

Ethical issues arising in research with people with mental health conditions

Seminar series 2021



Case study: A spectrum of challenges in conducting research for the early identification of Autism Spectrum Disorders

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Background

There has been growing evidence for the potential for early identification in autism.¹ Early identification of autism spectrum disorders (ASD) however remains a challenge², especially in a country such as India with limited health care infrastructure for the same. A multi-pronged strategy is the focus of current research at our centre, CARE-ADD (Centre for Advanced Research and Excellence in Autism and Developmental Disorder) that has been set up, amongst other things, to help in the early identification and treatment of ASD.

The 2011 Government of India experts meeting adopted 1 in 250 as a prevalence rate for ASD in India for planning purposes³. Prevalence of ASD as per studies in the last decade in India has been reported to range from 1 in 400⁴ to 1 in 90⁵. No study has explored early identification below 18 months of age in India. Service provisions for early interventions for ASD in India are varied, more concentrated in urban sectors and not organised within the public health services network⁶. Efforts to bring childhood disability, including that arising from ASD are included within the plans to establish Early Intervention Centers at district level across India⁷, but are yet to have a clear process including measures and human resources.

Brief description of the research project

This study was carried out across Bangalore, India. The study was funded by the Indian Council for Medical Research and carried out after approval by the Institutional Ethics Committee (IEC) of the St John's National Academy of Health Sciences, from where the study was carried out. The project team included senior and junior psychiatrists, psychologist, pediatrician, speech therapists and experts from community health department. Using a mixed methods approach, we designed a 24 item screening tool for autism in children between 9 and 18 months of age⁸. The screening tool is called Early Screening for Social and Communication Skills. The project plan included a detailed assessment of all screen positives at baseline (to see if additional help was necessary) and then follow-up all screen positives and a fraction of the screen negatives six months later, to explore the predictive validity of the tool. The community centers were expected to help recruit about six hundred children with a six month period and anticipated to provide a specified number of screen positives for the exercise. These centers were visited by carers with infants and toddlers for a variety of health care purposes and included hospitals and pediatricians' offices. High risk children based on obstetric factors, neonatal

ICU care, history of convulsions and developmental delays, were recruited from within specific institutions.

We kept sets of forms – subject information sheets, informed consent, questionnaire and contact details – in various centers around the city. After obtaining permissions from the professionals at the clinic, the secretary at the clinic was requested to indicate the families in the waiting room to go through the information sheet and complete the forms if they chose to do so. The parents' participation was voluntary. Doctors at the clinic could also request parents to participate voluntarily in the study.

The information sheet and the forms were in English and local languages. They had been specifically cleared by the IEC. In the forms it was mentioned that if the research team found it necessary, the child would be called for a detailed evaluation/ assessment. The inclusion criteria were children between 9 and 18 months of age and parents being literate. Research workers periodically collected the forms filled by parents and contacted them as per the research plan.

The Index Scenario: Child XYZ, 18 months old was recruited from a pediatric clinic after the parents filled the questionnaire that was kept at the clinic by the researchers. The research team, on scoring the questionnaire found that the child required a detailed evaluation. The parents were contacted soon after, only to be turned down saying that they were not interested.

The research team persisted. They informed the primary pediatrician who was seeing the child regularly. The doctor got in touch with the family and spoke to them about seeing the research team for the detailed evaluation. The research team was also requested by him to get in touch with the family and schedule an appointment. The team did so with the intention that the child could be enrolled into an Early Intervention program, if needed. The family, especially the mother was very apprehensive and delayed the appointment. Finally, after about 3-4 months, and multiple phone calls, the parents came forward to do the assessment. On the day of the assessment, they visited the center where the various assessments were planned. Professionals including child psychiatrist, a psychologist and a speech language pathologist were to assess the child across various domains. The psychiatrist explained the outcomes of the assessments to the parents. But the mother insisted that they had just filled the questionnaire and that they did not wish to get any further assessment done. The professionals showed them the SIS and the consent form they had signed. The mother maintained that she had not read the SIS or the consent form and had just filled out the questionnaire, not taking it seriously. She refused any further support from us. It was resolved by the Research Team to not actively pursue the matter any further. We informed the concerned community clinician and coded the subject's participation in the study as closed.

Ethical issues with commentary on each issue

The research team felt under pressure to convince the parents of the child to come for a detailed assessment as they felt the child may need referral after assessments. All the forms were available in 4 different vernacular languages (English, Hindi, Kannada and Tamil) so that only parents who read any of these languages could fill it out. Parents who could not read were not included as it was self-rated questionnaire. The information sheet clearly mentioned that the parents may be requested to come for an assessment based on their ratings of their child. Although, the research team had taken extra care to keep the SIS and CF very simple and easy to understand, it is possible that many parents may not have read them adequately. When the researchers try to follow up with the families fulfilling the screening criteria, it is hard to get them to bring their children for assessments/evaluation. The study had provisions to support transport charges for families coming for assessments.

1. **Research issue:** In a low base condition such as autism, it is important to assess all screen positives when developing screening instruments. This improves the likelihood of finding the requisite Positive Predictive Value and confirming that the subjects screening positive truly

have the disorder. So it is necessary to have further assessments especially for screen positives.

2. **Clinical issue:** Early identification and intervention improves outcomes. This study targeted children below 18 months, arguably a golden period to start interventions, if identified. Researchers who are also clinicians find it hard to ignore this opportunity. This had prompted us to carry out a detailed assessment of all screen positives at baseline itself.
3. **Ethics issue:** If families refuse to come, the defined process is 'not to proceed'. However, as in case XYZ, the researcher is also committed to ensure that an identified clinical need is supported and not ignored. The conflict arises primarily from the families' lack of preparedness to get the children assessed. Non-engagement could also be related to cultural or financial contexts or inadequate support / clarity during the research recruitment stage.
4. **LMIC issue:** Subjects filling forms in the community may not read and fully understand what they are consenting for. Even notices in the peripheral centers (as was arranged in this study) may not have been read well. There may not be enough funds to have researchers remain at all community sites to clarify the consent process. Community service providers may not adequately educate families in this regard. Clinician researchers may be aware of the limited opportunities for help for families if the child needs interventions and do not wish to face the regret of not intervening early when they had an opportunity. Given general low awareness levels of certain conditions (autism in this case), being called for assessments may prove frightening to families. This, on the other hand, further justifies the need for such studies exploring the development of locally meaningful screening instruments.

Potential solutions

- a) SIS and consent sheets as well as the process need to be more user-friendly. This may have limitations, in the absence of ambient awareness and limited funds. There is an opportunity for engaging in research on consenting methods in such contexts.
- b) There is a need to do some formative research that can help understand barriers to uptake of screening forms in the community centers and use that information to improve the methodology.
- c) One can formally train the receptionist / secretary in the community centers to support families when responding to screening forms. To clarify what the entire process was related to; also, specifically explain that it was not part of the clinic's procedures.
- d) Have the support of stakeholders to adequately inform the researcher on treading the narrow path more optimally. In the absence of widespread public health structures to support research, we feel families already facing such clinical challenges can become good advocates for both the community and the researchers. As our center intends pursuing research into trajectories of childhood development, we have initiated the presence of a review body consisting of families of children with autism to oversee such research process, to hopefully help resolve such challenges, with minimal distress to participants.

References

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In 2021 GFBR hosted a series of five online seminars on the broad theme ‘Ethical issues arising in research with people with mental health conditions’. This case study was prepared for the seminar ‘The ethics of neurodevelopmental disorders research’. Recordings of the seminar series are available at www.gfbr.global.