

## Participant Information Sheet for PASS Plus- Caregiver Copy (Delhi)



### Participant Information Sheet

#### About Sangath

Sangath is a reputed non-governmental organisation working for the physical and mental well-being of children and their families since 1996. We work in different parts of India and have offices in Goa, Delhi, Haryana, Madhya Pradesh and Telangana.

#### About NAMASTE

Sangath has started a community-based programme called NAMASTE which stands for Neurodevelopment and Autism in South Asia Treatment and Evidence. As a part of NAMASTE, we plan to identify children in the communities between the age group of 1 to 9 years who may be experiencing social, communication and similar difficulties. Following this, we would like to provide them with appropriate services.

Children experiencing social communication, thinking reasoning, behavioural and other difficulties may have problems related to understanding and interacting with their environment and communicating with others. They may be over or under-sensitive to things in their environment, such as sounds and light. We also know that all children are different and will behave and act in different ways.

In NAMASTE, we are working with the government, and aim to identify and provide services to these children in the communities by working with their parents or caregivers. At the end of NAMASTE, we will recommend similar programmes to the government for all children in the country.

#### Why are we contacting you?

On the basis of the Anganwadi workers' questions and observations, we believe that [CHILD'S NAME] may have some social communication and similar difficulties. Therefore, as a part of NAMASTE, we would like to provide you with some sessions, of an intervention called PASS Plus which stands for Parent-Mediated Autism Social Communication intervention for Non-specialists Plus. These sessions may be helpful for children between the age range of 1-9 years with these difficulties and their parents or caregivers. We believe these sessions would be helpful for you and your child as well. We will be providing you with all the information about these sessions that would help you decide whether you wish to participate in NAMASTE or not.

#### What will be the procedure of NAMASTE?

##### What will the sessions involve?

We have trained a select group of ASHAs in Delhi who would like to come to your home for these sessions. PASS Plus has two parts; the first part addresses the communication difficulties of children. The second part supports other difficulties that many children may have with their restlessness, their feeding and sleeping along with support for your own well-being.

In total, there are 13 visits which will be conducted over a period of 6-9 months. The initial visit will introduce you to the PASS Plus counsellor. After this each session involves a six-minute play period

between you and your child, which is recorded on a video. The ASHA will use clips from these play sessions to guide you to think of ways in which you can help your child to communicate better. Each session takes approximately 1 hour and is delivered every 15 days. To ensure that the intervention works, we recommend that the parent practice the skills they learn in the session for 30 minutes every day.

### **What will the assessments involve?**

To understand how this intervention has helped you and your child we would also like to conduct some assessments with [CHILD'S NAME] and you at your home and at Sangath office. These assessments will be done twice - before and after delivering the sessions. These assessments will help us understand whether you found this intervention useful and whether it is something we can recommend to the government to give to all children who need such support.

Additionally, since you did not know about the difficulties your child had until Anganwadi worker asked you the questions, we would like to refer you to Chacha Nehru Children's Hospital or IHBAS (Institute of Human Behaviour and Allied Sciences) which you can visit and discuss more about these difficulties.

### **What information will you collect about me?**

As part of the assessments, we will be collecting some identifying information like your and your children's name, address, date of birth, and contact numbers. Additionally, details about your education, occupation and family income will be collected. We will also ask questions about [CHILD'S NAME], concerning their development, behaviour, well-being, as well as your well-being. During the assessments, we would also like to understand the time and money that you are currently spending on [CHILD'S NAME]'s care. These assessments will take around 3 hours and will be done in the comfort of your home at a time convenient for you.

In addition to these assessments, we will also observe you and [CHILD'S NAME] interacting and playing with one another and will record a 13-minute video of this interaction at the Sangath office. We will be organising your transport to pick you from your home and drop you back safely, or you can come on your own and the amount which you spend on your travel, will be paid back to you by Sangath.

Additionally, our team would also reach out to you to talk to you about your experiences in NAMASTE.

### **Do I have to take part?**

Your participation in NAMASTE is entirely voluntary. If you wish to take part, you will be required to complete a consent form. Even if you decide to take part initially, you are free to withdraw from NAMASTE at any point, without giving any reason and any services you are receiving will not be impacted in any way.

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

Your participation will help your child receive the appropriate services that may be helpful for children who experience social, communication and similar difficulties. Additionally, we will be providing you with a token to thank you for your time and commitment. At the end of NAMASTE, if parents like you have found the program and interventions useful it will allow us to recommend the government to provide similar services to all children across the country, and your participation can play an important role in this initiative.

### **What are the possible disadvantages of taking part?**

We do not anticipate any unwanted effects or disadvantages of participation in NAMASTE except that it will require a time commitment for the assessments and sessions.

### **Will the outcomes of NAMASTE be published?**

The outcomes of NAMASTE programme will be published, and used in conferences and meetings. However, none of this reporting will include any information that could identify you or your child. The data collected from you, including direct quotes of your responses, may be included in a manner by which they cannot be connected to you.

### **Data protection & confidentiality**

The personal information we collect and use to conduct NAMASTE will be processed in accordance with national and international data protection guidelines.

We are collecting and storing this personal identifiable information in accordance with data protection law of your country which protects your rights.

#### **What are my rights in relation to the information that you collect about me?**

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including audio recordings.

#### **Will my participation in NAMASTE be confidential and my personal identifiable information be protected?**

In accordance with data protection law, Sangath is the Data Controller for this programme. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All programme staff are trained with this in mind, and your data will be looked after in the following way:

The NAMASTE team will store your identifying information (name and contact details) securely and separately from your programme data. Your data will be marked with an ID number and not your name. The key for linking your ID number to your identity will be accessible only to the programme team. Once all of the data has been analysed, we will destroy the key, anonymising your data. Your consent form (including your name and signature) will be retained separately for 5 years after the end of the programme in a locked filing cabinet on Sangath premises.

The NAMASTE Programme has collaborators in South Asia and the UK with whom we would like to share anonymised data. They will not be able to identify you as all personal information would be removed before sharing your data.

#### **Potential disclosures of your information**

If during our conversation you reveal any information which means you may be at risk of harming yourself or others, we will be required to break confidentiality in order to put you in touch with the correct support. This may involve informing you about appropriate services or calling emergency services. It may also involve informing your family members and friends.

Please also note that individuals from Sangath, the University of Manchester or regulatory authorities may need to look at the data collected for NAMASTE to make sure the programme is

being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the programme will have a strict duty of confidentiality to you as a participant.

#### **Who has reviewed NAMASTE?**

Sangath's Institutional Review Board, Health Ministry Screening Committee, and Indian Council of Medical Research have reviewed the NAMASTE programme. It has also been appropriately reviewed by the University of Manchester.

#### **Who is funding NAMASTE?**

The NAMASTE programme is being funded by the NIHR/UK-ID (National Institute for Health and Care Research / United Kingdom International Development).

#### **What if I have any questions or complaints?**

If you have any complaints or feedback regarding the discussion, you can share that either with me, or you can independently contact the senior Sangath official mentioned below, Monday to Friday between 10 AM- 4 PM.

<b>Dr. Gauri Divan</b>  Sangath   Principal Investigator   NAMASTE  <b>Delhi Office:</b> NAMASTE site office, 31 Dayanand Block, Madhubhan Road, Shakarpur, Delhi-110092  Telephone: +91 8882701524	<b>Raj Vaidya</b>  Sangath   Chairperson   Institutional Review Board  <b>Goa Office: 451 Bhatkar Waddo, Succor, Bardez, Goa- 403501</b>  Telephone: +91 9881207761
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## Participant Information Sheet for PASS Plus- Caregiver Copy (Goa)



### Participant Information Sheet (PIS)

#### About Sangath

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#### What will be the procedure of NAMASTE?

##### What will the sessions involve?

We have trained a select group of Anganwadi workers in Goa who would like to come to your home for these sessions. PASS Plus has two parts; the first part addresses the communication difficulties of children. The second part supports other difficulties that many children may have with their restlessness, their feeding and sleeping along with support for your own well-being.

In total, there are 13 visits which will be conducted over a period of 6-9 months. The initial visit will introduce you to the PASS Plus counsellor. After this each session involves a six-minute play period

between you and your child, which is recorded on a video. The Anganwadi workers will use clips from these play sessions to guide you to think of ways in which you can help your child to communicate better. Each session takes approximately 1 hour and is delivered every 15 days. To ensure that the intervention works, we recommend that the parent practice the skills they learn in the session for 30 minutes every day.

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Additionally, since you did not know about the difficulties your child had until Anganwadi workers asked you the questions, we would like to refer you to DEIC (District Early Intervention Center), North Goa, District Hospital and Pediatrics Neuro-Rehab Center, Goa Medical College which you can visit and discuss more about these difficulties.

### **What information will you collect about me?**

As part of the assessments, we will be collecting some identifying information like your and your children's name, address, date of birth, and contact numbers. Additionally, details about your education, occupation and family income will be collected. We will also ask questions about [CHILD'S NAME], concerning their development, behaviour, well-being, as well as your well-being. During the assessments, we would also like to understand the time and money that you are currently spending on [CHILD'S NAME]'s care. These assessments will take around 3 hours and will be done in the comfort of your home at a time convenient for you.

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

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in auditing and monitoring the programme will have a strict duty of confidentiality to you as a participant.

#### **Who has reviewed NAMASTE?**

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## Participant Information Sheet (PIS) for WHO CST– Caregiver Copy (Delhi)



### Participant Information Sheet

#### About Sangath

Sangath is a reputed non-governmental organisation working for the physical and mental well-being of children and their families since 1996. We work in different parts of India and have offices in Goa, Delhi, Haryana, Madhya Pradesh and Telangana.

#### About NAMASTE

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In NAMASTE, we are working with the government, and aim to identify and provide services to these children in the communities by working with their parents or caregivers. At the end of NAMASTE, we will recommend similar programmes to the government for all children in the country.

#### Why are we contacting you?

On the basis of Anganwadi workers' questions and observations, we believe that [CHILD'S NAME] may have some social, communication and similar difficulties. Therefore, as a part of NAMASTE, we would like to provide you with some sessions of an intervention, called WHO CST which stands for World Health Organisation Caregiver Skills Training. These sessions may be helpful for children between the age range of 1-9 years with these difficulties and their parents or caregivers. We believe these sessions would be helpful for you and your child as well. We will be providing you with all the information about these sessions that would help you decide whether you wish to participate in NAMASTE or not.

#### What will be the procedure of NAMASTE?

##### What will the sessions involve?

We have trained a select group of ASHAs in Delhi to deliver the WHO CST intervention. This intervention has 9 group sessions and three home visits, which are delivered every week over a period of 3 months. Each group session will last 2-3 hours, including a break. For the group sessions you will be required to travel to Sangath office. The 3 home visits will be scheduled at the beginning, middle and end of the training. These sessions will help with your child's engagement in play, communication, and support managing their daily living activities. It also aims to promote positive behaviours in your child.

##### What will the assessments involve?

To understand how this intervention has helped you and your child we would also like to conduct some assessments with [CHILD'S NAME] and you at your home and at Sangath office. These

assessments will be done twice - before and after delivering the sessions. These assessments will help us understand whether you found this intervention useful and whether it is something we can recommend to the government to give to all children who need such support.

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#### **What information will you collect about me?**

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#### **Do I have to take part?**

Your participation in NAMASTE is entirely voluntary. If you wish to take part, you will be required to complete a consent form. Even if you decide to take part initially, you are free to withdraw from NAMASTE at any point, without giving any reason and any services you are receiving will not be impacted in any way.

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

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Because you will need to come to the centre for the group sessions, the amount which you spend on your travel, will be paid back to you by Sangath.

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We do not anticipate any unwanted effects or disadvantages of participation in NAMASTE except that it will require a time commitment for the assessments and sessions.

#### **Will the outcomes of NAMASTE be published?**

The outcomes of NAMASTE programme will be published, and used in conferences and meetings. However, none of this reporting will include any information that could identify you or your child. The data collected from you, including direct quotes of your responses, may be included in a manner by which they cannot be connected to you.

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## Participant Information Sheet (PIS) for WHO CST – Caregiver Copy (Goa)



### Participant Information Sheet (PIS)

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You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including audio recordings.

#### **Will my participation in NAMASTE be confidential and my personal identifiable information be protected?**

In accordance with data protection law, Sangath is the Data Controller for this programme. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All programme staff are trained with this in mind, and your data will be looked after in the following way:

The NAMASTE team will store your identifying information (name and contact details) securely and separately from your programme data. Your data will be marked with an ID number and not your name. The key for linking your ID number to your identity will be accessible only to the programme team. Once all of the data has been analysed, we will destroy the key, anonymising your data. Your consent form (including your name and signature) will be retained separately for 5 years after the end of the programme in a locked filing cabinet on Sangath premises.

The NAMASTE Programme has collaborators in South Asia and the UK with whom we would like to share anonymised data. They will not be able to identify you as all personal information would be removed before sharing your data.

#### **Potential disclosures of your information**

If during our conversation you reveal any information which means you may be at risk of harming yourself or others, we will be required to break confidentiality in order to put you in touch with the correct support. This may involve informing you about appropriate services or calling emergency services. It may also involve informing your family members and friends.

Please also note that individuals from Sangath, the University of Manchester or regulatory authorities may need to look at the data collected for NAMASTE to make sure the programme is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the programme will have a strict duty of confidentiality to you as a participant.

### **Who has reviewed NAMASTE?**

Sangath's Institutional Review Board, Health Ministry Screening Committee, and Indian Council of Medical Research have reviewed the NAMASTE programme. It has also been appropriately reviewed by the University of Manchester.

### Who is funding NAMASTE?

The NAMASTE programme is being funded by the NIHR/UK-ID (National Institute for Health and Care Research / United Kingdom International Development).

### What if I have any questions or complaints?

If you have any complaints or feedback regarding the discussion, you can share that either with me, or you can independently contact the senior Sangath official mentioned below, Monday to Friday between 10 AM – 4 PM.

<b>Dr. Gauri Divan</b> Sangath   Principal Investigator   NAMASTE <b>Goa office:</b> NAMASTE Site office, 451 Bhatkar Waddo, Succor, Bardez, Goa – 403501 Telephone: +91 8882701524	<b>Raj Vaidya</b> Sangath   Chairperson   Institutional Review Board <b>Goa Office:</b> 451 Bhatkar Waddo, Succor, Bardez, Goa – 403501 Telephone: +919881207761
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## Participant Information Sheet (PIS) for PASS Plus – Caregiver Copy (Nepal)



### Global Health Research Unit on Neurodevelopment and Autism in South Asia Treatment and Evidence – NAMASTE

#### Participant Information Sheet (PIS) - Script

Namaste! I am [ASSESSOR's NAME] from AutismCare Nepal Society (ACNS).

#### About AutismCare Nepal Society

The ACNS is an active autism organization in Nepal led by parents of individuals with autism. It has been actively engaged in assessment and diagnostic services, intervention programs, autism awareness, capacity building of individuals with autism, their parents and caregivers and advocating for the rights of individuals with autism.

#### About NAMASTE

AutismCare Nepal Society has started a community-based programme called NAMASTE which stands for Neurodevelopment and Autism in South Asia Treatment and Evidence. As a part of NAMASTE, we plan to identify children in Godawari Municipality between the age group of 1.5 to 9 years who may be experiencing social, communication and similar difficulties. Following this, we would like to provide them with appropriate services.

Children experiencing social, communication and similar difficulties may have challenges related to thinking, remembering, interacting with the world, communicating with others, and sharing their interests with others. They may be over or under-sensitive to things in their environment, such as sounds, light or texture. In NAMASTE, we are working with the government, and aim to identify and provide services to these children in the communities by working with their parents or caregivers. At the end of NAMASTE, we will recommend similar programmes to the government for all children in the country.

#### Why are we contacting you?

On the basis of the assessments done with you previously by Female Community Health Volunteers (FCHV), we believe that [CHILD'S NAME] could possibly be experiencing some social, communication and similar difficulties. Therefore, as a part of NAMASTE, we would like to provide you with some sessions, called PASS Plus which stands for Parent-Mediated Intervention for Autism Spectrum Disorders in South Asia. These sessions have been found to be helpful for children between the age range of 2-9 years with such difficulties and their parents or caregivers. We believe these sessions would be helpful for you and your child as well. We will be providing you with all the information about these sessions that would help you decide whether you wish to participate in NAMASTE or not.

#### What will be the procedure of NAMASTE?

##### What will the sessions involve?

For delivering PASS Plus, we have trained a select group of individuals in Lalitpur who would like to come to your home for these sessions. PASS Plus has two parts; the first part addresses

the communication difficulties of children. The second part supports other difficulties that many children have with their restlessness, their feeding and sleeping along with support for your own well-being.

In total, there will be 13 sessions which will be delivered over a period of 6-9 months. Each session involves a six-minute play session between you and your child, which is recorded on a video. The PASS Plus trainer will use clips from these play sessions to guide you to think of ways in which you can help your child to communicate better. Each session will be approximately 1 hour. Additionally, to support your child it is important that you practice the skills you learn in the session for 30 minutes every day with your child.

#### **What will the assessments involve?**

In addition to the sessions, we will also do some assessments with [CHILD'S NAME] and you at your home and at the ACNS Office. These assessments will be done twice - before and after delivering the sessions. These assessments will help us understand the impact of PASS Plus on you and your child.

#### **What information will you collect about me?**

As part of the assessments, we will be collecting some identifying information like your and your children's name, address, date of birth, and contact numbers. Additionally, details about your education, occupation and family income will be collected. We will also ask questions about [CHILD'S NAME], concerning their development, behaviour, well-being, as well as your well-being. During the assessments, we will enquire about the cost and provision of care for your child. These assessments will take around 3 hours and will be done in the comfort of your home or at the ACNS at a time convenient for you.

In addition to these assessments, we will also observe you and [CHILD'S NAME] interacting and playing with one another and will record a 13-minute video. To facilitate the assessments, ACNS will reimburse the amount that you spend on your travel.

Additionally, our team would also reach out to you to talk to you about your experiences in NAMASTE.

#### **Do I have to take part?**

Your participation in NAMASTE is entirely voluntary. If you wish to take part, you will be required to complete a consent form. Even if you decide to take part initially, you are free to withdraw from NAMASTE at any point, without giving any reason and being impacted in any way.

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

Your participation will help your child receive the appropriate services that have been proven to be helpful for children who experience social, communication and similar difficulties. Additionally, as a thank you for your time and commitment, we will provide you an incentive of Rs. 2000 at the end of the sessions and a toy kit for your child. At the end of NAMASTE, we will recommend the government to provide similar services to all children across the country and your participation can play an important role in this initiative.

#### **What are the possible disadvantages of taking part?**

We do not anticipate any unwanted effects or disadvantages of participation in NAMASTE except that it will require a time commitment for the assessments and sessions.

#### **Will the outcomes of NAMASTE be published?**

The outcomes of NAMASTE programme will be published. None of this reporting will include any information that could identify you or your child. The data collected from you, including direct quotes of your responses, may be included in anonymised manner in publications and conference presentations.

#### **Data protection & confidentiality**

The personal information we collect and use to conduct NAMASTE will be processed in accordance with national and international data protection guidelines. We are collecting and storing this personal identifiable information in accordance with data protection law of Nepal which protects your rights.

#### **What are my rights in relation to the information that you collect about me?**

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including audio recordings.

#### **Will my participation in NAMASTE be confidential and my personal identifiable information be protected?**

In accordance with data protection law, ACNS is the Data Controller for this programme. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All programme staff are trained with this in mind, and your data will be looked after in the following way:

The NAMASTE team will store your identifying information (name and contact details) securely and separately from your programme data. Your data will be marked with an ID number and not your name. The key for linking your ID number to your identity will be accessible only to the programme team. Once all of the data has been analysed, we will destroy the key, anonymising your data. Your consent form (including your name and signature) will be retained separately for 5 years after the end of the programme in a locked filing cabinet on ACNS premises.

The NAMASTE Programme has collaborators in South Asia and the UK with whom we would like to share anonymised data. They will not be able to identify you as all personal information would be removed before sharing your data.

#### **Potential disclosures of your information**

If during our conversation you reveal any information which means you may be at risk of harming yourself or others, we will be required to break confidentiality in order to put you in touch with the correct support. This may involve informing you about appropriate services or calling emergency services. It may also involve informing your family members and friends. Please also note that individuals from ACNS, the University of Manchester or regulatory authorities may need to look at the data collected for NAMASTE to make sure the programme is being carried out as planned. This may involve looking at identifiable data. All individuals

involved in auditing and monitoring the programme will have a strict duty of confidentiality to you as a participant.

**Who has reviewed NAMASTE?**

NAMASTE has been reviewed by the Nepal Health Research Council (NHRC), the Social Welfare Council, and Godawari Municipality. It has also been proportionately reviewed by the University of Manchester.

**Who is funding NAMASTE?**

The NAMASTE programme is being funded by the NIHR-UK (National Institute for Health and Care Research).

**What if I have any questions or complaints?**

If you have any complaints or feedback regarding the discussion, you can share that either with me, or you can independently contact the senior ACNS official mentioned below, Monday to Friday between 10 am to 5 pm.

**If you have any further queries please contact the senior ACNS officials mentioned below:**

<b>Dr Sunita Maleku Amatya</b> ACNS   Principal Investigator   NAMASTE <b>Address: Harisiddhi, Lalitpur</b> Telephone: 015912549	<b>Dr. Rena Shrestha</b> ACNS   Co-Principal Investigator   NAMASTE <b>Address: Harisiddhi, Lalitpur</b> Telephone: 015912549
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If you have queries, concerns, or information regarding the ethics of this research, please contact Ethical Review Board at the NHRC.

Address: Ram Shah Path, Kathmandu, Nepal  
Telephone: 01-4254220, 01-4254220  
Email: [nhrc@nhrc.gov.np](mailto:nhrc@nhrc.gov.np)

## Participant Information Sheet (PIS) for WHO CST – Caregiver Copy (Nepal)



### Global Health Research Unit on Neurodevelopment and Autism in South Asia Treatment and Evidence – NAMASTE

#### Participant Information Sheet (PIS)

Namaste! I am [ASSESSOR NAME] from AutismCare Nepal Society (ACNS).

#### About AutismCare Nepal Society

The ACNS is an active autism organization in Nepal led by parents of individuals with autism. It has been actively engaged in assessment and diagnostic services, intervention programs, autism awareness, capacity building of individuals with autism, their parents and caregivers and advocating for the rights of individuals with autism.

#### About NAMASTE

AutismCare Nepal Society has started a community-based programme called NAMASTE which stands for Neurodevelopment and Autism in South Asia Treatment and Evidence. As a part of NAMASTE, we plan to identify children in Godawari Municipality between the age group of 1.5 to 9 years who may be experiencing social, communication and similar difficulties. Following this, we would like to provide them with appropriate services.

Children experiencing social, communication and similar difficulties may have challenges related to thinking, remembering, interacting with the world, communicating with others, and sharing their interests with others. They may be over or under-sensitive to things in their environment, such as sounds, light or texture. In NAMASTE, we are working with the government, and aim to identify and provide services to these children in the communities by working with their parents or caregivers. At the end of NAMASTE, we will recommend similar programmes to the government for all children in the country.

#### Why are we contacting you?

On the basis of the assessments done with you previously by Female Community Health Volunteers (FCHV), we believe that [CHILD'S NAME] could possibly be experiencing some social, communication and similar difficulties. Therefore, as a part of NAMASTE, we would like to provide you with some sessions, called WHO CST which stands for World Health Organisation Caregiver Skills Training. These sessions have been found to be helpful for children between the age range of 2-9 years with such difficulties and their parents or caregivers. We believe these sessions would be helpful for you and your child as well. We will be providing you with all the information about these sessions that would help you decide whether you wish to participate in NAMASTE or not.

#### What will be the procedure of NAMASTE?

##### What will the sessions involve?

For delivering WHO CST, we have trained a select group of FCHVs of Godawari Municipality who would like to come to your home for these sessions. WHO CST includes 9 group sessions which will be delivered every week over a period of 3 months. Each group session will last 2-3 hours,

including a break. Additionally, 3 home visits will be conducted by these trained FCHVs for individual sessions, which will be scheduled at the beginning, middle and end of the training. These sessions will help with your child's engagement in play, communication, and support managing their daily living activities. It also aims to promote positive behaviours in your child, as well as managing their challenging behaviours and supporting your own well-being as a parent. For the group sessions you will be required to travel to a Primary health centre/Health Post.

#### **What will the assessments involve?**

In addition to the sessions, we will also do some assessments with [CHILD'S NAME] and you at your home or at the ACNS office. These assessments will be done twice - before and after delivering the sessions. These assessments will help us understand the impact of WHO CST on you and your child.

#### **What information will you collect about me?**

As part of the assessments, we will be collecting some identifying information like your and your children's name, address, date of birth, and contact numbers. Additionally, details about your education, occupation and family income will be collected. We will also ask questions about [CHILD'S NAME], concerning their development, behaviour, well-being, as well as your well-being. During the assessments, we will enquire about the cost and provision of care for your child. These assessments will take around 3 hours and will be done at ACNS at a time convenient for you.

To facilitate the assessments, ACNS will reimburse the amount which you spend on your travel.

Additionally, our team would also reach out to you to talk to you about your experiences in NAMASTE.

#### **Do I have to take part?**

Your participation in NAMASTE is entirely voluntary. If you wish to take part, you will be required to complete a consent form. Even if you decide to take part initially, you are free to withdraw from NAMASTE at any point, without giving any reason and being impacted in any way.

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

Your participation will help your child receive the appropriate services that have been proven to be helpful for children who experience social, communication and similar difficulties. Additionally, as a thank you for your time and commitment, we will provide you with an incentive of Rs. 500 per session and a toy kit for your child after completing the nine sessions and home visits. At the end of NAMASTE, we will recommend the government to provide similar services to all children across the country and your participation can play an important role in this initiative.

#### **What are the possible disadvantages of taking part?**

We do not anticipate any unwanted effects or disadvantages of participation in NAMASTE except that it will require a time commitment for the assessments and sessions.

#### **Will the outcomes of NAMASTE be published?**

The outcomes of NAMASTE programme will be published. None of this reporting will include any information that could identify you or your child. The data collected from you, including direct quotes of your responses, may be included in anonymised manner in publications and conference presentations.

### **Data protection & confidentiality**

The personal information we collect and use to conduct NAMASTE will be processed in accordance with national and international data protection guidelines.

We are collecting and storing this personal identifiable information in accordance with data protection law of Nepal which protects your rights.

#### **What are my rights in relation to the information that you collect about me?**

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including audio recordings.

#### **Will my participation in NAMASTE be confidential and my personal identifiable information be protected?**

In accordance with data protection law, ACNS is the Data Controller for this programme. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All programme staff are trained with this in mind, and your data will be looked after in the following way:

The NAMASTE team will store your identifying information (name and contact details) securely and separately from your programme data. Your data will be marked with an ID number and not your name. The key for linking your ID number to your identity will be accessible only to the programme team. Once all of the data has been analysed, we will destroy the key, anonymizing your data. Your consent form (including your name and signature) will be retained separately for 5 years after the end of the programme in a locked filing cabinet on ACNS premises.

The NAMASTE Programme has collaborators in South Asia and the UK with whom we would like to share anonymised data. They will not be able to identify you as all personal information would be removed before sharing your data.

#### **Potential disclosures of your information**

If during our conversation you reveal any information which means you may be at risk of harming yourself or others, we will be required to break confidentiality in order to put you in touch with the correct support. This may involve informing you about appropriate services or calling emergency services. It may also involve informing your family members and friends. Please also note that individuals from ACNS, the University of Manchester or regulatory authorities may need to look at the data collected for NAMASTE to make sure the programme is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the programme will have a strict duty of confidentiality to you as a participant.

### **Who has reviewed NAMASTE?**

NAMASTE has been reviewed by the Nepal Health Research Council (NHRC), the Social Welfare Council, and Godawari Municipality. It has also been proportionately reviewed by the University of Manchester.

**Who is funding NAMASTE?**

The NAMASTE programme is being funded by the NIHR (National Institute for Health and Care Research).

**What if I have any questions or complaints?**

If you have any complaints or feedback regarding the discussion, you can share that either with me, or you can independently contact the senior ACNS official mentioned below, Monday to Friday between 10 am to 5 pm.

<b>Dr Sunita Maleku Amatya</b>  ACNS   Principal Investigator   NAMASTE <b>Address: Harisiddhi, Lalitpur</b> Telephone: 015912549	<b>Dr. Rena Shrestha</b>  ACNS   Co-Principal Investigator   NAMASTE <b>Address: Harisiddhi, Lalitpur</b> Telephone: 015912549
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If you have queries, concerns, or information regarding the ethics of this research, please contact Ethical Review Board at the NHRC.

Address: Ram Shah Path, Kathmandu, Nepal  
Telephone: 01-4254220, 01-4254220  
Email: [nhrc@nhrc.gov.np](mailto:nhrc@nhrc.gov.np)





## INFORMATION SHEET / CONSENT FORM

### ETHICS REVIEW COMMITTEE

### SRI LANKA COLLEGE OF PAEDIATRICIANS

We, Dr. Asiri Hewamalage, Consultant Community Physician attached to the Family Health Bureau, Ministry of Health, and, Dr. Dilini Vipulaguna, Consultant Community Paediatrician attached to Colombo North Teaching Hospital, Ayati Center, Ragama and Wathupitiwala Base Hospital of the Ministry of Health, would like to invite you to take part in the research study titled “A program to implement and evaluate an integrated identification and support pathway for 36- month-old children at high likelihood of autism spectrum disorder and their parents delivered by non-specialist health workers in the Colombo district of Sri Lanka.” This is carried out as part of a research study conducted by NAMASTE (Neurodevelopment and AutisM in South ASia - Treatment and Evidence) which is a research collaboration between the Sri Lanka College of Paediatricians and the University of Manchester, United Kingdom. The study is submitted for review by the Ethics Review Committee of the Sri Lanka College of Paediatricians and once approved, for proportionate review by the University of Manchester.

#### **1. Purpose of the study**

Children experiencing social, communication and similar difficulties may have challenges related to thinking, remembering, interacting with the world, communicating with others, and sharing their interests with others. They may be over or under-sensitive to things in their environment, such as sounds, light or texture. NAMASTE which stands for Neurodevelopment and AutisM in South ASia - Treatment and Evidence is an implementation study, which plans to take proven interventions to identify and support children with social communication disorders such as autism and see how these interventions can be applied practically in Sri Lanka. In NAMASTE, we are working to train Public Health Midwives to identify and provide services to these children in the communities by working with their parents or caregivers.

Identifying children with a high likelihood of developing autism at a young age allows them to receive the support they need early. Research has shown that Social Attention and Communication Surveillance (SACS) tools are effective at assessing and determining if children show a high likelihood of autism. As a part of NAMASTE, we plan to identify children in the communities between the age group of 31 to 41 months who may be experiencing social, communication and

similar difficulties using the SACS-PR screening tool (Social Attention and Communication Surveillance-Preschool).

The purpose of this study is to observe and find out what makes the NAMASTE project work successful and what barriers are faced when implementing the identification and support service provision work. We will modify the process of delivering such support services based on what we find in the Colombo district, and we will recommend similar programmes to the government for all children in the country.

## **2. Voluntary participation**

Your participation in NAMASTE is entirely voluntary. If you wish to take part, you will be required to complete a consent form. Even if you decide to take part initially, you are free to withdraw from NAMASTE at any point, without giving any reason and being impacted in any way.

## **3. Duration, procedures of the study and participant's responsibilities**

A Public Health Midwife (PHM), who has been trained in SACS, will play with your child for 7 – 10 minutes in your presence to observe and assess your child at the MOH clinic. They will also speak to the primary caregiver to find out some basic information about the child's family and circumstances including birth and medical history, socio demographic and economic history and other relevant details from the medical records.

After SACS is conducted alongside the CHDR, if it is found that your child is experiencing some social, communication and similar difficulties, the next steps include the following:

1. A referral to the Child Development Intervention Center (CDIC)
2. If you are willing to take part in NAMASTE, you will be offered one of the following programs for parents called PASS Plus (Parent-Mediated Intervention for Autism Spectrum Disorders in South Asia Plus) or WHO CST (World Health Organisation Caregiver Skills Training).

During these two programmes, non-specialist healthcare workers train parents to support them to better communicate with the children and to help parents manage behavioral and sensory issues, sensitivities, and sleep management issues often seen in children with a high likelihood of ASD.

You will have the option of deciding whether you want to participate at that time and we will provide you all the information that would help you decide whether you wish to participate in NAMASTE or not.

### **PASS Plus**

A NAMASTE facilitator trained by an international team in Pass Plus would visit your home for these sessions. PASS Plus has two parts; the first part addresses communication difficulties children face. The second part supports other difficulties that many children have with restlessness, feeding and sleeping, along with support for your own well-being.

In total, 13 sessions will be delivered over 6-9 months. Each session involves a six-minute play session between you and your child, which is recorded on a video. The NAMASTE facilitators will use clips from these play sessions to guide you to think of ways in which you can help your child to communicate better. Each session will be approximately 1 to 2 hours. Additionally, to support your child it is important that you practice the skills you learn in the session for 30 minutes every day with your child. The videos will not be used for any other purpose except with your specific permission, will be stored safely at the Ministry of Health and will be destroyed at the end of the Project.

### **WHO-CST**

A NAMASTE facilitator trained by an international team will conduct the training sessions for WHO CST. WHO CST includes 9 group sessions which will be delivered every week over a period of 3 months. Each group session will last about 2 hours, including a break. Additionally, the Facilitator will conduct 3 home visits for individual sessions, which will be scheduled at the beginning, middle and end of the training.

These sessions will help with your child's engagement in play, communication, and support managing their daily living activities. It also aims to promote positive behaviour in your child, as well as to manage their challenging behaviour and support your own well-being as a parent. For the group sessions you will be required to travel to the Medical Office of Health (MOH) office in your area or to the NAMASTE office.

In addition to the above sessions, we will also do some assessments with your child and you at your home and at an MOH Clinic / NAMASTE office. These assessments will be done twice - before and after delivering the intervention sessions. They will help us understand the impact of this training on you and your child. Our team would also reach out to talk to you about your experiences in NAMASTE.

The study will begin in November 2024.

### **4.Potential benefits**

If your child has a high likelihood of autism or social communication difficulties, your child will benefit from being identified early and being directed to the appropriate services. At the end of NAMASTE, with the data you provide, we will recommend to the government to

provide similar services to all children across the country.

If your child does not have any likelihood of autism or social communication disorders, there may not be any direct, immediate benefits for you, but your participation will help benefit children with autism by helping to identify them early. Your participation will also inform a large database that will help researchers learn more about autism and social communication disorders in children.

## **5.Risks, hazards and discomforts**

We do not anticipate any unwanted effects or disadvantages of participation in NAMASTE except that it will require a time commitment for the assessments and sessions. If you wish to stop at any point, you may do so and your data will be removed from the system if you wish at that point.

## **6.Reimbursements**

The administration of SACS will be an addition to the routine checkups done by the public health midwife to assess your child's development, and therefore there will be no reimbursements for your participation.

If your child is identified as having a high likelihood of autism, and you decide to move forward with the NAMASTE study, you would get a travel reimbursement of Rs.1000/- for all instances you are required to travel to during the interventions and assessments.

## **7.Confidentiality**

Confidentiality of all records is guaranteed and no information by which you can be identified will be released or published.

The personal information we collect and use to conduct NAMASTE will be processed in accordance with national and international data protection guidelines. NAMASTE will be the data controller. All programme staff are trained with this in mind, and your data will be looked after in the following way:

The NAMASTE team will store your identifying information (name and contact details) securely and separately from your programme data. Your data will be marked with an ID number and not your name. The key for linking your ID number to your identity will be accessible only to the senior members of the programme team. Once all the data has been analyzed, we will destroy the key, anonymising your data.

Your consent form (including your name and signature) will be retained separately for 1 year after the end of the programme in a locked filing cabinet on NAMASTE Sri Lanka premises.

Your identifiable data will not leave the country. The NAMASTE Programme has collaborators in South Asia and the UK with whom we would like to share anonymised data. They will not be able

to identify you as all personal information would be removed before sharing your data.

The outcomes of the NAMASTE programme will be published. None of this reporting will include any information that could identify you or your child. The data collected from you, including direct quotes of your responses, may be included in an anonymised manner in publications and conference presentations.

If during our conversation you reveal any information which means you may be at risk of harming yourself or others, we will be required to break confidentiality in order to put you in touch with the correct support. This may involve informing you about appropriate services or calling emergency services. It may also involve informing a family member or a friend.

All individuals involved in auditing and monitoring the programme will have a strict duty of confidentiality to you as a participant.

## **8.Termination of study participation**

You may withdraw your consent to participate in this study at any time, with no penalty or effect on medical care or loss of benefits.

Please notify the investigator as soon as you decide to withdraw your consent.

## **9.Clarifications**

If you have any complaints or feedback regarding the NAMASTE programme, you can share that with our team members, our principal investigators, or you can independently contact the Ethics Review Committee, Sri Lanka College of Paediatricians using the contact details mentioned below, during Monday to Friday between 9:00 AM - 4:00 PM.

**Dr. Dilini Vipulaguna**

Principal Investigator | NAMASTE

Telephone: 0772007952

Email: [dilvip777@yahoo.com](mailto:dilvip777@yahoo.com)

**Dr. Asiri Hewamalage**

Principal Investigator | NAMASTE

Telephone: 0777513650

Email: [asiri11@yahoo.com](mailto:asiri11@yahoo.com)

**Ethics Review Committee**

Sri Lanka College of Paediatricians

Address: 44/1, Gnanartha Pradeepa Mawatha, Colombo 08, Sri Lanka

Telephone: 0112683178

Email: [paedsslcp@gmail.com](mailto:paedsslcp@gmail.com)

If you need mental health support, you can call or email

National Institute of Mental Health - National Mental Health Helpline - 1926

Call: 0112-578234 to 7 Email: [info@nimh.health.gov.lk](mailto:info@nimh.health.gov.lk)