



SANTA Study (Simvastatin in Neurofibromatosis Type 1 - Autism Study)...

...at the NIHR/Wellcome Trust Manchester Clinical Research Facility

Background

- Neurofibromatosis is a genetic condition that affects 1 in 2,500 people
- Recent studies show that 25% of children with Neurofibromatosis Type 1 also have Autism Spectrum Disorder
- SANTA is an experimental study using Simvastatin to modify the NF1 behavioural phenotype.
- The study is a Phase II, 12 week, randomised controlled trial. There are 4 trial visits including 3 blood tests and 2, hour long MR scans.

Role of Play

- A person centred assessment tool is filled in over the phone to ensure the children's specific needs are met.
- A social story booklet is sent to the child prior to their first appointment, explaining each visit through the use of pictorial information.
- Identifying specific requirements adapting bespoke pathways for each individual child and family.
- Establishing trust through continuity, routine and play.

Staff involvement



Ruth Ellicott :
Senior Paediatric
Research Nurse



Emma Harrison:
Research Health
Play Specialist



Neal Sherratt:
Senior Radiographer

Learning Successes

- 30 children have been successfully scanned without sedation using the 3T MR Scanner.
- Positive implications for future clinical scanning.
- Play has been an integral part of effectively obtaining blood through preparation and distraction.
- Excellent feedback from parents / families about a positive patient experience.
- Access to large conservatory area, on-site parking, refreshments and isolated, quiet treatment rooms.

Methodology

- Participants will be screened for Autism Spectrum Disorder through the use of a postal screening questionnaire.
- Those meeting the screening criteria will be invited for detailed ASD assessments.
- VISIT 1: Detailed ASD Assessment
- VISIT 2: WEEK 0 - Blood test and MR Scan
- VISIT 3 WEEK 4 - Blood test
- VISIT 4 WEEK 12 - Blood test and MR Scan

