



Parent Information Sheet for Telephonic Assessments

NOTE: SUPPLEMENTARY DETAILS ARE IN THE BLUE BOXES. READ OUT ONLY IF PARENTS REQUEST MORE INFORMATION.

“Hello! I am [ASSESSOR NAME] and I’m calling from Sangath. Our organization, Sangath has been working in the field of child development for the last 25 years.”

I have received your details from [NAME OF PERSON FROM REFERRING INSTITUTION] from AIIMS

I would like to speak to [CHILD’S NAME] primary caregivers or both parents; is this a good time to talk to you/ both? I will need about 30 minutes for this call and slightly longer to answer questions you may have. If this is not a good time, I can also call back when it is convenient for you.

I have called you today to invite you to take part in a research study for children with autism. Before you decide whether to take part it is important for you to understand why this research study is being done and what it will involve. In this call, I will be explaining everything to you so that you can make a clear decision on whether you would like to be involved in this research study.

RECONFIRMING IDENTIFYING INFORMATION

Before we go ahead, I would just like to confirm some details that we have received from AIIMS

S. No.	Question	Response	Variable Name
1	Date of call <i>(Prefill)</i>	D D / M M M / Y Y Y Y	DATE_CALL
2	Assessor Code <i>(Prefill)</i>		ASSESSOR_CODE
3	Recruitment site <i>(Prefill)</i>	ORGANIZATION NAME 1(MAMC-LNH).....0 ORGANIZATION NAME 2(AIIMS).....1 ORGANIZATION NAME 3.....2 ORGANIZATION NAME 4.....3	RECRUITSITE
4	Reference ID <i>(Prefill)</i>		REF_ID
5	Child’s name as received from recruitment site <i>(Prefill)</i>		CHILDNAME_RECSITE
6	Family’s contact number as received from recruitment site <i>(Prefill)</i>		CONTACTNO1
7	What is your relationship with [CHILD’S NAME]? <i>(Prefill)</i>		RELATIONSHIP_CHILD
8	How do you spell [CHILD’S NAME]? <i>(Prefill)</i>		CHILD_NAME

9	Child's gender <i>Note: Clarify with respondent if unsure about child's gender.</i>	Girl.....0 Boy.....1 Other.....2	CHILD_GENDER
10	What is [CHILD'S NAME] date of birth?	D D / M M M / Y Y Y Y	CHILD_DOB
11	What is [CHILD'S NAME] father's name?		FATHER_NAME
12	What is [CHILD'S NAME] mother's name?		MOTHER_NAME
13	Do you stay in Delhi?	No.....0 Yes1	STAY_DELHI
14	What is your full home address and landmark?		ADDRESS
15	Please mention Area Code Central=1, East=2, New Delhi=3, North=4, North East=5, North West=6, Shahdara=7, South=8, South East=9, South West=10, West=11, Outside Delhi NCT =12		DISTRICT_CODE
16	Do you have any other contact number?	No.....0 Yes.....1	OTHERCONTACTNO
17	What is the alternate contact number?		CONTACTNO2
18	Alternate contact number 2		CONTACTNO3

Thank you so much for giving me your information! Let me tell you a little bit about our research study.

In this study called Communication-centred Parent-mediated treatment for Autism Spectrum disorders (ASD) in South Asia, which we call 'COMPASS' in short, we are trying to compare two treatments. One is the usual treatment that you receive from AIIMS and other organisations or service providers. The other is PASS plus combined with this usual treatment that you receive. We want to understand which of these two works better before we can recommend it for all children with autism in India.

Supplementary details: We will be recruiting from AIIMS where children are already receiving some treatment. We are doing this in order to recommend the Government of India which treatment should be provided to children with autism in India.

During this call, please feel free to ask any questions or ask for additional information. Also let me know if you need a break anytime in between. You can also speak to others who you may want to consult, for example elders in the family or [NAME OF PERSON FROM ORGANIZATION] from AIIMS from where we have received your contact, before you make your decision.

I would like to start by telling you a little bit more about Sangath. Our organisation has been working in the field of child development, including Autism, since 1997 across many states and union territories in India including Delhi, Haryana, Madhya Pradesh, Maharashtra, and Goa.

We have over the years realized that most treatments that are being offered to families of children with Autism tend to be ‘imported’ and are often not suitable to our setting.

As you know children with Autism have difficulty communicating with others, interacting with the world around them, sharing their interests or may find themselves over or under sensitive to the things in their environment (for example, sounds, light and textures).

With this in mind, the PASS Plus treatment has been developed and evaluated in Goa and Kolhapur. The treatment has two parts. The first part addresses the communication difficulties of children with autism. The second part supports other difficulties that many children have with their restlessness, their feeding and sleeping. As a part of this, a video of you playing with your child is recorded and used by our team member for the treatment.

Supplementary details: The PASS Plus is adapted and developed by Dr Gauri Divan, a paediatrician and Vivek Vajaratkar, an occupational therapist with colleagues in Manchester, UK. As a part of this treatment, our team member, whom we refer to us as a ‘COMPASS counsellor’ will get in touch with you. This is a home delivered treatment, though we are adapting it to take into concerns around the pandemic. In the traditional version, you are asked to play with your child with toys for six minutes, which is video recorded. The COMPASS counsellor then uses clips of the play video to help you to think about ways in which you can help your child to communicate. You are expected to practice the skills for 30 minutes every day with your child using play materials in the house. The sessions are held every 15 days.

Before we go any further, I would like to confirm a few things which would help us decide if you meet the criteria to be part of our research study. Please note that this is in no way indicative of your child’s abilities. In COMPASS, we are offering a very specific treatment that may not be a good fit for all children with Autism. We may find that this treatment is not for your child and we will not include you in the work ahead. However, please note that this will not affect any services you may be getting from AIIMS or any other organisations and service providers.

EXCLUSION CRITERIA RECONFIRMATION

NOTE: ASK FOR EACH CRITERION INDIVIDUALLY AND CIRCLE 1 FOR YES AND 0 FOR NO.

S. No.	Question	Response	Variable Name
1.	Does the [CHILD’S NAME] reside in Delhi? <i>(Prefill)</i>	Yes.....1 No.....0	EXCLUDE_RESIDEDELHI
2.	Does [CHILD’S NAME] have a twin?	Yes.....1 No.....0	EXCLUDE_TWIN
3.	Did [CHILD’S NAME] have a seizure in the last 6 months?	Yes.....1 No.....0	EXCLUDE_SEIZURE6M
4.	Does [CHILD’S NAME] have a significant hearing/visual problem?	Yes.....1 No.....0	EXCLUDE_CHILDPRBLMHearSee
5.	Does [CHILD’S NAME] have any other significant genetic, neurodevelopmental or physical disability?	Yes.....1 No.....0	EXCLUDE_OTHRDISABILITY
6.	Is [CHILD’S NAME] involved in any other research study in MAMC-LNH/AIIMS?	Yes.....1 No.....0	EXCLUDE_OTHRSTUDY
7.	Does the primary caregiver/parent have significant hearing/visual problem?	Yes.....1 No.....0	EXCLUDE_CAREGIVERPRBLMHearSee
8.	Does the primary caregiver have a severe learning disability or current severe psychiatric disorder?	Yes.....1 No.....0	EXCLUDE_CAREGIVERLDRPDCURNT

If participant is ineligible: “Thank you so much for talking to me. Your participation & cooperation was great help and I really appreciate it. However, as I had explained earlier, the treatment can be delivered only to a certain section of children with Autism. Unfortunately, since [REASON FOR EXCLUSION], the treatment may not be a good fit for [CHILD’S NAME] we will not be able to go ahead with you on the COMPASS research study. I’m really sorry if this has caused you any disappointment. Please feel free to ask me any questions you may have or express anything that you might be feeling about this.”

The reason we are asking for your participation is because, according to our initial screening, we think that the treatment would be a good fit for your family. We are hoping that after listening to the information I share with you, you will think about volunteering for this study. However, you are free to choose whether to take part. If you do decide to take part, you are free to withdraw from the study at any time, without giving a reason, and this will not affect the care you receive from your current services with AIIMS.

RANDOMIZATION

For our study, we will be recruiting 240 families with a child with Autism under the age of 9 years like yours, who meet certain criterion.

In order to do the comparison of treatments, the families will be divided into 2 groups, Group ‘X’ and Group ‘Y’. Families in Group ‘X’ will continue to receive the usual treatment which they are receiving currently while families in Group ‘Y’ will receive PASS Plus treatment along with the usual treatment which they are receiving.

It is not possible for us to know which group you will be assigned to, as this depends on chance. Each family will have an equal chance of being placed in either of these two groups. This decision will be made by a computer and is not dependent on any member of COMPASS team or any characteristics of the family. This process is called ‘random allocation’ and it basically ensures that all families have an equal chance of being in either group.

It is very important for us that you understand this process. Please watch the video which I sent to you to get a better understanding (Share Randomization video with the family). In case the respondent doesn’t have access to a smartphone, ask for any other person who would have a smartphone and the respondent would be comfortable in viewing the randomization video on their device).

Families who get placed in the group getting the PASS Plus treatment, will receive 12 sessions of approximately 1 hour each with a COMPASS Counsellor, who may be a trained community health worker, such as an ASHA. The treatment is usually delivered within eight months.

Apart from this, all 240 children recruited into the study will also get detailed assessments.

I know I have shared a lot of information with you right now. Let me stop and ask if you have any questions or if you would like to take a break.

ASSESSMENT INFORMATION

NOTE: THE DETAILS ABOUT THE ASSESSMENTS IS PLACED AFTER ASCERTAINING INCLUSION AS WE WOULD WANT TO SHARE FURTHER DETAILED INFORMATION WITH THE FAMILY ONLY IF THEY ARE ELIGIBLE FOR THE TRIAL.

We need to conduct a number of assessments at three time points. We will do the first assessments now, the second one after 9 months and the final one after 15 months. These assessments will be conducted based on your convenience and availability over 6 days, including today. Given the safety concerns over the COVID-19 pandemic, we would be doing most of the assessments over telephonic calls. Only on one of the days, you will need to come to our Sangath office in Saket. A cab will be sent by us to pick you up and drop you safely to your home. Please note that the cab will be sanitized properly before picking you up. Safety measures recommended by the Government of India are being

followed by Sangath and its staff members to minimize the risk of exposure to COVID-19. The assessment room including the toys we use for the assessment will be sanitized before and after every use. During this visit, we will observe you and [CHILD'S NAME] interacting and playing with one another and will record a video of this. A team member will also play some games with your child for another video. These videos allow us to see changes in play and communication over time. This visit would take about 45 minutes. The other assessments conducted over five days, will be conducted telephonically, we will be asking questions around [CHILD'S NAME]'s behaviour, the medical expenses around [CHILD'S NAME]'s autism, and your well-being. Each phone call will take between 30-45 minutes.

As I said earlier, all these assessments will be done keeping your convenience and availability in mind. You can take breaks during a telephonic assessment, whenever need be. However, when you schedule an appointment, please try to be available till the end of assessment. This is so that there can be some degree of consistency and a flow during the questionnaires.

Supplementary details:

1. If you agree to participate in the study, then I will first audio record your consent to participate. I will then ask you a few questions about [CHILD'S NAME]'s ASD symptoms, at the end of today's call. This will take about 20 minutes.
2. On the second day, I will contact you and would spend some time asking you about basic information like your education and employment and then will talk to you about [CHILD'S NAME] behaviour. This telephonic call would take between 1 hour 25 minutes to 1 hour 45 minutes.
3. On the third day, we will need you to come to Sangath Office. A cab will be sent by Sangath to pick you up and drop you safely to your home. Please note that the cab would be sanitized properly before picking you from your home to ensure your safety. Safety measures recommended by government of India are being followed by Sangath and its staff members to minimize the risk of COVID-19. The assessment room including the assessment toys would be sanitized before and after every use. During this visit, we would observe you and [CHILD'S NAME] interacting and playing with one another and will record video of this. Besides this, we will also play some games with your child and make another video of it. Like I said earlier, this visit would take about 45 minutes.
4. On the fourth day, I will spend some time asking questions about [CHILD'S NAME]'s behavior in detail and would ask few questions about you. This telephonic call would take about 30 minutes.
5. On the fifth day, I will ask you some questions about you and [CHILD'S NAME] again, including the kind of services you use for your child and the medical expenses around them. This telephonic call would take around 45 minutes.
6. On the sixth and final day, I will ask you a few questions about your perspective on Autism, your child's language skills and their general functioning and mood. This call is a bit longer and would take about 1 hour 30 minutes.

DISADVANTAGES, BENEFITS AND CONFIDENTIALITY

In terms of side effects, we have not found any unwanted effects from this treatment in our research conducted in Goa and Kolhapur. The only disadvantage of taking part is that participation in the trial will require a time commitment for the assessments and if you receive the treatment, then time commitment for the sessions and home practice. For attending these multiple assessments all participating families will receive a participation token.

There are many possible benefits of taking part. All families in this study (i.e. those in both the COMPASS treatment and non-COMPASS treatment groups), will have detailed assessments from skilled professionals at the beginning, the end of nine months and 15 months after the first assessments. You will receive a detailed report after initial assessment and then at the end of 15 months.

Supplementary details: The COMPASS research team will be in touch with all of you regularly through the study to find out how you are progressing and to hear your experiences and reactions. You will have an opportunity to evaluate the treatments that you receive and to talk about difficulties in your family. Most families find this useful. The treatments, including the PASS Plus treatment that you may get during the study may be helpful to you and your family. The main aim of this research study is to help in the development of Autism treatments throughout India and help other families like you.

Confidentiality is very important to us. All the information that we obtain during the course of this study and assessments will be kept strictly confidential and will be stored in a way that cannot be linked back to your child or to your family. This means that we will not share your or other study identities with anyone who is not a part of the COMPASS team, except in case of some special circumstances.

Supplementary details: You may tell us things during our assessments that would be useful to pass on to the other professionals treating your child; for instance, matters that might help in their treatment of your family. In this case, we will discuss this with you and get your consent before any information is passed on in this way. All the information collected about you and your child and the videos we make of you will be kept in a secure place and no one will be able to see this information except for COMPASS team. After the research period, you will continue with your regular treatment.

We will keep you updated as to the progress of our research during the study by a newsletter. The results of the study will begin to emerge in the six to twelve months after the study finishes. We will publish the main results. None of this reporting will include any information that could identify you as an individual or family.

The COMPASS project is a collaboration between the following institutes:

- Sangath,
- the University of Manchester (UK), and
- Harvard University (USA)

It is funded by the UK Medical Research Council, Wellcome Trust and UK Government and sponsored by University of Manchester.

The project is led by Professor Jonathan Green (University of Manchester, UK), with leadership in India from Dr. Gauri Divan (Sangath), Prof Monica Juneja (MAMC-LNH), Prof Sheffali Gulati (AIIMS), and Prof Vikram Patel (Harvard University).

If you have any further questions regarding the study, you can independently contact senior Sangath officials. If you prefer, I can also message you their details on this phone number

Prof Sheffali Gulati Chief, Child Neurology Division Department of Paediatrics All India Institute of Medical Sciences (AIIMS) Ansari Nagar, New Delhi – 110029 Contact No.: 011-26594679	Dr Gauri Divan Sangath Plot No. E5, Lane 1, 3rd & 4th Floor Western Marg, Saiyad-UI-Ajaib, Saket New Delhi 110030 Contact No.: 011-40046640	Dr Raj Vaidya IRB Chairperson, Sangath Bhatkar Waddo, Succor Goa 403501 Contact No.: 07887872345
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S. No.	Question	Response	Variable Name
19	<i>Are you willing to take part in the project?</i>	No.....0 Yes.....1	PARTICIPATE_PROJE CT