Telerehabilitation Program: An innovative and sustainable Early Intervention service for children with Autism Spectrum Disorders

01/12/2020

INFORMED CONSENT FORM

1. Study Information

Protocol Title:

Telerehabilitation Program: An innovative and sustainable Early Intervention service for children with Autism Spectrum Disorders

Principal Investigator & Contact Details:

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Study Sponsor:

MOH Health Services Development Program (HSDP)

2. Purpose of the Research Study

Your child is invited to participate in a research study. It is important to us that you first take time to read through and understand the information provided in this sheet. Nevertheless, before your child takes part in this research study, the study will be explained to you and you will be given the chance to ask questions. After you are properly satisfied that you understand this study, and that you allow your child to take part in the study, you must sign this informed consent form. You will be given a copy of this consent form to take home with you.

You are invited because your child has been screened by the developmental pediatrician and found to be at risk for autism spectrum disorders (ASD).

This study is carried out to find out if early intervention through home-based video conferencing (also referred to as telerehab program) can be used to improve the results of your child's Mullen's Scales of Early Learning (MSEL) which is also used to assess a child's development in standard clinic-based early intervention.

This study will recruit approximately 200 subjects from the National University Hospital over a period of 3 years. About 200 subjects will be involved in this study.

3. What procedures will be followed in this study

If your child take part in this study, your child will be randomized to receive either the standard care program (clinic-based) or telerehabilitation program (mixture of clinic-based and video conferencing-based early interventions). Randomization means assigning your child to one of 2 groups by chance, like tossing a coin or rolling dice.

If your child takes part in this study, and is assigned to the standard care program intervention group, you (or an identified caregiver for your child) will be asked to bring them to Child Development Unit (CDU) for weekly clinic-based intervention with a therapist and follow up with a home program at home. You will also need to bring them to CDU for midterm and final reviews.

If your child takes part in this study, and is assigned to the telerehab program Intervention group, you (or an identified caregiver for your child) will be asked to have video conferences

with the therapist at home, where you will be coached and guided on how to provide early intervention for your child. You (or an identified caregiver for your child) will need to spend at least 2 hours a week providing the intervention to your child, as learned from video conferencing sessions with the therapist. You will also need to bring them to CDU for midterm and final reviews.

Please see table at the end for a detailed week-by-week schedule.

If you are randomized to the Standard Care Program group, your participation in the study will last up to 48 weeks (or up to 60 weeks if sessions require rescheduling). Your child will undergo:

1) 1 parent education workshop conducted in a group
2) 16 clinic-based intervention sessions
3) Total of 7 Review/ follow up sessions at the clinic
    a. Pediatrician: Visit 6, Visit 8 and Visit 10
    b. Therapist: Visit 6, Visit 7, Visit 8 and Visit 9
4) 2 semi-structured interviews of about 30-45 minutes at the beginning and end of the program (if selected and interested). These semi-structured interviews will be conducted with a trained research associate, on a one to one basis. They will be audio recorded for further inquiry after the end of the program. These interviews will be centered around your experience, as a parent being part of the program. Your written consent will be sought before any form of interview will take place. Your participation is completely optional and refusing to participate will not have an impact on the care your child will receive in the program.

If you are randomized to the Telerehab Program Group, your participation in the study will last up to 48 weeks (or up to 60 weeks if sessions require rescheduling). Your child will undergo:

1) 1 parent education workshop conducted in a group
2) 2 clinic-based intervention
3) 16 video conference-based intervention sessions,
4) Total of 7 review/follow up sessions at the clinic
    a. Pediatrician: Visit 6, Visit 8 and Visit 10
    b. Therapist: Visit 6, Visit 7, Visit 8 and Visit 9
5) 2 semi-structured interviews of about 30-45 minutes at the beginning and end of the program (if selected and interested). These semi-structured interviews will be conducted with a trained research associate, on a one to one basis. They will be audio recorded for further inquiry after the end of the program. These interviews will be centered around your experience, as a parent being part of the program. Your written consent will be sought before any form of interview will take place. Your participation is completely optional and refusing to participate will not have an impact on the care your child will receive in the program.

You will be encouraged to work on the goals set for at least 2 hours weekly with your child.

If you agree to take part in this study, the following will be the schedule for the program for your child.

Screening:
Visit 1: Your pediatrician will assess your child to screen to know if your child is at risk for ASD. If your child is at risk your pediatrician will offer you to consider being part of the proposed research study and explain the details of the Telerehab study. If you consent, an appointment will be arranged to assess your child further to confirm that your child meets the inclusionary

criteria for the study. If you don't want to participate in the study your pediatrician will refer you to standard care as required.

If your child meets the criteria for the study, you will be randomly assigned to either the telerehab program intervention group or standard care program intervention group.

Baseline and eligibility Assessments (Visits 2 and 4) required for the study will be completed within the first 8 weeks of your enrolment for the study. Some parents will be invited to participate in a semi-structured interview (lasting between 30-45 minutes) to understand their perceptions and expectations of the different programs they are randomized to, with a member of the study team at a time and place of their convenience. If your child has an MSEL score of less than 35 or does not meet the cut off score for autism on the ADOS (Autism Diagnostic Observation Schedule), your child will no longer be eligible for the program and will not continue in the trial. These tests will also be offered to you in the event you choose not to consent to this trial.

Standard care intervention program:
If your child is assigned to be in the standard care intervention group, you (or an identified caregiver for your child) will attend a parent workshop to introduce you to the program and explain your role in the program. If you are unable to attend the workshop at the stipulated time, the team will email you the training slides. Your therapist will develop an individualized intervention plan (IIP) with you to set goals and identify effective strategies to develop your child's learning. You (or an identified caregiver for your child) will attend 16 intervention sessions across approximately 48 weeks (or up to 60 weeks if sessions require rescheduling) in the clinic wherein effective strategies will be demonstrated in the context of play activities with your child. Your therapist will work with you to develop and follow a home program.

Telerehab intervention program:
If your child is assigned to be in the Telerehab intervention group, you (or an identified caregiver for your child) will attend a parent workshop to introduce you to the program and explain your role in the program. If you are unable to attend the workshop at the stipulated time, the team will email you the training slides. You (or an identified caregiver for your child) will attend 2 intervention sessions in the clinic and 16 intervention sessions across 48 weeks (or up to 60 weeks if sessions require rescheduling) through MOHH developed video conferencing portal. Therapists will coach you (or an identified caregiver for your child) during your interactions with your child and develop your confidence and competence in using early intervention strategies to achieve the goals set in your child's plan.

Reviews:
Your pediatrician will review your child's progress and address your concerns periodically (Visit 6, Visit 8 and Visit 10). The final review and concluding session for this study will be on visit 10. However, your attending pediatrician will continue to see your child and make appropriate referrals as required for your child subsequent to the final review in Visit 10.

In addition to following up with you during each intervention session, your therapist will review your child's progress and address your concerns at Visit 6, Visit 8 and Visit 9. The final review by therapist will be in Visit 9. At the final review, parents who were previously interviewed at the beginning of the intervention will participate in a follow up interview to understand their experiences of care provided in both programs, which will be used to evaluate and adjust future interventions. All 4 Therapist assessment/review sessions (Visit 6, Visit 7, Visit 8 and Visit 9 - clinic-based for standard care arm; clinic and video conference-based for telerehab arm) will be video-recorded and used for data analysis. It will not be used for any publications.

Transfer to Early Intervention Programs:
The CDU provides interim therapy for children pending enrolment into an EIPIC (or private early intervention service). In the first 10 weeks upon enrolment into an EIPIC, no

intervention is provided for your child as assessments are being completed. In this transition period, your child will continue to receive to receive intervention at the CDU per study protocol. Similarly, children who has been accepted by a private intervention service may continue to receive intervention per the study protocol until intervention at the private service begins.

Children also continue to remain as CDU patients under the care of their doctors until age 7, regardless of whether they have been enrolled to an EIPIC or private service. As such, study subjects that have been transferred to an EIPIC will still be assessed per protocol at three therapist review time points (Visits 6, 8 and 9). As far as possible, these assessments will be scheduled to coincide with their doctor's follow-up at the CDU as part of standard care.

The study does not involve the collection of any biological materials.

This study will not result in any anticipated/ unanticipated incidental findings. For example, "Incidental findings" are findings that have potential health or reproductive importance to research participants like you/your child and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study. Hence, there will be no re-identification for re-contacting as it will not be relevant.

Individually-identifiable information obtained from participants will not be used for future biomedical research.

4. Your Responsibilities in This Study

If you agree to participate in this study, you should follow the advice given to you by the study team. You (or an identified caregiver for your child) should be prepared to participate in the study and undergo all the procedures that are outlined above.

5. What Is Not Standard Care or is Experimental in This Study

The study is being conducted because telerehabilitation for behavioral intervention and parent coaching is not yet proven to be a standard intervention in children with ASD. We hope that your participation will help us to determine whether telerehabilitation is as good as the existing standard clinic-based early intervention.

Use of randomization (intervention selection by chance) is only done for research studies.

Autism Diagnostic Observation Schedule (ADOS-2), Joint Engagement Rating Inventory (JERI), Vineland Adaptive Behaviour Scales (VABS-III), Parenting stress index (PSI-SF) and Family Early Intervention Quality of Life (FEIQoL), are only being performed for the purposes of the research and are not part of standard care.

6. Possible Risks and Side Effects

Telerehabilitation and parent-mediated behavioral intervention have no known side effects.

Telerehabilitation in terms of being a modality for early intervention is still being tested; therefore, your child may experience other side effects that have not yet been reported. However, you will be kept informed of any significant new findings that may relate to your willingness to allow your child to continue taking part in this study.

If your child experiences any new symptoms, you should contact your pediatrician or the Principal Investigator as soon as possible.

7. Possible Benefits from Participating in the Study

If your child participates in this study, you may expect to benefit from the program in the following ways:

- More in-depth assessment and understanding of your child's function
- More intervention sessions at a higher frequency
- Improvement in parental interaction with child
- Improvement in cognitive and adaptive behavior in child

Nevertheless, there is no assurance your child will definitely benefit from participation in this study.

However, your participation in this study may add to the medical knowledge about the use of telerehabilitation for early intervention. The findings of the study may help future patients with similar condition in terms of cost saving without compromising the efficacy. The table below illustrates the similarities and differences in the assessment and treatment plans for children participate if they were in the study versus if they were under standard clinical care.

Assessment and treatment in the study	**Assessment and treatment in standard clinical care**
• Mullens Scales of Early Learning (MSEL) • Autism Diagnostic Observation Schedule (ADOS-2) • Vineland Adaptive Behavior Scales (VABS-III) • Parent Stress Index-Short Form (PSI/SF) • Joint Engagement Inventory Rating (JERI) • Family Early Intervention Quality of Life (FEIQoL)	• Mullens Scales of Early Learning (MSEL)
• 2 pediatrician reviews	• 3 pediatrician reviews
Standard arm: • 1 initial assessment • 16 clinic intervention sessions • 2 review sessions • 1 final clinic assessment Telerehab arm: • 1 initial clinic and video conference (VC) assessment • 2 clinic and 16 VC intervention sessions • 2 review sessions • 1 final clinic and VC assessment	• 1 initial assessment • 1 review session • 8 clinic intervention sessions
• Demographic survey • Cost survey • Parental satisfaction survey	• NIL

8. Alternatives to Participation

If you choose not to take part in this study, your child will receive standard care for their condition. In our institution, this would be weekly clinic-based intervention (what the standard care group receives in the proposed research study).

The benefits may be:

- Improvement in parental interaction with child
- Improvement in cognitive and adaptive behavior

There are no known risks associated with standard care/clinic-based behavioral intervention.

9. Costs & Payments if Participating in the Study

For Singaporean or PR registered as subsidized patients:

If you are a Singaporean or PR eligible for subsidized health care costs and taking part in this study, your doctor will initiate EIPIC application with your consent to align with the early intervention service pathway in Singapore.

You will have to pay for the same cost as you would in standard clinical care which would be up to $1000 for the program. The costs involved are same as the cost that you will have to pay as per standard clinical care (i.e. even if you do not participate in the study, the costs involved are the same and there are no additional costs incurred for participation in this study).

A breakdown of what you are paying for is shown in the table below:

Standard care arm	Telerehab arm
4 pediatrician visits	4 pediatrician visits
1 parent education workshop	1 parent education workshop
	2 clinic-based intervention sessions
16 clinic intervention sessions	16 VC intervention sessions
1 midpoint IIP review session with therapist	1 midpoint IIP review session with therapist

The following will be provided/performed at no charge to you:

- **For Standard arm only:** 1 initial assessment session (Visit 4), 2 clinic review sessions (Visits 6 and 8) and 1 final assessment (Visit 9)
- **For Telerehab arm only:** 1 initial clinic assessment session (Visit 4), 1 initial VC assessment session, 2 clinic review sessions (Visit 6 and 8), 1 final clinic assessment session (Visit 9) and 1 final VC assessment session
- **For both Standard and Telerehab arms:**
    - 1 midpoint paediatrician review (Visit 6)
    - 1 final paediatrician review (Visit 10)
    - Study-related evaluations at baseline and endpoint:
        - Autism Diagnostic Observation Schedule (ADOS-2)
        - Vineland Adaptive Behavior Scales (VABS-III)
        - Parent Stress Index-Short Form (PSI/SF)
        - Family Early Intervention Quality of Life (FEIQoL)
        - Joint Engagement Inventory Rating (JERI)

You will also be reimbursed for your time if you take part in the semi-structured interview at the beginning and end of the program (if selected and interested) as follows:

- If you complete the entire interview, you will be paid $10.
- If you do not complete the entire interview for any reason, you will still be paid $10.

10. Voluntary Participation

Your participation in this study is voluntary. You may stop participating in this study at any time. Your decision not to take part in this study or to stop your participation will not affect your medical care or any benefits to which you are entitled. If you decide to stop taking part in this study, you should tell the Principal Investigator.

If you withdraw from the study, you will be required to inform the Principal Investigator in writing.

However, the data that have been collected until the time of your withdrawal will be kept and analyzed. The reason is to enable a complete and comprehensive evaluation of the study.

Your doctor, the Investigator and/or the sponsor of this study may stop your participation in the study at any time

- If they decide that it is in your best interests.
- They may also do this if you do not follow instructions required to complete the study adequately.
- If you have other medical problems or side effects, the doctor and/or nurse will decide if your child may continue in the research study.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (*or your legally acceptable representative, if relevant*) will be informed in a timely manner by the Principal Investigator or his/her representative.

11. Compensation for Injury

If you follow the directions of the doctors in charge of this study and your child is physically injured due to the trial substance or procedure given under the plan for this study, the National University Hospital will pay the medical expenses for the treatment of that injury.

Payment for management of the normally expected consequences of your child's treatment will not be provided by the National University Hospital.

National University Hospital without legal commitment will compensate you for the injuries arising from your child's participation in the study without you having to prove National University Hospital is at fault. There are however conditions and limitations to the extent of compensation provided. You may wish to discuss this with your Principal Investigator

By signing this consent form, you will not waive any of your or your child's legal rights or release the parties involved in this study from liability for negligence.

12. Confidentiality of Study and Medical Records

Your participation in this study will involve the collection of "Personal Data". "Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organization has or likely to have access. This includes medical conditions, medications, investigations and treatment history.

Information and “Personal Data” collected for this study will be kept confidential. Your child’s records, to the extent of the applicable laws and regulations, will not be made publicly available for a period up to years as per institutional policy.

However, the Sponsoring company National University Hospital, Regulatory Agencies and NHG Domain Specific Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you (*or your legally acceptable representative, if relevant*) are authorizing (i) the collection, access to, use and storage of your “Personal Data”, and (ii) the disclosure to authorized service providers and relevant third parties.

Data collected and entered into the Case Report Forms are the property of National University Hospital. In the event of any publication regarding this study, your identity will remain confidential.

Research arising in the future, based on your “Personal Data”, will be subject to review by the relevant institutional review board.

By participating in this research study, you are confirming that you have read, understood and consent to the Personal Data Protection Notification available at *http://www.nuhs.edu.sg/personal-data-protection/nuhsnuh-data-protection-policy.html*

13 Who To Contact if You Have Questions

If you have questions about this research study, you may contact the Principal Investigator,
Dr. Isaac Sia
Senior Principal Speech Therapist
Dept. of Rehabilitation
National University Hospital
Tel: 6779 5555 (O)
E-mail: isaac_sia@nuhs.edu.sg

In case of any injuries during the course of this study, you may contact the Principal Investigator,
Dr. Isaac Sia
Senior Principal Speech Therapist
Dept. of Rehabilitation
National University Hospital
Tel: 6779 5555 (O)
E-mail: isaac_sia@nuhs.edu.sg

The study has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval.

If you want an independent opinion to discuss problems and questions, obtain information and offer inputs on your rights as a research subject, you may contact the NHG Domain Specific Review Board Secretariat at 6471-3266. You can also find more information about participating in clinical research, the NHG Domain Specific Review Board and its review processes at www.research.nhg.com.sg.

If you have any complaints or feedback about this research study, you may contact the Principal Investigator or the NHG Domain Specific Review Board Secretariat.

CONSENT FORM

Protocol Title:

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Principal Investigator & Contact Details:

Dr. Isaac Sia
Senior Principal Speech Therapist
Dept. of Rehabilitation
National University Hospital
Tel: 6779 5555
E-mail: isaac_sia@nuhs.edu.sg

I voluntarily consent for my child _____(Name) to take part in this research study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to my satisfaction. I have also been informed and understood the alternative treatments or procedures available and their possible benefits and risks.
By participating in this research study, I confirm that I have read, understood and consent to the National University Hospital Personal Data Protection Notification.

Consent for participation in semi-structured interview

□ Yes, I would like to be contacted to take part in the 2 semi-structured interviews to be conducted at the beginning and end of the study via:

□ Phone_____

□ Email_____

□ No, I do not want to be contacted to take part in the 2 semi-structured interviews to be conducted at the beginning and end of the study.

Consent for use of health status information after discontinue participation

□ No, I do not allow information about my child's health status and medical condition obtained from the study assessments and reviews conducted by NUH to be used for the purposes of this study after I withdraw from the study.

□ Yes, I agree to allow relevant information about my child's health status and medical condition obtained from the assessment and reviews conducted by NUH to be used for the purposes of this study, even if I withdraw from the study.

_____	_____	_____
Name of Parent / legally acceptable representative	Signature	Date

Translator Information
The study has been explained to the Parent / legally acceptable representative in

_____ by _____.

Witness Statement
I, the undersigned, certify that:

- I am 21 years of age or older
- To the best of my knowledge, the participant/ the participant's legally acceptable representative signing this informed consent form has the study fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant/ the participant's legally acceptable representative giving the consent.
- I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

_____	_____	_____
Name of Witness	Signature	Date

1. In accordance with Section 6(d) of the Human Biomedical Research Act and Regulation 25 of the Human Biomedical Research Regulations 2017, appropriate consent must be obtained in the presence of a prescribed witness who is 21 years of age or older, and has mental capacity. The witness must be present during the entire informed consent discussion, and must not be the same person taking the appropriate consent. The witness may be a member of the team carrying out the research.
2. However, if the participant/ the participant's legally acceptable representative is unable to read, and/ or sign and date on the consent form, an impartial witness should be present instead. The impartial witness should not be a member of the study team.

Investigator Statement
I, the undersigned, certify that I explained the study to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of his / her participation in the study.

_____	_____	_____
Name of Investigator / Person administering consent	Signature	Date

Study Schedule

ASSESSMENT PHASE (STANDARD CARE AND TELEREHAB GROUPS)

Activity\ Visit no.	Visit 0	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
Meet Pediatrician Procedures: - Screening for ASD (DSM-5) Total Time: 30 Minutes						
Pediatrician Visit Procedures: - Initiate consent for study - Refer for ADOS if consented Total Time: 30 Minutes						
Therapist Assessment Procedures: - Parental Stress Index PSI-SF - ADOS - VABS - MSEL Total time: 4 Hours						
Pediatrician Visit Procedures: - Confirm enrolment into the trial Total Time: 30 Minutes						
Therapist Assessment Procedures: - Foundational Skills Curriculum assessment - Parent interview on routines Program Evaluation indicators:						

- Joint Engagement Rating Scale (JERI) - Family Early Intervention Quality of Life Survey (FEIQol) - Demographic survey - Cost Survey Total Time: 90 Minutes						
Video Conferencing Observation (FSC, JERI) ***for Telerehab group*** Total Time: 30 Minutes						
Parent Education Workshop Total Time: 90 minutes						

LEGEND

STANDARD CARE	
TELEREHAB	

INTERVENTION PHASE (STANDARD CARE)

Activity\Visit no.	1st and 2nd Intervention block			Visit 6	Break	Visit 7	3rd Intervention block		Visit 8	Break	Visit 9	Visit 10
Clinic-based intervention (In clinic) Total Time: 60 Minutes per session	**6 sessions**		**4 sessions**				**6 sessions**					
Parent-delivered therapy (Home-based) - *Break*												
Pediatrician visit and therapist review (In Clinic) Procedures - Foundational Skills curriculum developmental profile - Joint engagement rating inventory - Cost Survey Total Time: 90 Minutes												
Therapist review (In clinic) Total Time: 60 Minutes												
Final review Procedures: - Foundational Skills Curriculum assessment - Parent interview on routines Program Evaluation indicators: - MSEL & PSI - VABS-III - Joint Engagement Rating Scale (JERI) - Family Early Intervention Quality of Life Survey - Demographic survey - Cost Survey - Parental satisfaction survey Total Time: 4.5 Hours												
Final Pediatrician visit												

INTERVENTION PHASE (TELEREHAB GROUP)

Activity\Visit no.	1st and 2 Intervention block				Visit 6	Break	Visit 7	3rd Intervention block					Visit 8	4th Intervention block		Visit 9	Visit 10
Clinic-based intervention (In clinic) Total Time: 60 Minutes per session	2 sessions																
Weekly Video-conference based intervention (Over video conference) Total Time: 30 Minutes per session		**4 sessions**		**4 sessions**					**1 sessions**		**1 sessions**			**6 sessions**			
Parent-delivered therapy (Home-based)																	
Pediatrician visit and therapist review (In Clinic) Procedures - Foundational Skills curriculum developmental profile - Joint engagement rating inventory - Cost Survey Total Time: 90 Minutes																	
Therapist review (In clinic) Total Time: 30 Minutes																	
Therapist review (Over video conference) Total Time: 30 Minutes																	
Final review Procedures: - Foundational Skills Curriculum assessment - Parent interview on routines Program Evaluation indicators: - MSEL & PSI - VABS-III - Joint Engagement Rating Scale (JERI) - Family Early Intervention Quality of Life Survey - Demographic survey - Cost Survey																	

- Parental satisfaction survey **Video Conferencing Observation (FSC, JERI)** Total Time: 5 Hours																	
Final Pediatrician visit																	