Sussex Community NHS
NHS Foundation Trust

brighton and sussex medical school

Establishing Accuracy Parameters of a Child Social Communication Assessment Tool

Research Protocol v2.0

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Summary of research project

Autistic Spectrum Disorders (ASD) affect at least 1.1 % of the population (CDC, 2014). NICE recommends that diagnosis requires a multidisciplinary team assessment, obtaining information from various settings including home and school, as well as testing for evidence of autistic behaviours and patterns of thinking (NICE, 2011). Various tools have been developed to aid this process including observational tools such as the Autism Diagnostic Observation Schedule (ADOS). This is a lengthy process, our own study of practice in UK suggesting this takes around 13 hours of professional time to complete, costing around £800 per child (Galliver et al., in submission). Most teams (10/12) employed a two-stage process including an initial screening clinic determining the need for the full multidisciplinary diagnostic assessment.

With diagnostic services reporting growing pressure to meet the growing level of demand, and families having to wait a long time (6 months to 2 years (Autism Achieve Alliance, 2014) for this to be completed, approaches that can improve decision making at initial contact could improve the patient journey and potentially reduce costs. We have developed an automated story that scores emotional cognition in children that could be used alongside parental history and school questionnaire at initial clinical contact, to support decision making. Initial pilot data in children attending for initial assessment for possible ASD, and in a sample of 32 children attending a local primary school, suggests good sensitivity (85%), specificity (92%), and parental and child acceptability in clinic and "typically developing" populations.

This study aims to expand the initial pilot study with increased sample size, testing its use in 62 primary school aged children with a diagnosis of ASD, and in a larger sample of typically developing children (n=62, total sample n=124) attending local primary schools.

Introduction (including the scientific background to the research question)

Background: Why is this Tool Needed?

Autistic Spectrum Disorders (ASD) affect at least 1.1 % of the population (Baird, 2006; Christensen et al, 2016) and could be even twice this figure allowing for possible under-representation, and improving recognition in girls. Affected children, and adults, would be expected to have difficulties in social interaction and communication particularly with their peer group, and repetitive and sensory behaviours, often described as "social communication difficulties". These difficulties can vary from a child with no speech who has minimal interaction with his peers, to a child who may be desperate to make friends but lacks the understanding as to how to do so, whilst having the language to describe their interests in extensive detail. In the absence of a diagnostic test, a multidisciplinary assessment process is recommended in the UK. This requires information being gathered from various environments including home and educational settings, as well as observation and testing for evidence of autistic behaviours and/or patterns of thinking in clinic (NICE, 2011). Various tools have been developed to aid this process including formal structured history tools such as the Autism Diagnostic Interview (ADI-R) and the Diagnostic Interview for Social Communication Disorders (DISCO), and observational tools such as the Autism Diagnostic Observation Schedule (ADOS) and the NEuroPSYchological developmental assessment (NEPSY). However, as NICE recognised, "no single tool alone seems to have adequate sensitivity and specificity for diagnosis of autism" (NICE, 2013).

The multidisciplinary process is lengthy. Our own study of practice in UK based Child Development Centres suggests this takes around 13 hours of professional time to complete costing around £800 per child (Galliver et al., in submission). We also identified that most teams (10/12) employ a 2-stage process (see figure 1) including an initial, "Stage One", screening or general developmental clinic which typically lasts 60-90 minutes (cost £100). This is often carried out by a paediatrician working alone where a decision is made about whether to proceed to the full multidisciplinary diagnostic assessment (NICE, 2011). At the initial clinic, the clinician may have access to information from validated screening questionnaires such as the Social Communication Questionnaire (SCQ) (Chandler et al, 2007) giving a parental perspective of the child, and information from an educational setting (often also in questionnaire form). However, the clinician largely relies on taking a broad developmental history from the parent/carer and observation of the child in clinic. A full "Stage Two" diagnostic assessment may include a paediatrician, a speech therapist and clinical psychologist and others (NICE, 2011), using formal history taking which specifically addresses the presence of autistic symptoms and formal observational assessment for signs of autism, and may include observation and discussion in the child's educational setting.

The combination of lengthy process and steady increase in referrals has placed diagnostic services under increasing pressure resulting in waiting times for complete assessment in the UK taking between 6 months and 2 years (Autism Achieve Alliance, 2014). Therefore, approaches that ease pressure on diagnostic pathways, e.g. by improving decision making at Stage One assessment, may potentially improve the quality and speed of the patient journey through the system and reduce costs. The importance of this for parents is reflected in an on-line survey we have just completed, (N =90) giving a mean rating score of

5.8/7 (scale 1-7) on the need to for research questions that could improve diagnostic pathways. Individual responses included:

"How can we identify autism more efficiently?"

"Early intervention is known to be important, yet diagnosis seems to be delayed again and again with a 'wait and see' approach. Why is this?"

"Why do families have to wait so long for a diagnosis?"

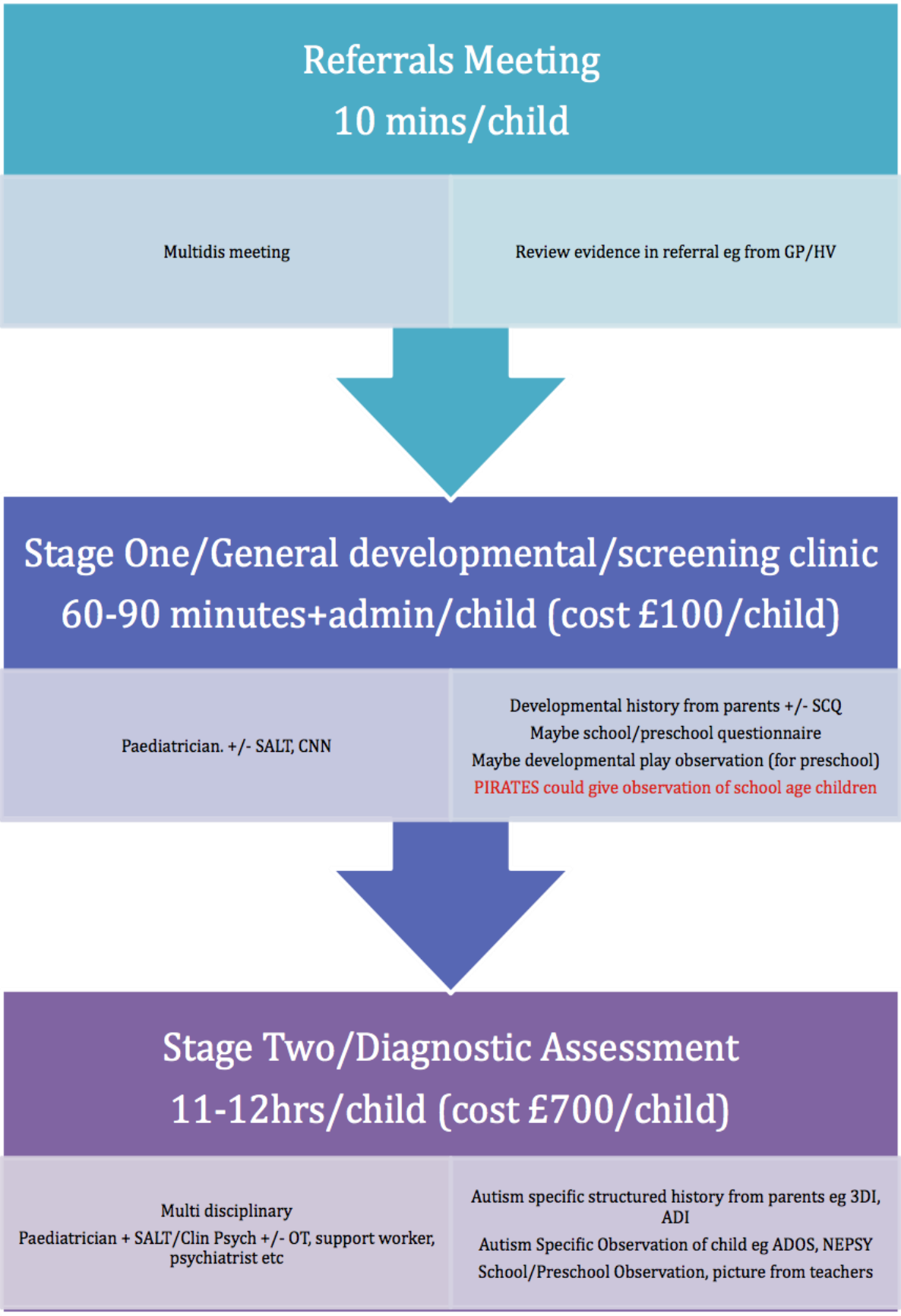


Figure 1. Example diagnostic pathway

The Automated Story: A Pirates Adventure

We conducted a detailed review of literature underpinning psychometric assessment of children with possible ASD. From this, storyboards were constructed incorporating identified tests, adapted into the context of a pirate adventure story line (Jordan et al, 2016). This includes tests of:

- Affect recognition (Golan et al, 2010), including ability to match facial expressions (see figure one), short-term recall of facial expression, and to identify appropriate situational facial expression.
- First Order Theory of Mind, adapting the "unexpected contents (Smarties tube) task" (see figure two) and Sally Ann tests (Baron-Cohen et al, 1985)
- Second Order Theory of Mind (Wimmer and Perner, 1985)
- Strange Stories exploring the child's ability to recognise and explain the use of sarcasm and a lie (Happé, 1994)
- Understanding of Idiom, such as "the treasure cost him an arm and a leg" (Barton, 2012)

We further explored principles of software design for children on the autistic spectrum. Design features likely to improve engagement, and which we've adopted for the software design, included:

- Text should be concise, literal and unambiguous, readable and avoiding capitalising whole sentences
- Navigation should be clear, e.g. using tap or swipe with clear prompts e.g. buttons or arrows. Buttons should be large and finger friendly
- Design features should include: uncluttered layout, engaging format and story line, clear feedback (e.g. progress bar), visual images, simple colour palette avoiding black text on white background (visually over stimulating), using easily readable font such as Sans Serif, no time restrictions and no penalising ("errorless learning"), avoiding flashing, fast animations (avoiding sensory overload), and abrupt changes, whilst using prompting and reinforcement (Fletcher-Watson, 2015).

The resulting scenarios were built into a sequential pirate adventure story line, incorporating the recommended design features, e.g. a Flesh-Reading Ease score of 93.7 (0 unreadable, 100 most readable).

Early use in 3 local Child Development Clinics suggested that the tool can help inform decision making around the need for further diagnostic assessment when used alongside parental history and information from other settings such as school questionnaires. In addition to information obtained from the questions within the tool, clinicians commented that they often obtained additional information around the child's interaction with themselves and with the tool. This experience, together with consultation with our wider team, including an academic expert in psychological testing, including Theory of Mind, (Prof Francesca Happe), Dr Dido Green (Head of OT, Royal Free), Dr Sue Fletcher-Watson (expert in use of digital technology in autism), and local parents, has allowed us to modify the story lines.

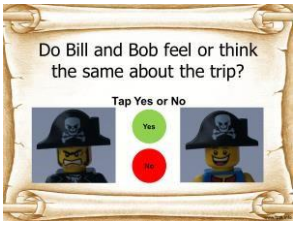


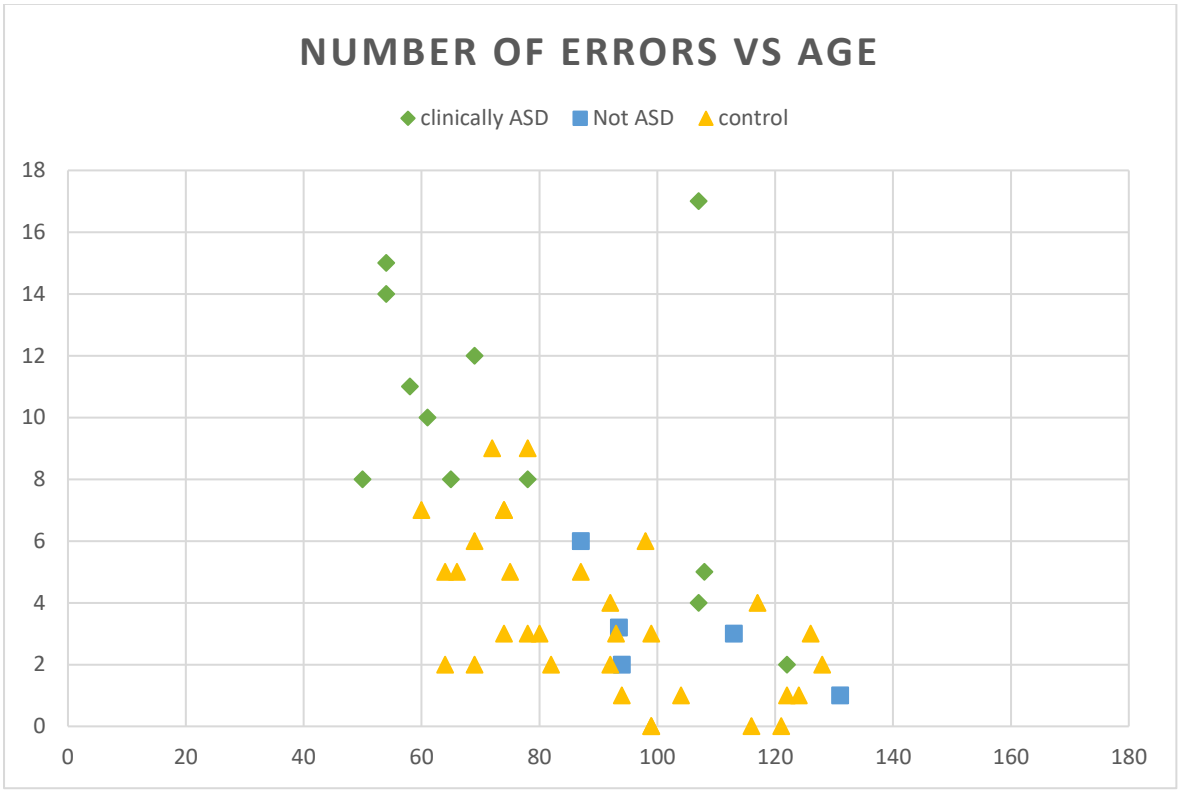
Figure 2. Affect recognition page

Figure 3. First Order Theory of Mind Test page adapted from Unexpected Contents False Belief Task.

Initial Pilot Study

(IRAS 217324 REC 16/LO/2138; HRA 201701014).

Pilot data, testing Pirates in 32 typically developing children (TD) attending a mainstream primary school (ages 4-11 years), and children attending the Child Development Centre following referral for possible ASD/social communication difficulties (ASD) showed a strong negative correlation ($p<0.001$) between number of errors and age (see figure 4), with most key stage one children (4-7.4 years) making 7 or fewer errors, and key stage two (7.5-11 years) less than 4. Taking data from children attending clinic for possible ASD in current study, suggests that most children where there were concerns about social communication were scoring at a higher level than this. Using the cut off scores identified in this study gave sensitivity 85%, specificity 92%, NPV 94%, PPV 79% which if confirmed in the proposed study would give a favourable performance in comparison with current screening tools such as the SCQ. By relating individual scores to these cut offs showed that typically developing children made a mean 1.9 (CI -2.5 to -1.3) fewer errors than the cut off, whilst children considered likely to have ASD clinically made a mean of 3.9 (CI 1.4 to 6.2) errors above the cut off, the difference being highly statistically significant (t test, $p<0.00001$). Children reported enjoying completing Pirates, whilst parents reported this increased their confidence in clinic assessment.



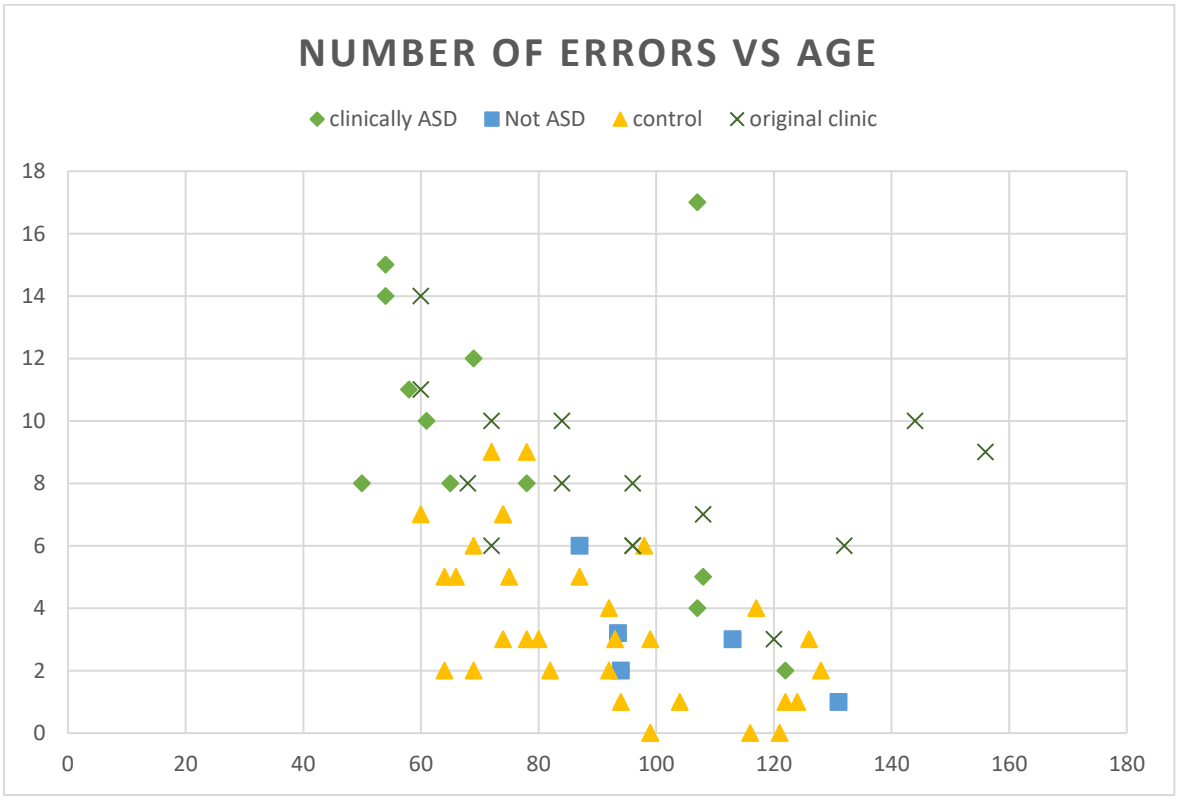


Figure 4. Total score compared to age in months

a) Pilot study data only. b) includes data from early clinical use prior to pilot study

Aims and objectives

Test automated story with children in mainstream school, and with those already diagnosed with autistic spectrum disorder (ASD) in child development centres (CDCs).

1. Primary objective: Investigate parameters of screening tool in a group of 4 to 11 year old children, i.e. of primary school age, with known ASD; estimate discrimination from a group of children who are "typically developing", i.e. who do not have a clinical diagnosis of ASD.
2. Assess sensitivity/specificity of individual questions and relationship to age - e.g. even typically developing younger children may not understand idiom.

Project design

Research methods

1. Sensitivity and Specificity of screening tool

User testing, two groups (children with a diagnosis of Autism Spectrum Disorder (ASD), typically developing children with no diagnosis (TD)) recruited to assess sensitivity of the automated story in a) a clinical environment (ASD, N=62), b) and in a school setting (TD, N=62).

Ethical approval

This has already been achieved for the initial pilot study in an investigation of typically developing children and children referred to a child development clinic for social communication difficulties (IRAS 217324 REC 16/LO/2138; HRA 201701014). We now hope to extend this to the proposed study through substantial amendment. The main change from the original pilot study is to change the "clinical group" from children referred for initial assessment of possible ASD to children already diagnosed with autism spectrum disorder. The methodology is essentially unchanged.

Subjects (including justification for sample size)

A sample of 124 children, suggested after consultation with Research Design service and Medical Statistician, with 62 typically developing children (31 male, 31 female), 62 with ASD (31 male, 31 female) aged 4 to 11 years will be recruited. With 62 children in each group, we will be able to further estimate the sensitivity and specificity of the software result with sufficient precision to enable us to isolate key parameters (Teare et al, 2014). For example, following Buderer (1996) with 62 ASD and 62 typical (i.e. a prevalence of ASD of 50%), assuming a sensitivity of 80%, the 95% confidence interval (CI) for sensitivity

would be from 70 to 90%. The same applies for specificity. For this first stage, we aim to cluster children into two groups from the results of the application: "at risk/no risk" of ASD, which should match with ASD/No ASD. These two groups would then be further analysed against results to see if there is specific clustering around certain scores (total score, and for individual questions/sections), or responses, that may relate to other common associated impairments and co-morbid conditions which are: learning difficulty, language impairment, attention deficit hyperactivity disorder.

Recruitment

Children aged 4 to 11 years with ASD will be identified through CDCs in Sussex Community NHS Trust, by paediatric clinicians; typically developing children will be identified through the headteacher/appropriate member of staff in mainstream primary schools. The parents of children identified will be given a participant information sheet, and asked to contact the research team if they are interested in taking part. We estimate that we will need to approach 240 parents to achieve the full sample of 120 children. This is based on previous local recruitment rates for neuro-disability research of approximately 50% response. We will need to approach 12 potential recruits per month, with 6 recruited per month or 1.5 per week. This means the recruitment and data collection will be spread over 24 months, which we believe is feasible. We will aim to recruit and case match by age and gender.

Information leaflets will be given to the clinical group either in clinic by a member of the clinical care team or from the clinical team by post. Following this, parents will be contacted by the research team, and written informed consent will be sought. The pirate app testing will take place either in the home, clinic or school depending on adult preference.

Children in school will be given study information via school. Parents will then be contacted by the research team to discuss the study and if appropriate consent will be returned to school and then handed to research team. Phone contacts may be made to remaining parents to seek consent, where appropriate.

Inclusion criteria

Children aged 4 to 11 years, of primary school age:

- Group One: ASD: children with a recently confirmed diagnosis of ASD. Diagnosis will have involved full multidisciplinary diagnostic assessment by a CDC.
- Group Two: Typically developing group attending mainstream school

Exclusion criteria

- Child non-verbal or severe learning difficulties or English as second language;
- Typically developing children with prior referral to a child development team or with known social communication or language difficulties or ADHD. These children may take part but results will not be included in typically developing results for analysis.
- Child not of primary school age (i.e. 4 to 11 years).

Process of gaining consent

All necessary consents will be obtained from parents and children following research ethical approval in advance of recruitment and data collection. Individual school policy will be followed for consenting and acceptability of school recruitment. A member of the team experienced in education will lead school recruitment (ex-Assistant Head teacher). Parental consent and child assent will be sought. Two schools in the local area have indicated interest in the study giving a potential recruitment base of 800 children.

Test

Participants in both groups will be given the screening tool to complete. A medical researcher will administer the application to children with ASD and typically developing children in clinic and/or in schools or in the child's home. The story produces pass/fail results recorded anonymously within the software. This data will be transferred to a paper record, and automatically deletes from the software once the individual testing is completed. Current cut-offs are set at 7 errors for key stage one children (4-7.4 YO) and 4 errors for key stage two (7.5-11YO). Results will be collated to attempt to see if it is possible for scores to cluster clearly around typical and ASD populations. There is already evidence of clustering for a clinically abnormal versus typically developing population.

Data analysis

Quantitative Analysis

The main aspects of data recorded will analyse the ASD group: SCQ score, clinical notes confirmation of ASD (yes/no), and automated story result (at risk of ASD yes/no using cut-off scores). Typically developing group will be scored only on automated story result (given that there has been no clinical contact). These will be used to assess sensitivity and specificity with three levels of cross sectional analysis:

a) Clinical notes diagnosis (i.e. does school observation support diagnosis Yes/No) vs. automated story result

b) SCQ score vs. automated story result

c) SCQ score + clinical notes (i.e. does school observation support diagnosis Yes/No) vs. automated story result

We will also calculate positive and negative predictive values. Sensitivity of the instrument with correct case finding will be based on clustering on types of ASD and typically developing children.

For this stage we aim to cluster children into two groups from the results: "at risk/not at risk" of ASD, which should match with ASD/Typically Developing.

These two groups would then go into secondary analysis to consider if there is clustering around certain scores or answers, and future study will explore relationship to other common associated impairments and co-morbid conditions such as: learning difficulty, language impairment, attention deficit hyperactivity disorder. We will estimate proportions of pass/fail recruited and retained for the clinical study and estimate sensitivity and specificity i.e. where sensitivity is the proportion of children with ASD that the tool correctly identifies, and specificity is the proportion without ASD that the screening tool correctly identifies. Thresholds and potential cut-off points for scores will be further clarified and defined using Receiver Operating Characteristic curves will to help refine the tool by comparing sensitivity/specificity and enable appropriate cut-offs to be decided. A logistic regression model will also be fitted to understand accuracy where the result of the tool is the predictor variable and we will also adjust for age and gender, as the at-risk of ASD and typically developing will be matched on these. If the tool detects accurately we will then aim to acquire European medical device regulation 93/42/EEC(MDD)8 for clinical trials [46]. If sensitivity/specificity trial is successful, the equipment will be used in a planned clinical trial.

Potential of research for patient care

Improving information at initial screening will reduce stress and anxiety for children and families and improve the experience and engagement of children. Further, quicker and better decision making will aid in determining which children require full assessment.

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Pirate Study Child Details

Age:

Study Number (research team to complete):

Is English his/her first language? Yes/No

If no, what is their first language _____

Does your child have any of the following? (please tick in box)

Autistic Spectrum Disorder/Aspergers syndrome/Autism ☐

Social Communication Difficulties ☐

Language difficulties/disorder ☐

ADHD ☐

General Learning Difficulties ☐

Dyslexia/Specific Learning Difficulties ☐

Does your child have access to an iPad? **Yes / No**

If yes, how often do they play on the iPad?

Every day, a few times each week, once a week, less than once a week, never

Child Information Leaflet for Mainstream Schools

4 to 11 year olds

Establishing Accuracy Parameters of a Child Social Communication Assessment Tool

We would like to ask you to help us test a new app we have made to see if children can understand what other people are thinking. Before we can use this in clinic, we need to find out if children, who can play, work and talk to each other easily, can answer the questions in the app.

In the app we will show you a story using Lego Pirates on an iPAD and ask you questions like how the pirates feel, or where they will look for the treasure. We will also ask you some questions about what you think of the app. It should take about 10 minutes. We will do this while you are in school, and will be doing this with other children at your school too.

Do I have to take part?

No. If you do not want to take part you do not have to. You only need to say yes if you want to join in. We will ask your mum or dad if it is OK as well. You can stop at any time. Just tell your mum or dad, your teacher, or the person doing the app with you and we will stop. We will not be cross with you.

Will joining in help me?

We hope this will be fun for you to do. If it works it could help us find out if other children find it difficult to talk, work and play with you or other children. If it does help then we may be able to use this to help other children.

What if something goes wrong?

If anything goes wrong, for example if you don't like playing the app, please tell us or your mum or dad or teacher. We will check that you are OK and can stop the study if you want.

Thank you

Child Information Leaflet for Children Coming to Clinic

4 to 11 year olds

Establishing Accuracy Parameters of a Child Social Communication Assessment Tool

We would like to ask you to help us test a new game we have made to see if children can understand what other people are thinking. Before we can use this we need to find out how easy children find it to answer the questions in the game.

In the game we will show you a story using Lego Pirates on an iPad and ask you questions like how the pirates feel, or where they will look for the treasure. We will also ask you some questions about what you the app. It should take about 10 minutes. We will do this when you come to see us, and will be doing this with children at school too.

Do I have to take part?

No. If you do not want to take part you do not have to. You only need to say yes if you want to join in. We will ask your mum or dad if it is OK as well. You can stop at any time. Just tell your mum or dad, or the person playing the game with you and we will stop. We will not be cross with you.

Will joining in help me?

We hope this will be fun for you to do. If it works it could help us find out if some children find it hard to talk, work and play with other children.

What if something goes wrong?

If anything goes wrong, for example if you don't like playing the game, please tell us or your mum or dad. We will check that you are OK and can stop the game if you want.

Thank you

Establishing Accuracy Parameters of a Child Social Communication Assessment Tool

Parent Information Leaflet for Mainstream School Children

We would like to invite you and your child to take part in our research study to help us find out whether we can use an App we have developed, based on a pirate adventure story, which may help us when we are seeing children with possible autism. In this part of the study we want to test children who do not have autism or similar difficulties, to make sure they use the app differently to children who do have autism. If your child does have autism and wants to take part that is fine, but please let us know on the attached questionnaire. Before you decide we would like you to understand why the research is being done and what it would involve for you and your child.

Part One tells you the purpose of this study and what you will need to do if you decide take part. Part Two gives you more detailed information about the conduct of the study. Ask us if there is anything that is not clear. **One of our team will be happy to go through the information sheet with you and answer any questions you have.** We would be grateful if you could return the signed consent form to us within 1 week of this to let us know if you wish to take part.
The study will be run from the Mid Sussex Child Development Centre in Haywards Heath

Part One:

What is the Purpose of the Study?

We need to test the app in children who we know do not have autism or any related conditions, so that we can tell if it can discriminate between children who do and do not have autism.

Why have we been invited?

We are inviting children attending (name of school) primary school to take part.

Do we have to take part?

No. It is up to you to decide if you want your child to join the study. If after reading this information leaflet you agree for your child to take part, we ask that you sign the consent form and return it to us in the enclosed stamped addressed envelope. If you have any questions please feel free to contact us on the phone number below. We would be grateful if you could read the child information leaflet with your child to check they are happy to take part as well. Your child is free to withdraw at any time, without giving a reason. This will not affect the standard of care your child receives.

What will happen if my child takes part?

We will come into school to play on the app with participating children. One of the research team will play the app with your child and ask the questions included. This will take about 10 minutes. We will also ask them some questions about what they think of the app. We will do this close to their classroom so they can still see their class/teacher. The app presents a series of questions (such as in the picture opposite) presented as a pirate adventure game exploring the child's ability to recognise facial expressions, think what someone else is thinking, to recognise sarcasm and the use of a lie, and to understand idiom. These are all based on tests we use when assessing a child for possible autism. Some skills being tested only emerge in school aged children so we want to find out at what age children can answer the questions. Please reassure your child therefore that they do not need to know all the answers - we will also reassure them whilst playing the app with them. The app has already been used with a number of children attending Child Development Clinics across W. Sussex with parents, children and doctors all giving positive feedback on its use.

What are the possible benefits and risks of taking part?

We hope that in time we will be able to use this app to improve our diagnostic process in assessing children with possible autism. As autism affects over 1 in 100 children you or your child may well have friends or relatives who will need such an assessment. We also hope your child will enjoy playing the app - it is meant to be a fun game to play.

We will exclude children with epilepsy who are sensitive to flashing lights or TV screens, to avoid setting off any seizures.

Part Two

What will happen if my child doesn't want to carry on with the study?

Your child is free to leave the study at any point, and you may request that any data relating to your child's involvement in the study be destroyed. This will have no effect on any ongoing treatment with the child development team.

What if there is a problem?

Any complaint about the way you or your child have been dealt with during the study or any possible harm you might suffer will be addressed. If you or your child have any concerns about the conduct of the study, you can discuss these with the Chief Investigator, Dr Ian Male on 01444 414100. You may contact our complaints department, who will investigate your concerns:

The Patient and Liaison Service (PALS) experience team,
Sussex Community NHS Foundation Trust,
Freepost (BR117),
Elm Grove,
Brighton BN2 3EW.
01273 242292

In the event that something does go wrong and your child is harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against our organisation (Sussex Community NHS Foundation Trust), but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). NHS Indemnity does not offer no fault compensation i.e. for non-negligent harm, and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm.

Will my child's taking part in this study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you and your child will be handled in confidence. Individual data will be recorded on paper questionnaires and test score sheets. These will be stored securely at the Child Development Centre in a locked cupboard. Anonymised data will be entered onto a password encrypted computer for statistical analysis. Results may be reported in medical journals but this will be done so anonymously. All information which is collected about your child during the course of the research will be kept strictly confidential, and any information about your child which leaves the Child Development Centre will have your child's name and address removed so that you and your child cannot be recognised.

Data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to your child taking part in this research, for the purposes of auditing and monitoring.

What will happen to the results of the research study?

We hope to present the results of the study at national meetings attended by other medical professionals and to publish our findings in the medical press. This is so children outside of the study can benefit from our findings. We will also display a poster at the Child Development Centres showing the results. Whenver the results are publicised you and your child will remain anonymous.

Who is organising and funding the research?

The study is being run by Dr William Farr, Research Psychologist, and Dr Ian Male, Consultant Community Paediatrician at the Mid Sussex Child Development Centre, employed by Sussex Community NHS Foundation Trust. Two fourth year medical students from Brighton and Sussex Medical School, Anokhee Patel and Kate Scanlon will be testing the app in school under the supervision of the above. They have both been DBS checked by the medical school. Our research team is being supported by Dr Dido Green, Reader in Rehabilitation, and Dr Anjum Memon from the local Research Design Service, and Prof Francesca Happe, Professor of Psychology at the Maudsley Hospital, Kings College, London. We also discussed the use of this app with a local parents support group for parents who have a child with autism and with your child's headteacher. The study is sponsored by the Sussex Community NHS Foundation Trust. There is no financial or other benefit to the research team resulting from this study.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Research Ethics Committee.

Further information and contact details

1.General information about research: contact The Patient and Liaison Service (PALS)

experience team, Sussex Community NHS Trust, Freepost (BR117), Elm Grove, Brighton BN2 3EW. 01273 242292.
2. Specific information about this research project: contact Dr William Farr or Dr Ian Male at the Mid Sussex Child Development Centre on 01444 414100.
3. Advice as to whether you/your child should participate: you can discuss with Dr William Farr or Dr Ian Male as above
4. If you have any concerns about the study please contact Dr Ian Male as above, in the first instance.

Establishing Accuracy Parameters of a Child Social Communication Assessment Tool

Parent Information Leaflet for Children Attending Clinic

We would like to invite you and your child to take part in our research study to help us find out whether we can use an App we have developed based on a pirate adventure story, which may help us when we are seeing children with possible autism. In this part of the study we want to test children who are attending our child development clinic when concerns have been raised about their social interaction. Before you decide we would like you to understand why the research is being done and what it would involve for you and your child.

Part One tells you the purpose of this study and what you will need to do if you decide take part. Part Two gives you more detailed information about the conduct of the study. Ask us if there is anything that is not clear. **One of our team will be happy to go through the information sheet with you and answer any questions you have.** If you are happy to take part we will ask you to sign a consent form in clinic. We will also be able to answer any questions you have about the study.
The study will be run from the Mid Sussex Child Development Centre in Haywards Heath

Part One:

What is the Purpose of the Study?
We have developed an app which includes a number of tests we use when assessing children with difficulties in social interaction in the format of a pirate adventure game. Before we can use this to help in that assessment we need to test the app in children attending clinic so that we can tell if it can recognise children who have such difficulties.

Why have we been invited?
We are inviting children attending our clinic to take part where they have been referred because of concerns about their social interaction skills.

Do we have to take part?
No. It is up to you and your child to decide if you want to join the study. If after reading this information leaflet you agree to take part, we will ask you to sign the consent form when you come to clinic. If you have any questions please feel free to contact us on the phone number below, or when you come to clinic. We would be grateful if you could read the child information leaflet with your child to check they are happy to take part as well. You and your child are free to withdraw at any time, without giving a reason. This will not affect the standard of care you receive.

What will happen if we take part?
When we see you in clinic we will play the app with your child as part of our assessment alongside our normal assessment when we will ask you about your concerns. This will take about 10 minutes. The app asks a series of questions (such as in the picture opposite) presented as a pirate adventure game exploring the child's ability to recognise facial expressions, think what someone else is thinking, to recognise sarcasm and the use of a lie, and to understand idiom. The app has already been used with a

number of children attending Child Development Clinics across W. Sussex with parents, children and doctors all giving positive feedback on its use. At the end of the clinic we will ask you and your child to answer a couple of questions about what you think of the app.

What are the possible benefits and risks of taking part?
We hope that in time we will be able to use this app to improve our diagnostic process in assessing children with difficulties in social interaction. We also hope your child will enjoy playing the app - it is meant to be a fun game to play.

We will exclude children with epilepsy who are sensitive to flashing lights or TV screens, to avoid setting off any seizures.

Part Two

What will happen if we don't want to carry on with the study?
You and your child are free to leave the study at any point, and you may request that any data relating to your child's involvement in the study be destroyed. This will have no effect on any ongoing treatment with the child development team.

What if there is a problem?
Any complaint about the way you or your child have been dealt with during the study or any possible harm you might suffer will be addressed. If you or your child have any concerns about the conduct of the study, you can discuss these with the Chief Investigator, Dr Ian Male on 01444 414100. You may contact our complaints department, who would investigate your concerns:

The Patient and Liaison Service (PALS) experience team,
Sussex Community NHS Foundation Trust,
Freepost (BR117),
Elm Grove,
Brighton BN2 3EW.
01273 242292

In the event that something does go wrong and your child is harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against our organisation (Sussex Community NHS Foundation Trust), but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). NHS Indemnity does not offer no fault compensation i.e. for non-negligent harm, and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm.

Will my taking part in this study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you and your child will be handled in confidence. Individual data will be recorded on paper questionnaires and test score sheets. These will be stored securely at the Child Development Centre in a locked cupboard. Anonymised data will be entered onto a password encrypted computer for statistical analysis. Results may be reported in medical journals but this will be done so anonymously. All information which is collected about you and your child during the course of the research will be kept strictly confidential, and any information about you and your child which leaves the Child Development Centre will have your name and address removed so that you and your child cannot be recognised.
Data collected during the study and case notes may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to you and your child taking part in this research, for the purposes of auditing and monitoring.

What will happen to the results of the research study?
We hope to present the results of the study at national meetings attended by other medical professionals and to publish our findings in the medical press. This is so children outside of the study can benefit from our findings. We will also display a poster at the Child Development Centres showing the results. Whenver the results are publicised you and your child will remain anonymous.

Who is organising and funding the research?
The study is being run by Dr William Farr, research psychologist, and Dr Ian Male, consultant community paediatrician at the Mid Sussex Child Development Centre, employed by Sussex Community NHS Foundation Trust. Our research team has been supported by Dr Dido Green, Reader in Rehabilitation, and Prof Anjum Memon from the local Research Design Service, and Prof Francesca Happe, Professor of Psychology at the Maudsley Hospital, Kings College, London. We also discussed the use of this app with a local parents support group for parents who have a child with autism and with your child's head-teacher. The study is sponsored by the Sussex Community NHS

Foundation Trust. There is no financial or other benefit to the research team resulting from this study.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Research Ethics Committee.

Further information and contact details

1.General information about research: contact The Patient and Liaison Service (PALS) experience team, Sussex Community NHS Trust, Freepost (BR117), Elm Grove, Brighton BN2 3EW. 01273 242292.

2. Specific information about this research project: contact Dr William Farr or Dr Ian Male at the Mid Sussex Child Development Centre on 01444 414100.

3. Advice as to whether you/your child should participate: you can discuss with Dr William Farr or Dr Ian Male as above

4. If you have any concerns about the study please contact Dr Ian Male as above, in the first instance.

Parent / Carer Consent / Child Assent Form

Childs Name:

PARENTAL CONSENT

Accuracy Parameters of a Child Social Communication Assessment Tool

Name of Researchers: Dr Ian Male, Dr William Farr

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated **[17/11/2016 mainstream school version 1.0, 15/08/2017 clinic version 1.1]** for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my/my child's participation is voluntary and that I/they are free to withdraw at any time without giving any reason, without my/their medical care or legal rights being affected. ☐

3. **[CLINICAL GROUP ONLY TO INITIAL]** I understand that relevant sections of my child's medical notes and data collected during the study, may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to him/her taking part in this research. I give permission for these individuals to have access to my child's records. ☐

4. I agree to take part in the above study and also agree for my child to participate too. ☐

Name of Parent	Date	Signature

Name of Person taking consent	Date	Signature

Patient Identification Number for this trial:

Patient Identification Number for this trial:

Establishing Accuracy Parameters of a Child Social Communication Assessment Tool

Child Assent Form

Name of Researchers: Dr Ian Male, and Dr William Farr

Child (or if unable, parent on their behalf) /young person to circle all they agree with:

- Has somebody else explained this project to you? Yes/No
- Do you understand what this project is about? Yes/No
- Have you asked all the questions you want to ask about the study? Yes/No
- Have you had your questions answered in a way you understand? Yes/No
- Do you understand it's OK to stop taking part at any time? Yes/No
- Are you happy to take part? Yes/No

If any answers are "no" or you don't want to take part, don't sign your name!

If you do want to take part, you can write your name below

Your name

Date

The doctor running this project will sign this too:

Print Name

Sign

Date

Thank you for your help.

Pirates Toolkit Autism Screen Score sheet (automated within software)

Score	*Test Section*	*Subtest*	*Screen*
	Facial Recognition (static)		
Pass/Fail	Facial Expression	Happy/sad	Screen 2
Pass/Fail	Matching	Happy/angry	Screen 3
Pass/Fail		Cross/cross	Screen 4
Pass/Fail		Which 2 same 1	Screen 5
Pass/Fail		Which 2 same 2	Screen 6
Pass/Fail		Pirate Polly	Screen 7
Pass/Fail		Short term memory	Screen 9
	Focus (none, prolonged)		
Seconds	Reaction time	Reaction time	Screen 10
	Situational Facial Recognition		
Pass/Fail	Facial Expression	Ship captured	Screen 13
Pass/Fail	Situational	Walk the plank	Screen 15
Pass/Fail	Control (language) same	Parrots	Screen 17
Pass/Fail	Control (language) different	Parrots	Screen 18
	First Order Theory of Mind (ToM)		
Pass/Fail	First order False Belief Test	What do the pirates think is in chest?	Screen 24
Pass/Fail	Control (reality) Crab test	What is in the chest?	Screen 25
	First Order False Belief		
Pass/Fail	Control Question (memory, naming)	Who is Pirate Tom	Screen 32
Pass/Fail	Control Question (memory naming)	Who is Pirate Jimmy	Screen 33
Pass/Fail	Sally Ann {Hiding treasure} (1st order TOM)	Where does Tom think the treasure is?	Screen 41
Pass/Fail	Control (reality)	Where is the treasure really buried?	Screen 42
Pass/Fail	Control (memory)	Where was the treasure in the beginning	Screen 43
	Second Order Theory of Mind		
Pass/Fail	2nd order Theory of Mind (Mentalising)	Where does sailor Jack think Tom thinks the treasure is?	Screen 53
Pass/Fail	First order false belief	Where will Tom really look for the treasure?	Screen 54
Pass/Fail	Control (memory)	Where was the treasure in the beginning?	Screen 55
	Higher Order Strange Stories 'Sarcasm'		
Pass/Fail	Question (comprehension)	It's a lovely day.. Telling truth	Screen 60
Pass/Fail	Justification	Why?	Screen 61
	Higher Order Strange Stories 'Lie'		
Pass/Fail	Question (comprehension)	Spilt beer...Telling truth	Screen 66
Pass/Fail	Justification	Why?	Screen 67
	Idioms		
Pass/Fail	Comprehension	Cost arm and leg	Screen 70
Pass/Fail	Comprehension	Cried his eyes out	Screen 72
Pass/Fail	Comprehension	Bone to pick with you	Screen 74

Please turn over/see next page

Child Age: **SCQ Score:**

Likely Diagnosis using history

Likely Diagnosis using settings questionnaire

Additional information obtained from child playing app-e.g. social engagement

Did findings support plan for full assessment or to not proceed with assessment

Did findings change plans for full assessment or to not proceed with assessment

Pirate Adventure App Operating Guidelines

1. Check Parental Consent has been completed correctly
2. Check Child Details to determine if they can be included or excluded in the control group
3. If appropriate, then generate participant ID (i.e 01KS or 01AP)
4. Prepare/fill in paperwork needed before assessment
    a. Child Assent Form for children in KS 2
    b. Score Sheet
    c. SFQ
5. Collect child from classroom
6. Explain briefly before beginning about the app and its use
7. Gain Assent if in KS 2 and get the child to sign the form and co-sign below as researcher
8. Start game
    a. Offer for the child to select their answers or press the 'Next' button, otherwise can click for them
    b. Wait at Screen 9 for Ocean Screen to load
    c. Screen 60 substitute word sarcastically for angrily
    d. Screen 76 ask child to hand back iPad after attempting Tile Game
9. Perform SFQ (Refer to prompts below to clarify questions)

    <u>Part 1</u>

    1. Did you enjoy playing the game?
    2. Did it feel like a story?
    3. Did you think you did well in the game?
    4. Did you find the app interactive? (instead of in control)
    5. Did you find the story interesting?
    6. Did you feel like you knew how to work the game?
    7. How much of the game did you not enjoy?

    <u>Part 2</u>

    8. How difficult did you find the game?
    9. Did you find any part of the game upsetting?
    10. What did you like? What did you not like in the game?

10. Now let child pick out a pirate sticker
11. Thank and return to appropriate classroom
12. Complete Score Sheet using iPad Results Screen
13. Fill in additional Observations on the back of the score sheet
14. Staple Score sheet and SFQ and file under completed children
15. Cross name of running list of children with consent forms
16. Find next child (keep in mind breaks and important lessons to avoid)