Effectiveness of Play Therapy Programme in Promoting Early Child Development of under-5 Children visiting Tertiary Care Hospital in Rural Settings: Study Protocol of A Randomized Controlled Trial

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Research Article

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Abstract

Background: Early childhood demands for good care, conscious and mindful parenting. The survival through childhood depends on adults who consciously handle the hunger, sickness and socioemotional needs of children. Good care also includes practices of keeping children safe from harm, giving them love, attention, and providing the opportunities to learn. Hospitalization is obviously quite stressful for the child of any age. For years, it has been known that play is an vital element for promoting the normal growth and development of children.

Methods: This Randomized Controlled Trial will be implemented through the hospital settings of Acharya Vinoba Bhave Rural Hospital, Wardha and the enrolled children will be followed at home visits at scheduled intervals over a period of one year from enrolment. Children in intervention arm will receive customized Play Therapy sessions during hospital stay and at scheduled home visits. Assessments will be done for child development parameters through a set of tools and difference in development scores will be compared between intervention and control groups.

Discussion: Intervention group is expected to show significant improvements in child development scores compared to control group. The customized play therapy programme will be adapted to different paediatric inpatient settings and attempts will be made to develop a dedicated and safe Play Therapy kit for hospitalized children.

Trial registration: Clinical Trial Registry of India Reg. No: CTRI/2022/03/041355 Dated 24/03/2022 http://ctri.nic.in/Clinicaltrials/regtrial.php?modid=1&compid=19&EncHid=94157.99481

Administrative Information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

<table>
<thead>
<tr>
<th>Title (1)</th>
<th>Effectiveness of Play Therapy Programme in Promoting Early Child Development of under-5 Children visiting Tertiary Care Hospital in Rural Settings: Study Protocol of A Randomized Controlled Trial.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial registration (2a and 2b).</td>
<td>Clinical Trial Registry of India Reg. No: CTRI/2022/03/041355 Dated 24/03/2022 <a href="http://ctri.nic.in/Clinicaltrials/regtrial.php?modid=1&amp;compid=19&amp;EncHid=94157.99481">http://ctri.nic.in/Clinicaltrials/regtrial.php?modid=1&amp;compid=19&amp;EncHid=94157.99481</a></td>
</tr>
<tr>
<td>Protocol version (3)</td>
<td>V3_16/04/2022</td>
</tr>
<tr>
<td>Funding (4)</td>
<td>No Funding Support has been received for this study.</td>
</tr>
<tr>
<td>Author details (5a)</td>
<td>Dr. Manoj Patil* Research Scholar, School of Epidemiology and Public Health Datta Meghe institute of Medical Sciences, Sawangi (M), Wardha. Mob. No. 9029167076; Email: <a href="mailto:drmanojpatil1979@gmail.com">drmanojpatil1979@gmail.com</a> Dr. Abhay Gaidhane Director, School of Epidemiology and Public Health, Professor Community Medicine, Jawaharlal Nehru Medical College Datta Meghe institute of Medical Sciences, Sawangi (M), Wardha. Mobile No. 9765404075; Email: <a href="mailto:abhaygaidhane@gmail.com">abhaygaidhane@gmail.com</a> Dr. Quazi Syed Zahiruddin Director, Research &amp; Development Professor Community Medicine, Jawaharlal Nehru Medical College Datta Meghe institute of Medical Sciences, Sawangi (M), Wardha. Mobile No. 9765404065; Email: <a href="mailto:zahirquazi@gmail.com">zahirquazi@gmail.com</a></td>
</tr>
<tr>
<td>Name and contact information for the trial sponsor (5b)</td>
<td>Dr. Manoj Patil* Research Scholar, School of Epidemiology and Public Health Datta Meghe institute of Medical Sciences, Sawangi (M), Wardha. Mob. No. 9029167076; Email: <a href="mailto:drmanojpatil1979@gmail.com">drmanojpatil1979@gmail.com</a></td>
</tr>
<tr>
<td>Role of sponsor (5c)</td>
<td>Study design; collection, management, analysis, and interpretation of data; writing of the report; the decision to submit the report for publication.</td>
</tr>
</tbody>
</table>

Introduction
Period of early childhood from birth to 6 years of life is a very crucial period. Early childhood demands for good care, conscious and mindful parenting. The survival through childhood depends on adults who consciously handle the hunger, sickness and socioemotional needs of children. Good care also includes practices of keeping children safe from harm, giving them love, attention, and providing the opportunities to learn. Right from birth, children get bonded to special adults and try to learn the important basic skills by copying them. The learnings from these relationships serve as a base for getting the children prepared for life skills(1). It was found that, globally over 200 million children fail to reach their developmental potential in the first 5 years due to poverty, poor health services, poor nutrition and lack of appropriate psychosocial care (2).

Early childhood is a period of rapid development. Play and recreation is naturally an essential part of childhood and is vital to normal development. Through various types of play and recreational activities, children start to learn, try to express themselves, cope with anxiety, develop their skills and master the experiences. Play can also help to facilitate in learning how to adapt and tolerate the healthcare and hospitalization experience. In a sense, play and recreation mimics a therapy of giving children the opportunity for exploring, processing and expressing their healthcare experiences in a safe and protected environment (3).

Hospitalization is obviously quite stressful for the child of any age. Even, the older children need their parents during the period of a serious illness, and cannot tolerate their absence even for a short period. They want their parents to be there when they need them and wish to be loved and missed. Play is very essential part of a child's life and is a key aspect in fostering child's growth and development. Toys serve as the "tools" of play and help to create a more "natural" environment for a child. Selection and use of appropriate toys can help to reduce the traumatic effects of hospitalization and healthcare experiences. It also aids in the speedy recovery from the illness. Play can be made an integral part of the hospitalized child's care and treatment plan. Play helps to support the child by offering the opportunity for creative expression, coping and diversion. There are a number of studies conducted in various hospitals which provide the evidence that a supervised play program can be an effective way of providing warm and child-friendly atmosphere which can be helpful to promote the child's growth and development. In bigger hospitals and healthcare facilities, a childcare specialist can coordinate the play therapy program provided that a proper play zone, suitable materials and playmates are available. It is evident that, for any child, play is an effective way of learning and play materials, toys and equipment serve as the 'learning tools'(4).

For years, it has been known that play is an vital element for promoting the normal growth and development of children. In many Western countries, play therapy is used to alleviate the stress experienced by paediatric patients and their families during hospitalization(5). Play constitutes an important parameter of a child's normal development. Also, play serves as an important means of communication in childhood. Although, child's ability to play may be influenced by the child's physical or mental disease. Play can prove to be of special therapeutic value for sick children. It can help to enhance their physical and emotional well-being. It can help to explore the issues related to the child's experiences during hospitalization, can help to reduce the influence of negative feelings during hospitalization. Play when blended with the treatment plan, can be quite helpful in promoting the child growth, development and life skills.

Healthcare professionals can incorporate play as a part of treatment and care strategy for hospitalized children. The role and value of play is greater in case of children with life-threatening disease, disability and vulnerable situations. Play therapy during hospitalization can help to reduce the child's ability to play which was discontinued due to hospital admission. It can help to manage child's confidence that he can continue his/her normal life even inside the hospital. With this understanding of play, healthcare professionals can explore the effects of hospitalization and disease on children in addition to enhancing their emotional development. Though the play, children can learn to gain control in different situations. Play can help to change the hospitalization experience into a positive experience. Appropriate activities need to be chosen which will help the children grow, encouraging the caregivers to bring the child's favourite toys to the hospital and get actively involved in the entire procedure. Play facilitates to promote healing, improves coping potential, helps in tackling fears and expressing feelings of the children. Hospitals should take every effort to use play activities for reducing the stress and converting the negative aspects of the hospital experiences into a positive experience (6).

Rationale:

As per Census 2011, India, had a population of 121.1 Cr, among which 16.45 Cr children were in the age group 0-6 years and 37.24 Cr belonged to the age group 0-14 years which constitute around 13.59% and 30.76% of the total population respectively. 74% of the children aged 0-6 years reside in rural areas where as the rural population constitutes 69% of the total population of India(7).

In India, rate of hospitalization of children aged 1-6 years is almost doubled due to common ailments like fever and diarrhoea whereas hospitalization due to non-communicable diseases and injuries has also increased to a great extent over last decade(8). The average length of hospital stay ranges between 6-15 days depending on the type of ailments(9).

The role and value of play is greater in case of children with life-threatening disease, disability and vulnerable situations. A number of diseases and conditions require hospitalization of children for weeks to a month. Play therapy during hospitalization can help to restore the child's ability to play which was discontinued due to hospital admission. It can help to manage child's confidence that he can continue his/her normal life even inside the hospital. With this understanding of play, healthcare professionals can explore the effects of hospitalization and disease on children in addition to enhancing their emotional development.

Acharya Vinoba Bhave Rural Hospital (AVBRH) in Wardha is a tertiary care hospital of Datta Meghe Institute of Medical Sciences and catering to the healthcare needs of rural population from 5 districts namely Wardha, Nagpur, Chandrapur, Yavatmal and Amaravati. AVBRH is a 1500 bedded healthcare facility with specialized Pediatric Department, dedicated Neonatal Intensive Care Unit and Child Development Centre.
This study will be focussed on the development of a locally adapted Play Therapy Programme for the hospitalized children, sensitization of parents regarding child development and developing a safe, harmless and sterilizable Play Kit for hospitalized children to minimize the risk of transmission of infection from child to child or healthcare staff.

**Objectives (7)**

**Primary Objectives:**

1. To develop a structured 'Play Therapy Programme' for the parents and children under-5 years visiting the paediatric inpatient facility of AVBRH.
2. To enhance knowledge and skills of parents on early child development and improve parent-child interactions.
3. To improve the Motor, Language, Cognitive and Social-emotional development parameters of under-5 children visiting AVBRH, through play therapy and follow-up at scheduled home visits.

**Secondary Objectives:**

1. To develop a dedicated Play Therapy Kit specially designed for hospitalized children, with provision of follow-up and assessment mechanisms through online mode.

**Trial design (8)**

This will be a Randomized Controlled Trial. The Study participants will be randomized into intervention and control groups with 1:1 ratio using Block Randomization.

**Methods: Participants, Interventions And Outcomes**

**Study setting (9)**

This study will be conducted at Department of Pediatrics in Acharya Vinoba Bhave Rural Hospital, Wardha and nearby villages within 25 KM radius. Wardha is the smallest district in Maharashtra State of India.

**Eligibility criteria (10)**

**Inclusion Criteria:**

1. Children admitted to Pediatric Ward of AVBRH aged 6 months to 4 years.
2. Children from villages within 25 Km periphery of AVBRH.
3. Parents consenting for Participation of Child in Play Therapy Programme.

**Exclusion Criteria:**

1. Seriously sick, Moribund children with life threatening conditions.

**Who will take informed consent? (26a)**

The investigator will take the written informed consent from the parents of the hospitalized children.

**Additional consent provisions for collection and use of participant data and biological specimens (26b)**

NA

**Interventions**

**Explanation for the choice of comparators (6b)**

All participants consenting for the participation in study will be assigned the Unique ID. Using blocked randomization process(10) with age groups as Blocking variable, participants will be allocated either to intervention or control groups. Age groups will be –

1. 6 months to 24 months,
2. 25 months to 48 months.

All children hospitalized in AVBRH, scheduled to have a stay of minimum 3 days in hospital and their parents signing the informed consent will be enrolled in the study.
Intervention description (11a)

A play therapy manual will be developed with the activities specified as per the following domains of child development-

1. Physical development: It focuses on increasing the skill and performance of the body. It includes control and coordination between nervous system, maturing brain and growing bones and muscles.

2. Psychosocial development and communication skills: It focuses on incorporating physical and mental health that takes into account knowledge, skills and capacity. It also refers to social connections and support. Psychosocial development influences an individual in the value systems, beliefs and norms of a particular society or culture. Language and communication skills help the child to express herself through words, gestures, facial expressions as well as her ability to understand others. Good communication and language skills can help in fostering achievements at school and beyond.

3. Emotional development: It incorporates learning what emotions and feelings are, understanding why and how they happen, recognition of one's own feelings and that of others and the ability to manage those feelings and emotions.

4. Cognitive development: This refers to the development of thinking and reasoning. Children learn to think in concrete ways such as they learn to combine, separate and sort. It includes abstract thinking and reasoning one's own thoughts and principles.

Duration of the Interventions:

1. All the children who fall in the age range of 6 months to four years old will receive intervention (along with their parents) every day during their hospital stay for one hour to 2 hours.

2. The children will receive fortnightly follow-up sessions through home visits (or through Social Media Group meetings if needed) till 12 months from enrolment in the programme.

3. Activities described in the Play Therapy Manual will be followed for the follow-up sessions.

Criteria for Group Sessions at hospital:

Hands of parents and their children will be washed before the activities start to avoid infectious contamination. Children will be divided into two groups as below-

1. 6 months to 30 months old

2. Above 30 months old

A particular criterion will be used for each activity. Each activity will be divided into four parts. The first part will state the purpose of activity such as how will an activity benefit a child and what are the aims and objectives of an activity. The second part state about the materials that are to be used for the activity. The third part will show the age of children who can participate in that activity. The fourth part will give the instructions as to how a particular activity should be performed.

The intervention delivery details are as below-
<table>
<thead>
<tr>
<th>Activity</th>
<th>Implementation Schedule</th>
<th>Delivery Point</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Interaction with Parents and Sensitization about Programme</td>
<td>Day-1 of hospitalization</td>
<td>Pediatrics IPD</td>
<td>Parents of Children aged 0-4 years visiting/hospitalized in AVBRH will be contacted and sensitized.</td>
</tr>
<tr>
<td>Enrolment of Parents in Programme and randomization</td>
<td>Day-1 hospitalization</td>
<td>Pediatrics IPD</td>
<td>Urban and Rural Parents will be enrolled and registered in Programme e-learning platform/ What's app Group.</td>
</tr>
<tr>
<td>1st Session: Introduction to Early Child Development, Importance and it's implications. Diet, Nutrition and Health care of Child.</td>
<td>2nd day of Hospitalization</td>
<td>Designated Play Area in AVBRH</td>
<td>This will be an 1 hour session and relevant brochures/ Documents/reading materials will be shared.</td>
</tr>
<tr>
<td>2nd Session: Cognitive and Language Development and ways to promote it.</td>
<td>2nd day of Hospitalization</td>
<td>Designated Play Area in AVBRH</td>
<td>This will be an 1 hour session and relevant Documents/reading materials will be shared.</td>
</tr>
<tr>
<td>3rd Session: Motor Development and activities to promote it.</td>
<td>3rd day of hospitalization</td>
<td>Designated Play Area in AVBRH</td>
<td>This will be an 1 hour session and relevant Documents/reading materials will be shared.</td>
</tr>
<tr>
<td>4th Session: Socioemotional Development and activities to promote it.</td>
<td>3rd day of hospitalization</td>
<td>Designated Play Area in AVBRH</td>
<td>This will be an 1 hour session and relevant Documents/reading materials will be shared.</td>
</tr>
<tr>
<td>5th Session: Promotion of Home Environment and Parent Child Interactions</td>
<td>15th Day after Hospital Discharge</td>
<td>Through Online Mode- What's app Video Call/ Google Classroom. Home visit will be scheduled as needed.</td>
<td>This will be an 45 min. session and relevant Documents/reading materials / videos will be shared through What's app.</td>
</tr>
<tr>
<td>Fortnightly Follow-up sessions till 1 year of child enrolment.</td>
<td>After 1 month of enrolment till 1 year</td>
<td>Through Online Mode-What's app Video Call/ Google Classroom. Home visit will be scheduled as needed.</td>
<td>This will be an 45 min. online session and relevant Documents/reading materials will be shared.</td>
</tr>
<tr>
<td>Assessment of Age appropriate Developmental Milestones.</td>
<td>At 1 year of enrolment.</td>
<td>This will be done in ECD Setting of AVBRH or at Home visit to the child's family.</td>
<td>Age appropriate Assessment Tools will be used. Reports will be shared with parents and follow-up instructions and meeting schedules.</td>
</tr>
</tbody>
</table>

**Assessment Schedules and Details:**

<table>
<thead>
<tr>
<th>Domain</th>
<th>Tools</th>
<th>Assessment time point</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Within 15 days of Enrolment</td>
<td>Outcome Point 1 after 1 year from date of enrolment</td>
</tr>
<tr>
<td>Socio-demographic Profile</td>
<td>Household Questionnaire</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Motor (Gross and Fine)</td>
<td>DMC-II</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Language</td>
<td>DMC-II</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Socioemotional development</td>
<td>PSED</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Mother child interaction</td>
<td>OMCI</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Home Environment</td>
<td>Home Scale Coding</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Parenting Knowledge and Skills</td>
<td>PP Quiz</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

1. **Variables:**

For all children, changes will be observed in the-
1. Physical Development (Using Developmental Milestones Checklist-II)
   a. Improvement in Fine Motor scores
   b. Improvement in Gross Motor scores

2. Cognitive Development Scores (Using Developmental Milestones Checklist-II)

3. Language Development Scores (Using Developmental Milestones Checklist-II)

4. Socioemotional Development Scores (Using Profile of Socio-emotional Development)

5. Home Environment (Using HOME Inventory Assessment)

6. Parent-child Interactions (Using Observation of Mother Child Interaction Tool)

Criteria for discontinuing or modifying allocated interventions (11b)

If Children and parents insist on discontinuation of Play Therapy, the sessions will be discontinued for those children.

Strategies to improve adherence to interventions (11c)

After discharge from the hospital, all children will receive follow-up home visits and Play therapy sessions at home visits by trained Research assistants.

Relevant concomitant care permitted or prohibited during the trial (11d)

Relevant medical and nursing care will be provided during hospital stay. Referral services will be provided if needed, during follow-up at home visits.

Provisions for post-trial care (30)

NA

Outcomes (12)

Primary Outcomes:

1. Improvements in mean scores of Child developmental parameters for Cognitive, Physical, Socioemotional and Language development by 0.5 SD by the end of 1 year of Intervention.

2. Improvements in knowledge and skills of parents regarding Early Child Development.

Secondary Outcomes:

1. A dedicated Play Therapy Kit specially designed for hospitalized children.

Participant timeline (13)

<table>
<thead>
<tr>
<th>Activities</th>
<th>Timepoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation of Play Therapy Manual</td>
<td>Q1</td>
</tr>
<tr>
<td>Enrolment of Patients, Baseline assessments and Intervention Delivery</td>
<td></td>
</tr>
<tr>
<td>Data collection during Home visit sessions</td>
<td></td>
</tr>
<tr>
<td>Endline Assessments</td>
<td></td>
</tr>
<tr>
<td>Data analysis</td>
<td></td>
</tr>
<tr>
<td>Reporting of results and Final Report Writing</td>
<td></td>
</tr>
<tr>
<td>Publication/Dissemination</td>
<td></td>
</tr>
</tbody>
</table>
Sample size (14)

The expected differences in child development outcomes between the intervention and control groups is 0.5 SD, considering a drop-out rate of 10%, Level of significance = 5%, Power = 80%.

Formula of calculating sample size for two independent means is:

\[ n = \frac{(Z_\alpha + Z_\beta)^2 \times \delta^2}{d^2} \]

where

- \( n \) = sample size required in each group,
- \( d \) = Expected clinically significant difference = 0.5
- \( \delta \) = standard deviation = 1.69 (As per Previous Study)
- \( Z_\alpha \): taking the level of significance as 5%, it comes to be 1.96
- \( Z_\beta \): taking the power of 80%, it comes to be 0.84

Based on the above formula, the calculations are as follows-

\[ n = \frac{(1.96+0.84)^2 \times 1.69^2}{0.5^2} \]

\[ = \frac{7.84 \times 2.86}{0.25} \]

\[ = \frac{22.42}{0.25} \approx 90 \]

Thus, the sample size required per group is 90. Hence total sample size required is 180.

A sample size of 180 subjects, 90 in each arm, is sufficient to detect a difference of 0.5 between groups in developmental scores assuming a standard deviation of 1.69 using a two-tailed t-test of difference between means with 80% power and a 5% level of significance. Considering a dropout rate (Loss to follow-up) of 10%, the sample size required is 200 (100 per group) with equal distribution into Intervention and Control Groups.

Recruitment (15)

All participants consenting for the participation in study will be assigned the Unique ID. Using blocked randomization process with age groups as Blocking variable, participants will be allocated either to intervention or control groups. Age groups will be –

1. 6 months to 24 months,
2. 25 months to 48 months.

All children hospitalized in AVBRH, scheduled to have a stay of minimum 3 days in hospital and their parents signing the informed consent will be enrolled in the study.

Assignment of interventions: allocation

Sequence generation (16a)

All participants consenting for the participation in study will be assigned the Unique ID. Using blocked randomization process with age groups as Blocking variable, participants will be allocated either to intervention or control groups.

Concealment mechanism (16b)

NA
Implementation (16c)

The principal investigator will generate the allocation sequence, will enroll the participants, and will assign participants to interventions.

Assignment of Interventions: Blinding

Who will be blinded (17a)

The outcome assessors will be blinded after assignment to interventions. Endline Assessments will be done by a separate team of researchers at home visits.

Procedure for unblinding if needed (17b)

NA

Data collection and management

Plans for assessment and collection of outcomes (18a)

Assessments will be conducted at following time points and tools as detailed below will be used for related assessments:

Assessment Schedules and Details:

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<td>PSEID</td>
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<tr>
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<td>PP Quiz</td>
<td>√</td>
</tr>
</tbody>
</table>

2. Variables:

For all children, changes will be observed in the-

7. Physical Development (Using Developmental Milestones Checklist-II)

a. Improvement in Fine Motor scores

b. Improvement in Gross Motor scores

9. Language Development Scores (Using Developmental Milestones Checklist-II)
10. Socioemotional Development Scores (Using Profile of Socio-emotional Development)
11. Home Environment (Using HOME Inventory Assessment)
12. Parent-child Interactions (Using Observation of Mother Child Interaction Tool)

3. Analysis Plan:

The pre and post intervention data of child development in specified domains will be collected and fed to STATA-14 after appropriate cleaning and compilation. Individual and Child Age-Group wise scores of development will be calculated and tabulated. Mean differences in child development scores for intervention and control groups will be calculated. The Effect Size by Cohen’s D will be calculated for each Child Age Group and Significance will be estimated.
Plans to promote participant retention and complete follow-up (18b)

To promote participant retention and complete follow-up, all enrolled children will receive scheduled home visits at fortnightly intervals. Also telephonic follow-up will be taken for those missing the home visits. The outcome data will detail on the participants who discontinue or deviate from intervention protocols.

Data management (19)

All data will be collected in Tablet PC based ODK collect app with in-built range check, double entry and value checks. Data will be exported to server after ensuring the correctness of data entered. The data from server can be downloaded as xls file.

Confidentiality (27)

Each participant will be allotted a Unique ID which will be used for analysis and reporting purpose. All data will be anonymous and personal information will be maintained to ensure protect confidentiality before, during, and after the trial.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use (33)

NA

Statistical methods

Statistical methods for primary and secondary outcomes (20a)

The pre and post intervention data of child development in specified domains will be collected and fed to STATA-14 after appropriate cleaning and compilation. Individual and Child Age-Group wise scores of development will be calculated and tabulated. Mean differences in child development scores for intervention and control groups will be calculated. The Effect Size by Cohen's D will be calculated for each Child Age Group and Significance will be estimated.

Interim analyses (21b)

NA

Methods for additional analyses (e.g. subgroup analyses) (20b)

Subgroup and adjusted analyses will be done for relevant parameters of developmental scores.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data (20c)

Attempts will be taken to ensure collection of complete data. In cases of missing data in few cases, imputation will be done.

Plans to give access to the full protocol, participant level-data and statistical code (31c)

Related Data on full protocol, participant level-data and statistical code will be shared through Personalized mails if requested

Oversight and monitoring

Composition of the coordinating centre and trial steering committee (5d)

The principal Investigator will look into data on real time basis and will share the data with the concerned statistician on quarterly basis.

Composition of the data monitoring committee, its role and reporting structure (21a)

As this is a PhD thesis, all related data will be managed and monitored by Principal Investigator along with the support from statistical expert.

Adverse event reporting and harms (22)

Since this is a Play Therapy intervention, hardly any adverse events and other unintended effects of trial interventions or trial conduct are expected. If encountered, those will be reported as per the guidelines from Institutional Ethics Committee.

Frequency and plans for auditing trial conduct (23)

NA

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) (25)

Important protocol modifications will be communicated to relevant parties (eg. Investigators, REC/IRBs, trial participants, trial registries through emails and printed Hard copies, as required).

Dissemination plans (31a)
Discussion

Impact of Hospitalisation on Children

Hospitalization plays a significant affect in a child’s life. Many children who are admitted to hospitals have complex healthcare needs and some of them require highly technical interventions. According to the 2013 statistics by WHO children under the age of five died from diseases like acute respiratory infections, birth asphyxia, diarrhoea, neonatal sepsis, injuries, congenital anomalies and infant prematurity(12). Children who are hospitalised with the above said diseases tend to have a traumatic experience at hospital such as in the long-run hospitalisation tends to demonstrate negative psychological and behavioural responses(13). Usually the hospitals are focused more on physical recovery and mortality than the overall wellbeing of the child and her family(14).

Children tend to perceive hospitals negatively which impact their physical and mental health. In a study that was conducted it was found out that children who were hospitalized felt scared, bored and alone(15). Children experience happiness, sadness, anger and fear in the presence of a doctor and nurse(16). In another study it was found out that there was a reciprocal relationship between anxiety, blood pressure and heart rate(17). It was also found out that when children were asked to draw a person in hospital, the drawings indicated anxiety. They drew pictures of people who were sad and dependent(18).

Furthermore, according to the parents a child’s behaviour, function and health before hospitalization and after hospitalization is significantly different. Children suffer from emotional distress three to five months after hospitalization and surgery and this is most common in the age range of one year to six years. Trauma that children face at the hospital has been termed as Paediatric Trauma Mental Stress which is characterized by avoidance, re-experience of the event, hyper arousal which arises from major illness or medical intervention that causes a threat to child’s health and is considered to be intrusive, painful and alarming medical care. Children tend to internalize their problems and may have symptoms of depression and anxiety which further aggravates their illness(19). There are certain risk factors that are involved when children are hospitalised or undergo surgery. Some risk factors may be attributed to their age range, temperament, baseline anxiety, past medical encounters and parents’ level of anxiety. Children tend to suffer from anxiety while hospitalized due to uncertain possibilities of their treatment(20).

Problems Children Face During Hospitalization:

The children suffer from various psychological problems at the hospital the following are some of the problems that children face on a daily basis in hospital.

Lack of Identity

The relationship between nurse, parents and children tend to vary. Nurses and children have different perspectives for one another. Children who suffer from acute conditions are not treated in a child-friendly manner but they are considered as beings on whom the goals need to be met. Children when hospitalised find it hard to maintain their own social identity and work hard to reduce the stigma around them. They tend to become resilient by resisting the way they are dehumanised by the hand of nurses. In a study that was conducted it was found out that the nurses tend to take children as patients on whom treatment needs to be performed and not as humans whose past experiences and history needs to be taken into account. Hospital ward is a place for children in which their voices cannot be heard and even for those children who would raise their voice it was taken to be as a challenge by nurses(21).

Lack of Communication

Studies have found out that there is a lack of communication between the hospital staff and patients which makes the stay at hospital threatening. It was found out that children who were readmitted were perceived by the nurses to be resilient and their families to be more experienced at caretaking hence this misunderstanding increase their chance of readmission. In another study it was found out that during the time of discharge when the nurses do not cascade the information properly the coping mechanism of parents as well as children negates. When it comes to Family Centred Care it was found out that nurses need skill training, managerial support and adequate resources to meet families’ needs appropriately. It has been concluded that hidden expectations and unclear suggestions are stressful for the families(22). Nurses who listen to parents with unconditional positive regard and empathy as well as reinforcing parenthood by praising parents tend to decrease the stress level of parents(23). Nurses play an important role to overcome the stress that parents and children face.

Play Stimulation for Hospitalised Children

Children when hospitalised tend to look for activities that can keep them calm. Such as in some instances they look towards their parents so that they can speak to them and they look towards other children with whom they can play instead of getting bored. Some children found the hospital as a place where they can explore, learn and make new friends(15). Physical exercise, healing touch, music therapy, therapeutic massage, and health education has decreased the symptoms of cancer(24). Play activities that include art has also affected children’s overall health at the hospital. In case of infants if their parents talk to
them, massage them, make eye contact, sing to them or put objects at a closer distance and infant grabs them, or show infants bold colours or play games like peek a boo or mimic what the child is saying can soothe the child(2).

Other activities have also assisted in alleviating the symptoms of anxiety and pain. In a study that was conducted it was found out that children tend to prefer natural landscapes with calming colours over abstract paintings that have bold colours. The natural painting paved way to positive physiological outcomes and it was used for distraction which reduced pain perception(25). Reading also influences children’s wellbeing and when caregivers read books to children when sick, children feel comfortable and emotional affiliation with the caregivers grow(26). Videoconferencing with family has also assisted in reducing the stress of children(27).

Surgical procedures can create anxiety in children as well as their parents. In a study that was conducted it was found out that before the children went through surgery the nurses taught the children the procedures and outcome of the surgery and the nurses as well as the children re-demonstrated the procedure in dolls. This reduced their anxiety as well as caregivers’ since they observed it as well(17). When children above the age of four were educated about their health they showed lower level of anxiety than children younger than them. When play routine was introduced to hospitalised children lower level of cortisol in their urine was indicated(28). Play activities can help in reducing the organic symptoms in children. The time span spent at the hospital can also be shortened when children participate in activities related to play stimulation.

While a child is engaged in play activities it plays an important role in decreasing the stress of parents and children. As the studies suggest play stimulation can play an important role in relieving the symptoms of stress and organic diseases. The hospital staff needs to be trained, play stimulation should take place in the wards and counselling should be given to the parents and their children to release their stress. Before the play stimulation activities should be practiced it is important for the caregivers, therapists, hospital staff and parents to understand what is to be expected in different age domains related to cognitive and psychosocial development.

Scope and Implications:

This Play therapy intervention package for hospitalized children is expected to bring out a evidence based Proof of Concept for the future ‘Play Therapy Stimulation Package’ for hospitalized children with ‘Special Stimulation Kit’ which can be later patented and commercialized as a business model for hospitals with Inpatient Child care Units in this region.

As this will be a Single Centre study, the Response Rate and Acceptance of intervention by beneficiaries may not be generalizable to different types /levels of inpatient child care facilities.

Minimum 3 days hospital stay is expected with initial Play therapy start. Stay less than this duration may not be that much effective to stimulate children and sensitize parents. Also follow-up after discharge may pose some challenges.

Trial status

Trial Registered Prospectively with Clinical Trial Registry of India. Recruitment of Participants is yet Not started. Expected date of recruitment is 1st June 2022 and trial will be completed by 30th May 2023.

Abbreviations

WHO: World Health Organization
ECD: Early Child Development
DMC: Developmental Milestones Checklist
PSED: Profile of Socioemotional Development
ODK: Online Data Kit
OMCI: Observation of Mother-Child Interaction
PP Quiz: Positive Parenting Quiz

Declarations

Trials guidance: All manuscripts must contain the following subheadings:

- Acknowledgements
- Authors’ contributions
- Funding
- Availability of data and material
- Ethics approval and consent to participate
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Authors’ contributions (31b)

MP is the Principal Investigator of this trial and taken efforts on collection of related literature, study design, compilation, documentation and preparation of Final Draft of this manuscript.

AG is the Research Guide for this study and provided all support needed in finalizing the topic of research, concept, strategies and finalization of manuscript.

ZQ is the Co-Guide for this study and provided all support needed in finalizing the topic of research, concept, strategies and finalization of manuscript equally along with directions to publish the Study Protocol.

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Availability of data and materials (29)

Data and materials related to this study will be availed on request by mail to the corresponding author.

Ethics approval and consent to participate (24)

Ethics Approval obtained from the Institutional Ethics Committee of Datta Meghe Institute of Medical Sciences University.

Written consents of parents of all children participating in the study will be obtained at the time of enrolment in the study.

Consent for publication (32)

NA

Competing interests (28)

Authors declare No Conflict of interest.

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AG and SZQ are working on ECD since last 15 years and has received 4 International grants and 4 National grants for various ECD related projects.

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