



**Parental Information Sheet**

**Computerised Motor Skills Training to Promote Language Development in Non-Verbal Children with Autism**

**IRAS Project ID 209775**

Your child is invited to take part in a research study sponsored by Nottingham Trent University, evaluating a new iPad 'app'. We are asking you to take part because you responded to an advertisement or to a referral from one of the schools/centres with which we work. The app, called 'Point OutWords', trains people to control movements of their fingers, hands or mouths. Before you decide if your child can take part it is important for you to understand why the research is being done and what it will involve. Please take a few minutes to read the following information carefully. Feel free to talk to others about participating and please ask us if there is anything that is not clear.

**What is the purpose of this study?**

We want to understand why many autistic children who have trouble with body movements also have trouble moving the mouth and lips to form words and to communicate. Our research has shown that about a third of autistic children who lack communicative speech – those who are called 'non-verbal' or 'minimally verbal' – have trouble controlling the way their bodies move. This movement difficulty extends to movements of the mouth and the throat, and so might be preventing them from speaking words that they know. We've shown that in these children, “receptive language” – the ability to understand words – outpaces “expressive language” – the ability to speak words. We wonder whether training these children in movement skills of the hands and/or the mouth might help them communicate by pointing or by vocalising.

**Does my child have to take part in the research?**

No, it is up to you to decide whether or not your child can take part. Before you decide you can ask us any questions. If you do decide your child can take part we will ask you to sign a consent form to show you have agreed for your child to take part. You can change your mind at any time without having to say why. You and your child's decision whether or not to take part in this study will not affect in any way the treatment that your child receives. You can change your mind about participating either by informing the researcher verbally, in writing, or via email at any of the contact details provided below.

**What we will ask you and your child to do:**

If you and your child agree for your child to be in this study, your child will have the use of an iPad (either at school or at home, depending on arrangements and on availability of iPads – or if you prefer, the software can be installed on your own iPad) and will be assigned to one of two groups: one group will begin using our movement-skills software straight away, whilst the other group will have access to other educational iPad software and will be provided the movement-skills software at a later time. (All the children in the study will have opportunity to use the software, on one or the other of these schedules.) We ask that whilst children are using the iPads, they aim to do so for at least half an hour a day, at least five days per week. We will arrange times, at your and your child's convenience (and at the school's convenience, if conducted in school), to conduct tests of your child's movement skills, language or vocalisation skills, and general developmental level. These tests shouldn't take more than about two hours in all, and can be split into separate sessions. The tests may be repeated after the end of your child's time with the iPad and again at a 3 month followup if you agree to this. We also will give you some brief questionnaires to fill, which shouldn't take more than about twenty minutes, and conduct a brief telephone interview asking about your child’s skills in communication and movement. We will also provide you with a diary where you can fill in anything you want to tell us about your child’s use of the software. To help us assess how Point OutWords might induce changes in your child's interaction and behaviour, we will ask you whether we can record twelve minutes of video whilst you and your child play, in each of two separate sessions before your child starts using Point OutWords and after (s)he finishes – but this video recording is not a requirement. If you agree to the video recording, it will be seen only by members of the project team and will be stored securely. It will be stored with other data from the project for up to 5 years after the project ends, which will then be destroyed.

Repeat tests at

3 months

*2 hours*

Post-tests of movement, language skills & development– *2 hrs*

Preliminary tests of movement, language skills & development *– 2 hrs*

iPad app Training

*½hr/day- 5 weeks*

There are two other optional parts to the study, which you can take part in if you would like to but are not requirements: 1) Using the Think Aloud protocol, where you have an option of recording your thoughts and experiences in real time while using the software; 2) There will be an option for you to take part in a focus group with other parents and a facilitator following your child’s participation in the study, to help us to understand what it was like for you and your child taking part in the research, and think about ways we might improve the study. This would take about an hour.

**Payment:** No payment will be provided to you or your child; however, your child will have the use of the software for the duration of the project. You will be reimbursed for any travel or parking expenses.

**What are the possible risks of taking part?**

We do not anticipate any risks to your child in participating in this study, other than those normally encountered in day-to-day life. If your child were to use the iPad excessively, then there would be some chance that (s)he might miss out on opportunities to practise and to develop skills of daily living; for this reason, iPads should be used in moderation, in much the same way that parents limit any other form of 'screen time'.

**What are the possible benefits of taking part?**

There is a possibility – though not a guarantee – that your child might benefit from use of the software, in the form of heightened motor and/or communicative skills; indeed, the possibility of such a benefit is what this study aims to test. Your child will help us to find out more about communication in autism, which will contribute to scientific knowledge and allow the development of future interventions.

**Your records will be confidential.**

The identifying records of this study will be kept private. In any sort of report that we make public, and in any records that we release to other researchers, we will not include any information that would make it possible to identify you or your child. All personally identifiable records will be maintained in a locked cabinet or on a secure, non-portable computing system; only the researchers will have access to personally identifiable records.

Cambridgeshire and Peterborough NHS Foundation Trust and Nottingham Trent University are co-sponsors for this study based in the United Kingdom. We will be using information from you and your child and from your child’s medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Cambridgeshire and Peterborough NHS Foundation Trust and Nottingham Trent University will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at <http://www.cpft.nhs.uk/RandD/about-research.htm> and/or from the Cambridgeshire and Peterborough NHS Foundation Trust Research and Development team on R&D@cpft.nhs.uk or 01223 217418, Cambridge University Hospitals, Hills Road, Cambridge CB2 0QQ.

Cambridgeshire and Peterborough NHS Foundation Trust will use your child’s name, date of birth and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Cambridgeshire and Peterborough NHS Foundation Trust, Nottingham Trent University and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Cambridgeshire and Peterborough NHS Foundation Trust will if needed pass these details to Nottingham Trent University along with the information collected from you, your child and your child’s medical record. The only people in Cambridgeshire and Peterborough NHS Foundation Trust and Nottingham Trent University who will have access to information that identifies you will be people who need to contact you to carry out the research or audit the data collection process. The people who analyse the information about the data collection process or the conduct of the study will not be able to identify you and will not be able to find out your child’s name, data of birth, or contact details.

By agreeing to participate in this study, you are giving us permission to release anonymous, non-identifying data to other researchers for their use in legitimate scientific research. These data may be posted on the World Wide Web for other scientists to download. At any time whilst the study remains ongoing – even after your child's participation in the study may have ended – you may withdraw your consent, and in this case we would delete your data from the study dataset and from the set of anonymised data that we release in future.

**What will happen to the information that the iPad records?**

The iPad will not record any data about your child unless you (or a teacher or caregiver per your instruction) decide to opt in to enable recording. Even if you have enabled recording, voice interactions in the iPad's 'Speak Mode' will not be recorded unless you decide to opt in to enable voice recording specifically. Instructions as to how to opt in, and how to switch back to opting out, are displayed within the Point OutWords software and will be explained to you by the research assistant who is working with you. Because this is an iPad-based intervention, data about how your child uses the iPad will be transmitted via the Internet. Although these data will not include any personal information (except for voice samples, if you have opted into voice recording), please be aware that Internet transmissions are neither private nor secure, and there is a small chance that such communications could be read by a third party.

**Will my child’s GP be informed?**

Your child’s GP will not be informed if they take part in the study unless you ask us to, in which case we would be happy to do so.

**What will happen at the end of the study and to the study results?**

We will inform you and your child about our findings and will send you a summary of our results at the end of the study. Also, we plan to publish the final results of the study, and to talk to other professionals so that they can help people who find communication difficult. Please note that if your child participates they will not be identified in any way.

**If you have questions:** The researchers in charge of this study are Dr Matthew Belmonte and Dr Emma Weisblatt, both scientists working in autism research. Dr Emma Weisblatt is also a consultant child psychiatrist in Developmental Neuropsychiatry at the Cambridgeshire and Peterborough NHS Trust and lead of the direct care team for Neurodevelopmental Disorders at the Peterborough Integrated Children's Health Services. Please ask any questions that you have.

If you have questions later on – before, during, or after the study – you may contact Dr Belmonte at matthew.belmonte@ntu.ac.uk or on 07986 422 338, or Dr Weisblatt at ejw44@cam.ac.uk or on 01223 333550. You also will receive the contact details of the research assistant who is conducting the study with you.

**What if there is a problem?** If you have a concern about anything to do with the study, you should contact Dr Emma Weisblatt or Dr Matthew Belmonte in the first instance and we will do our best to help you. For independent advice about the research or if you remain concerned and wish to complain you can contact the Patient Advice and Liaison Service on 0800 376 0775 or write to Patient Advice and Liaison Service, Cambridgeshire and Peterborough NHS Foundation Trust, Elizabeth House, Fulbourn Hospital, Cambridge CB21 5EF.

*You will be given a copy of this form to keep for your records.*

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