration with Dr. Stephen Porges is making the SSP intervention available to clinicians. Integrated Listening Systems is not funding any part of this study. But have made available the SSP device.

Signing this form indicates Consent to participate in this study

Sign

Date

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