IMPACT OF SIMULATION-BASED INTERVENTION ON DOMESTIC CARE OF SEIZURES IN CHILDREN BY PRIMARY CAREGIVERS- A RANDOMIZED CONTROL STUDY

THESIS SUBMITTED TO

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, JODHPUR

In partial fulfillment of the requirement for the degree of

DOCTOR OF MEDICINE (M.D.)

(PEDIATRICS)

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JULY, 2020

AIIMS, JODHPUR

(DECLARATION BY THE CANDIDATE)

DECLARATION

I hereby declare that the thesis titled **"Impact of simulation-based intervention on domestic care of seizures in children by primary caregivers- a randomized control study."** embodies the original work carried by the undersigned in the All India Institute of Medical Sciences Jodhpur, (Rajasthan)

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CERTIFICATE

This is to certify that the thesis titled **"Impact of simulation-based intervention on domestic care of seizures in children by primary caregivers- a randomized control study."** is the bonafide work of **Dr. Sanjana** carried out under our guidance and supervision in the Department of Pediatrics, All India Institute of Medical Sciences, Jodhpur.

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Acknowledgements

These are not acknowledgements, these are dedications...

I dedicate this dissertation to Dr. Kuldeep Singh, Professor and Head, Department of Pediatrics, AIIMS, Jodhpur, for being the perfect guide and source of inspiration. His relentless guidance, ideas, encouragement and reassuring presence throughout make the very fibre of this dissertation. I have gained many life lessons from him, on topics ranging from credibility to enthusiasm, punctuality to objective criticism - lessons which I am still trying to satisfactorily imbibe.

I dedicate this dissertation to Dr Bharat Choudhary, Associate Professor of Department of Trauma and Emergency Medicine (Pediatrics) for his guidance in teaching me the basics and very core of simulation and his objective criticism throughout the thesis. No amount of words can contain the magnitude of my gratitude for his guidance.

I also thank my co guides Dr Lokesh Saini and Dr Manoj Kumar Gupta for their very valuable inputs from the beginning till end.

A lot of appreciation is due to my wonderful teachers- Dr Arun Singh, Dr. Jagdish Prasad Goyal, Dr. Neeraj Gupta, Dr Daisy Khera, Dr. Prawin Kumar, Dr Aliza Mittal, Dr Varuna Vyas, Dr Siyaram Didel, Dr Jitender Kumar Meena, Dr Thanigai Nathan, Dr Sushil Kumar Choudhary- Each one of my professors I have learnt something from, and without their teachings my training as a researcher or as a student would be incomplete.

I dedicate this dissertation to all of my patients, who in the course of this study- the planning, counselling, discussion and preparation, taught me more about trust, patience and humanity than any other part of my training has.

I dedicate this dissertation to Mr. Rajbir Singh and Mrs. Sunita, my parents of whose authentic grey hair not a few have been caused by myself. They have shared my every dream, every hope, and every aspiration and provided every means- emotional, psychological, and material to fulfill them. No amount of words can contain the magnitude of my gratitude or affection towards them.

I dedicate this dissertation to my sibling- Ajay Saharan and Abhay Saharan who have been my support system throughout residency from afar.

I dedicate this dissertation to my friends Dr. Kajal, Dr. Anureet Kaur, Dr Dushyant, Dr Yamini, Dr Jagriti, Dr Kanupriya, Dr Aravind who've proved that in this age of email, whatsapp and social networking, distances can be no barrier in fulfilling friendships or lending a helping hand.

A special dedication to my seniors-Dr Amarpal Singh, Dr Anil, Dr. Nikhil Rajvanshi, for their constant guidance and support and turning this arduous task into a memorable journey.

A very special gratitude goes out to my postgraduate seniors Dr Sujatha, Dr Rahul, Dr Prakshi, Dr Veena Lakshmi, Dr Ashna, Dr Akash, Dr Jashan, Dr Sarita, Dr Pujitha, Dr Ashwani, Dr Lekshmi, Dr Dyvik, Dr Siddanagouda, my colleagues specially Dr Kkomal, my juniors Dr Deeksha, Dr Saket, Dr Saurabh, Dr Asha, Dr Khushi, Dr Saranya, Dr Paras, without their assistance, this dissertation would not be complete.

There are several other exceptional individuals who have played a role, to a noticeable extent, in my thought process and my work. I shall, by way of gratitude, avail myself of their continued contact and inspiration, and be for them an ever yielding well of friendship and trust.

Dr Sanjana

LIST OF ABBREVIATIONS

PFCR	Patient and family centered rounds
PFCC	Patient and family centered care
ELT	Experiential learning theory
CE	Concrete experience
AC	Abstract conceptualization
RO	Reflective observation
AE	Active experimentation
SBE	Simulation based education
AIIMS	All India institute of medical sciences
SPSS	Statistical package for social sciences
HFS	High fidelity simulation
USA	United states of America
LTMV	Long term mechanical ventilation
CF	Cystic fibrosis
RCT	Randomized control trial
HPS	Human patient simulation
OPD	Outpatient department
IPD	Inpatient department
SD	Standard deviation
IQR	Interquartile range

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INTRODUCTION

Seizures constitute the commonest neurological problem in children with a significant proportion of epilepsy having its onset in childhood. Seizure and status epileptics constitute one of the major medical emergencies in children. The incidence of epilepsy studies in the children has usually been restricted to new-onset epilepsy before 16 years of age. The reported incidence of epilepsy in the children has quite a wide range, for example from 41/100,000 in all children in Nova Scotia to 187/100,000 in children 6-9 years of age in Kenya (1).

Seizure disorders are very common and parents are usually not able understand the discharge instructions. Most of the pediatric seizures occur in the outpatient setting, where family members act as primary caregivers; proper intervention by them can lead to better management, decreased morbidity and decreased chances of progressing to status epilepticus. Just like health care workers, caregivers have the abilities and strengths and capacity, to improve their competence and should, therefore, be afforded opportunities to acquire and/or display competencies.

To acquire competency for management of seizures caregivers need to have adequate knowledge and skills. For this purpose, simulation-based intervention can be used as a means of teaching, as simulation provides caregivers an opportunity to practice managing stressful medical situations in a risk-free environment leading to better retention and reproduction of those skills (2). As pioneers in revolutionary interventions such as patient- and family-centered rounds (PFCRs), many centers have modeled, and taught effective communication with patients and families during rounds. Patient- and family-centered care (PFCC) is more than just effective communication, however, and it extends beyond morning rounds and even beyond the manner in which a patient encounters the health care system at large (3).

Simulation is an evidenced based strategy that has been proven to impact office-based readiness to respond in a medical emergency. Simulation-based training has been recognized as an established component of medical training for medical students, residents, and fellows (4). Experiential learning theory (ELT) serves as the skeleton of simulation-based education. The first step in this theory is that a learner engages in a “concrete experience,” in our context, is a simulated medical procedure or patient

encounter, and the components of that experience form the basis for the second step of the cycle, “observation and reflection.” After this second step, learner develops their internalized operational model for working through a procedure or encounter. In the third step, learners test their operational model in a novel situation, which add to a concrete experience, and the cycle repeats itself, until if and when a learner achieves mastery (5). Key elements of this Kolb’s ELT model are paired, gaining new knowledge, through concrete experience (CE), and abstract conceptualization (AC) and then transforming this experience through reflective observation (RO) and active experimentation (AE) (6). This is basic principle of ELT required for simulation-based education (SBE).

There is another concept of fidelity in simulation-based education. In simulation-based health professional’s education, the simulator fidelity is usually understood as the degree to which a simulator looks, feels, and acts like a human patient (7). Although it can be a useful in designing simulators, this definition emphasizes technological advances and physical resemblance over principles of educational effectiveness, which is the main aim of simulation-based education. Hence most of the studies don’t emphasize on the fidelity of the simulator, rather the process of training and debriefing.

Traditionally, during discharge only verbal teaching is done about use of rescue medication and care to be provided during and after seizures. Using SBE for family centered care is a developing domain, needing further research. However, to the best of the present author's knowledge, there are a few studies on the effect of simulation-based education on confidence and competence of primary caregivers to manage seizures at home, that too in developed countries, no similar study has been done in any of the developing country. This study, therefore, aimed to examine the impact of simulation-based intervention on domestic care of seizures by primary caregivers.

REVIEW OF LITERATURE

The origin of simulation ages back to when models of human patients were built in clay and stone to demonstrate the clinical features of diseases and their effects on humans. Such simulators were used across different cultures, and also enabled male physicians to diagnose diseases in women in societies where social laws of modesty did not allow exposure of body parts. “Simulator” refers to any physical object or representation of the full or part task to be replicated. Whereas “Simulation” refers to their application for education or training. The term fully immersive simulation is used by some specifically to refer to using technologies that recreate the full environment in which one or more targeted tasks are to be carried out. (8). Although the use of simulation technology, which includes multimedia computer programs, is recently gaining wider acceptance in the medical field, such technology is already well established in other disciplines. Such as, the use of simulation in other fields like flighting simulators for pilots and astronauts, war games and training exercises for military training, management games for business executives, and technical operations for nuclear power plant personnel.

Changes in medical practice that limit instruction time and patient availability, the expanding options for diagnosis and management, and advances in technology are contributing to the greater use of SBE in the medical field. Major areas of high-technology SBE currently being used are laparoscopic techniques, which provide surgeons with opportunities to enhance their motor skills without any harm to patients; multimedia computer systems, which include case-based programs that constitute a generalist curriculum in cardiology; and anesthesia simulators, which have a controlled response that vary according to numerous possible scenarios (9).

It is a well-documented fact in the literature that intrinsic motivation in learning activities is strongly correlated with the outcome of the learning process (10). By promoting the direct participation of students in their knowledge building, SBE incentives intrinsic motivation in the hands-on learning activities developed by the instructors and developed under their supervision and guidance. Learning practices based on the use of Simulation education software and games are catching the eye of academic and industrial partners, who see in SBE a way to improve the training of students and future employees (11). Specifically, high-fidelity simulation (HFS) has

provided solution to the challenges of providing clinical experiences to students in traditional care settings.

Care transitions from the hospital to home are very critical and crucial to the sustainability of our health care system. Inadequate care transitions from the hospital to home are not uncommon as indicated by research demonstrating a high incidence of adverse events post hospitalization, along with poor communication with patients and families during transitions and inadequate information exchange among health care providers and caregivers. PFCC is defined as a care that is "respectful of and responsive to individual patient preferences, needs, and values, and ensures that patient values guide all clinical decisions" (12). Patient and family engagement is fundamental to a PFCC approach, and also key to improving overall patient care in our health care system. PFCC is an approach to healthcare that is found on this mutually beneficial partnership between patients, families, and healthcare providers. This collaboration actively engages family members and encourages them to share their insights, observations, perspectives and doubts as care plans for their child are developed and carried out. Positive PFCC interactions can eventually lead to improved patient outcomes, increased parental confidence, improved patient safety, and improved family satisfaction (13). Family-centered care in high-income countries has been explored as a care that is led by parents, with the health professional acting as a consultant, encouraging open and honest conversation with the family (14). The family is acknowledged as an expert in the care of their child, and the perspectives and information provided by the family have been described as an important tool to clinical decision-making (15).

Table 1: Outline of similar studies

Author, year and place of study	Title	Sample size	Outcome
Siaglet et al 2014 Calgary, Canada	A simulation-based intervention teaching seizure management to caregivers: A randomized controlled pilot study	61	Benefit for caregiver competence and confidence in managing seizures when traditional seizure discharge teaching is supplemented with simulation-based seizure curriculum.
Shasha et al 2022 Menoufia university, Egypt	Effect of Simulation Training on Seizure Management and Anxiety level among Mothers of Children with Epilepsy	60	Significant increase in the knowledge of mothers after simulation training as compared to no intervention along with decrease in anxiety levels after simulation (16).
Shah et al 2016 Texas, USA	Impact of High-Fidelity Paediatric Simulation on Paramedic Seizure Management	250	Simulation-based training on paediatric seizure management may have utility. Data support the need to optimize the route and dose of midazolam for seizing children. Blood glucose measurement in seizure protocols may warrant reprioritization due to low hypoglycemia prevalence.

Thrasher et al 2018 Colorado, USA	Hospital to Home: A Quality Improvement Initiative to Implement High-fidelity Simulation Training for Caregivers of Children Requiring Long-term Mechanical Ventilation (LTMV)	87	Rehearsal of emergency management in a simulated clinical setting increases caregiver confidence to assume care for their ventilator-dependent child
Sanseau et al 2018 Seattle, USA	Paediatric Simulation Cases for Primary Care Providers: Asthma, Anaphylaxis, Seizure in the Office	100	Participants overall felt the curriculum was relevant to their practice in the realms of medical management and patient-provider communication.
Prickett et al 2019 Atlanta, USA	Simulation-based education to improve emergency management skills in caregivers of tracheostomy patients	39	Two patterns of responses emerged: caregivers with progressive increase in confidence through training, and caregivers who initially rated confidence highly, and had confidence decrease as the complexity of true emergency management became apparent. All participants found the simulations to be realistic and helpful.
Kahraman et al 2019 Izimir, Turkey	The effect of simulation-based education on childhood epileptic seizure management knowledge, skills, and attitudes of nursing students	72	Simulation-based training was beneficial for students insofar as it helped them to develop positive attitudes toward epilepsy

Schandevyl et al 2022 Brussels, Belgium	A medication adherence–enhancing simulation intervention in pediatric cystic fibrosis	21	Multistep medication adherence–enhancing simulation intervention in pediatric CF is feasible, effective, and well accepted by children with CF and their parents alike.

- A similar randomized control study conducted by E Siaglet et al, in a tertiary care centre in Calgary in 2014. It included caregivers of children <18 years of age, recently diagnosed with an acute seizure disorder. 61 patients were enrolled and randomly assigned according to family unit into to one of two arms: a control group receiving traditional seizure discharge teaching alone; and an experimental group receiving the traditional seizure teaching and additional simulation-based seizure teaching. Caregiver performance was analysed using a seizure management checklist. Caregivers' perception of self-efficacy was captured using a self-efficacy questionnaire. Both of these instruments were developed and validated for this study. Caregivers in the experimental group achieved significantly higher postintervention performance scores than caregivers in the control group in both premedication and post-medication seizure management ($P<0.05$). Additionally, they achieved significantly higher scores on the self-efficacy questionnaire including items reflecting confidence managing the seizure at home ($P<0.05$) (2).

- A two-year retrospective cohort study conducted by Shah et al in 2016, to determine if Paediatric simulation training for emergency prehospital providers enhances seizures protocol adherence in blood glucose measurement and midazolam administration for seizing children. They concluded that simulation-based training on paediatric seizure management may have utility. Data support the need to optimize the route and dose of midazolam for seizing children. Blood glucose measurement in seizure protocols may warrant reprioritization due to low hypoglycaemia prevalence (17).

- A quality improvement initiative conducted by Thrasher et al using an innovative educational tool for caregivers of children requiring Long Term Mechanical Ventilation (LTMV). Aim was to create a multimodal discharge preparedness curriculum, incorporating high-fidelity simulation training, to prepare family caregivers of children with complex medical conditions requiring LTMV. They observed that simulation-enhanced curriculum was well-received by participants. Participants reported that post-simulation debriefing was the most beneficial component. We observed a trend toward reduced readmissions within 7 days of discharge since implementation of our revised curriculum (18).

- A study conducted by Sanseau et al, including paediatric simulation cases for primary caregivers of patients. The cases were facilitated by faculty at an annual conference on urgent paediatric problems. Three cases are included in this curriculum: asthma, anaphylaxis, and seizure. Each featured a brief narrative description of the case, learning objectives, instructor notes, an example of the ideal flow of the scenario, and anticipated management mistake. The simulations were carried out annually for 4 years with over 100 providers. It was concluded by the researcher that participants felt the curriculum was relevant to their practice in the realms of medical management and patient-provider communication (19).

- A study conducted by Prickket et al using simulation-based education demonstrated improvement in emergency management skills among caregivers of tracheostomised patients. High fidelity simulation-based education was designed and caregivers completed three scenarios: desaturation, mucous plugging and dislodgement, after which they rated confidence using visual analogue scale. This study concluded that High-fidelity simulation training allows for realistic exposure to tracheostomy-related emergencies, also that caregivers overestimate their ability to handle emergencies and gain important insight through simulation (20).

- A randomized control trail (RCT) conducted by Kahraman et al to study the effect of training given to nursing students using simulation and standard child mannequins on their childhood epileptic management knowledge, skills, and attitudes revealed important outcome. The epilepsy knowledge scale mean scores of both groups significantly increased after their respective trainings ($p < 0.001$), but the difference between the groups was not statistically significant ($p = 0.829$).

There was no statistically significant difference between the pre- and post-training epilepsy attitude scale mean scores of the control group ($p = 0.630$), however, a statistically significant increase was observed in the epilepsy attitude scale mean score of the intervention group ($p = 0.008$) (21).

- A study conducted by Schandevyl et al studied the effectiveness of a multistep medication adherence-enhancing simulation intervention for pediatric Cystic fibrosis (CF) in adherence to chronic pulmonary drug in CF. Dornase alfa-treated patients aged 7-13 years were included. PowerPoint slides were presented and discussed. The final slide invited the patient to perform the simulation experiments, and, in so doing, they experienced what happened when they either do or do not take their medication. An educational film was applied as a summary tool. Two months later a questionnaire was filled by patients. The results suggested that experiential simulation-based learning is extremely appropriate, and that this multistep intervention is feasible and effective in pediatric CF (22).

- A RCT conducted by Chang et al in 2016, to assess the effectiveness of SBE on childhood fever management by Taiwanese parents. Data on parental fever information, motivation, behavioural skills, and management behaviours were collected before the 1st day, on the 1st day (except management behaviours), at the 6-month, and at the 12-month marks post-training with a self-developed instrument based on the information-motivation-behavioural skills model. The results of a generalized estimating equation analysis indicated that the information, motivation, behavioural skills, and management behaviours of all participants had improved at the post-test assessment, with the Experimental group showing significantly better improvement than the Control group. This study supports that simulation-based education effectively enhances fever management of parents for a long period of time (23).

- A RCT conducted by Ramchandani et al in 2016, using human patient simulation (HPS) to enhance parents learning diabetes self-management with children with new-onset Type 1 diabetes was highly useful. The majority of parents were positive about learning with HPS. Although a few parents said that seeing a seizure increased their fear although they would have panicked if they had not had

that learning experience, and it helped build their diabetes self-management confidence (24).

- A mixed method study conducted in 2020 by Rodriguez et al to evaluate the knowledge that family caregivers of individuals with spinal cord injuries acquired through the use of a high-fidelity simulation-based learning program found to be effective in increasing the knowledge and skills of caregivers (25)

LACUNAE IN LITERATURE

Recently there has been increase in the number of studies including PFCC and simulation, but most of them are in critical illnesses and adults. Only one study has been done till date with simulation-based intervention teaching seizure management to caregivers (2). There have been no similar studies in India so far with regard to simulation-based intervention in pediatric seizures. Therefore, we planned to carry forward with this study.

RESEARCH QUESTION

Does simulation-based intervention teaching lead to increase in confidence and competence in seizure management by caregivers at home?

AIM AND OBJECTIVES

Primary objective:

To study the effect of simulation-based teaching intervention on the confidence and competence of caregivers in managing seizures at home.

Secondary objective:

1. To compare the difference in management of seizures by parents taught through simulation-based education (SBE) and traditional discharge teaching.
2. To compare the retention of knowledge in two arms at follow up after 3 months of intervention.
3. To study emergency visits in status epilepticus in both arms after simulation - based teaching**.**

MATERIALS AND METHODS

Ethics approval

Institute's Ethics committee approval was obtained. Certificate reference number-

AIIMS/IEC/2021/3397.

Study Design

This is a randomized control study. Simple randomization was done using computer generated randomization scheme. After taking consent, patient's care givers were randomly allocated to two arms on the basis of order and date of enrollment. Participants were assigned to two arms, control arm receiving traditional seizure discharge teaching alone, and an intervention arm receiving the traditional discharge teaching and additional simulation- based seizure teaching. Participants in both groups were asked to complete an assessment with a self-efficacy questionnaire after enrollment, post intervention and 3 months after intervention.

Study Site

Department of Pediatrics, AIIMS Jodhpur

Study duration

1.5 years (March 2021-August 2022)

Study Population

The study included caregivers of all patients who have tendency of having recurrent seizures (0 to 18 years of age) coming to Pediatric Outpatient (OPD), inpatient ward (IPD) and emergency.

Inclusion Criteria

1. Caregivers of children (0 to 18 years) who are at risk of getting recurrent seizures (like space occupying lesions, epilepsy syndromes, recurrent febrile seizures etc)
2. Guardian of patients willing to give informed consent.

Exclusion Criteria

1. Caregivers of patients with transient seizure that is less likely to recur (like trauma, metabolic causes, meningitis).

Enrollment

Parents of subjects who satisfy the above eligibility criteria were approached for participation in the study. An Information Sheet giving the details of the study were provided and the nature of the study was also verbally explained. Written informed consent was obtained. Enrollment, recording of baseline information was done immediately after written informed consent was obtained. After which self-efficacy questionnaire was

Randomization

Caregivers of patients were randomly allocated in order of time of their enrollment in study through computer generated randomization.

Intervention

1.The caregivers of the arms were given traditional seizure discharge teaching, including recognition of seizures, administration of rescue medicine, positioning of patient and care during and after seizure episode, which was given in a written format in both Hindi and English as well as explained verbally by the investigator. The total duration of teaching depended on the educational needs of care givers. Care givers of intervention arm also received simulation-based discharge teaching, which included seizure recognition, preventing injury and maintaining recovery position, medication administration, and post seizure care. For simulation-based teaching pedia-sim manikin (PN:165K240100) was used, which is available in the skill and innovation center at AIIMS jodhpur. Local modifications were done in our purchased model to simulate seizures. Each session of simulation-based teaching included, 4 -6 caregivers at a time, with each session lasting for 15-20 minutes. Post-simulation feedback was obtained and debriefing session of around 30-40 mins was held out. Debriefing was done using stop and pause method. Performance gaps were closed by providing specific feedback, in a supportive manner, in a psychologically safe and confidential learning environment.

Figure 1: Pedia-Sim Manikin

Figure 2: Debriefing

Instrument:

The Parent Seizure Self-Efficacy Questionnaire

The Parent Seizure Self-Efficacy Questionnaire (Annexure IV) was adapted from the Kid SIM self-efficacy questionnaire used in Calgary study (2). Each item was used to examine caregiver confidence in their ability to recognize and provide seizure management. A five-point Likert scale, ranging from 0 ('not sure at all') to 4 ('completely sure'), was used to differentiate between levels of reported caregiver confidence. The questionnaire was used after obtaining permission from the authors of study done by Siaglet et al in Calgary through mail. The questionnaire was translated into Hindi using a translation procedure and validated. Two independent bilingual speakers and experts in seizures treatment performed the forward translation. An independent bilingual speaker familiar with the field assisted. This questionnaire was filled during enrollment, post intervention and 3 months after intervention.

Outcome

1. Confidence level and competence in managing seizures in control and intervention arm.
2. To compare the difference in management of seizures by parents taught through simulation-based education (SBE) and traditional discharge teaching.
3. To compare the retention of knowledge in two arms at follow up after 3 months of intervention
4. To study emergency visits in status epilepticus in both arms after simulation - based teaching**.**

Data collection

1. There were two arms- one which received education through traditional discharge teaching and other one which received traditional discharge education and simulation-based learning.

2. Subject's history (including demographic details, diagnosis, chronicity of disease, ongoing treatment and no. of hospital visits, education of caregiver,

occupation of caregiver) according to predetermined data sheet (Annexure 3) were obtained during enrollment.

3. Along with data collection, all subjects underwent self-assessment using self-efficacy questionnaire during enrollment.

4. Another self-assessment was done after traditional discharge teaching in one arm and simulation-based intervention teaching in second arm.

5. Both groups were assessed again at 3 months using the same self-efficacy questionnaire.

Sample size calculation:

The sample size was calculated based on study done by Siaglet et al (2), with alpha error of 5%, effect size of 0.5, power of 80%, attrition of 10 % and it is estimated to be 114. We randomly allocated caregivers in two arms using computer generated randomization. We enrolled the participants satisfying inclusion exclusion criteria who attended the pediatric OPD, pediatric emergency and pediatric IPD at AIIMS Jodhpur.

Statistical analysis:

All data collected was entered in to a pre-prepared excel worksheet. Descriptive statistics were completed using SPSS version 26.0 (IBM Corporation, USA) to present median and Inter-quartile range (IQR) for questionnaire items for participants in the control and intervention arm. A χ^2 test was used to examine differences between characteristics of participants in the control and intervention arm. Independent *t* tests were used to assess differences between the participant scores in both arms for the self-efficacy questionnaire at baseline, post intervention and at 3 months follow up. Mann-Whitney U test was used to calculate the difference between both the arms at all intervals by calculating p value.

ETHICAL CONSIDERATION

RESEARCH ETHICS APPROVAL: The study was undertaken after the clearance from institute's ethics committee (AIIMS/IEC/2021/3397)- Annexure VI

Caregivers were enrolled after obtaining informed consent.

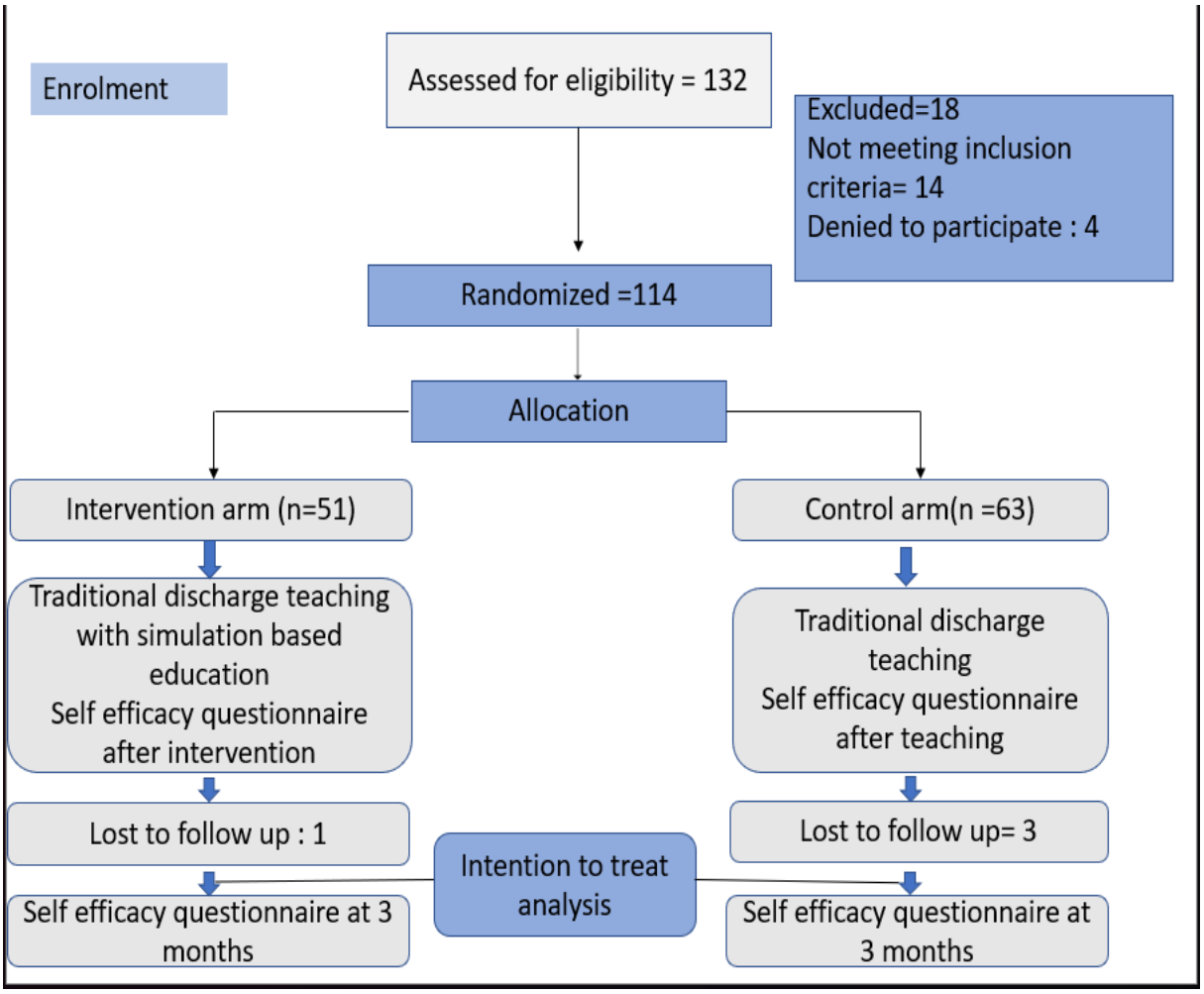
The purpose and design of study was explained to the caregivers.

The parents or consenting family members were informed that they can ask to withdraw at any time without having reasons for the same.

OBSERVATIONS AND RESULTS

This was a randomized control study titled “Impact of simulation-based intervention on domestic care of seizures in children by primary caregivers -A randomized controlled study” with the aim to assess the changes in confidence and competence of primary caregivers in managing seizure at home after educational intervention to patient’s primary caregivers was performed at skills and innovation center, AIIMS Jodhpur. Education was provided to two arms, in one using traditional written discharge instructions which were verbally explained and given to caregivers and in another group using simulation-based teaching along with traditional written discharge instructions. A total of 114 caregivers were enrolled in the study. They were randomly assigned to each arm (control, n=63; intervention, n=51). There were 4 patients who were lost on follow up at 3 months (1 in intervention and 3 in control arm). Intention to treat analysis was used, so data of post intervention or discharge teaching was used to complete data of 3 month follow up.

Figure 3: Consort flowchart



Participants Demographics

1. Distribution of baseline characteristics between two arms

   It was seen that there was no significant difference between distribution of sex of the patient, caregiver relation to the patient, caregiver education status and caregiver occupation among the two arms. Although there was a significant difference in the caregiver age and age of the patient. There were a greater number of patients with age more than 5 years (68.6%) in intervention arm as compared to control arm. In control arm there were a greater number of caregivers with age less than 30 years and vice versa in intervention arm.

Table 2: Baseline characteristics distribution

Variable	Control arm (n=63) N(%)	Intervention arm (n=51) N(%)	P value
Age of patient			
≤1 year	11(17.5)	5(9.8)	0.036
1-5 years	24(38.1)	11(21.6)	
>5 years	28(44.4)	35(68.6)	
Sex of patient			
Male	37(58.7)	32(62.7)	0.663
Female	26(41.3)	19(37.3)	
Caregiver age in years			
≤30 years	38(60.3)	21(41.2)	0.042
>30 years	25(39.7)	30(58.8)	
Caregiver relation to patient			
Father	36(57.1)	27(52.9)	
Mother	24(38.1)	20(39.2)	0.765
Others	3(4.8)	4(7.8)	
Caregiver education status			
Up to primary	21(33.3)	15(29.4)	
Up to secondary	14(22.2)	12(23.5)	0.905
Above secondary	28(44.4)	24(47.1)	
Caregiver occupation			
Homemaker	25(39.7)	19(37.3)	
Unskilled worker	17(27)	15(29.4)	0.676
Skilled worker	17(27)	16(31.4)	
Professional	4(6.3)	1(2)	

2. Comparing clinical features between two arms

There was no significant difference between the baseline features between the two arms including type of seizures, frequency of use of medications at baseline, history of status epilepticus and family history of epilepsy revealed by p value of more than 0.05 in all characteristics.

Table 3: Comparing clinical features between two arms

Variable	**Control group (n=63) N(%)**	**Intervention group (n=51) N(%)**	**P value**
Clinical features at presentation			
Focal seizures	16(25.4)	15(29.4)	0.779
Generalized	33(52.4)	17(45.1)	
Others	14(22.2)	13(25.5)	
Frequency of use of rescue medications			
Nil	45(71.4)	34(66.7)	0.701
<5/year	11(17.5)	12(23.5)	
>5/year	7(11.1)	5(9.8)	
History of status epilepticus	24(38.1)	14(27.5)	0.231
Family history of epilepsy	14(22.2)	13(25.5)	0.683

Figure: 4 Types of seizures

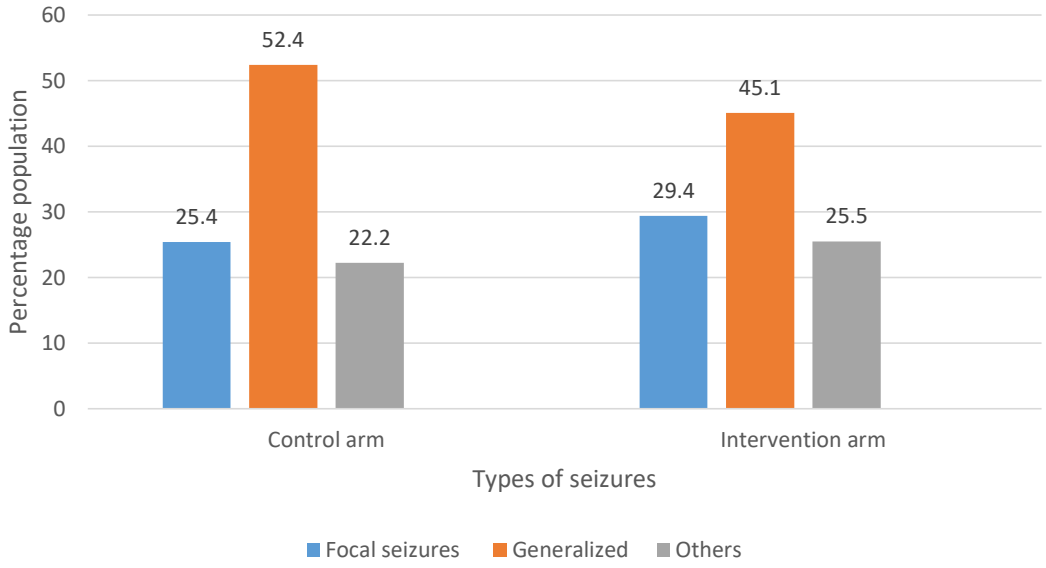
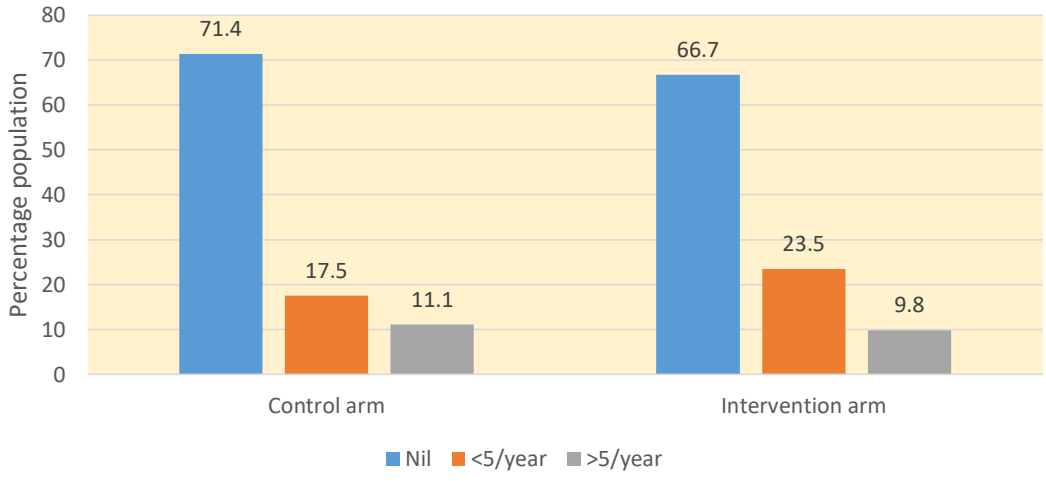


Figure: 5
Comparing Frequency of use of rescue medications at baseline



3. Comparison of duration of disease between two arms

The difference between total duration of disease among patients calculated by independent t test in both groups is significant as revealed by p value of 0.016.

Table 4: Comparison of duration of disease in patients

	Control group (n=63) Mean ±SD	**Intervention group (n=51) Mean ±SD**	**P value**
Total duration of disease (months)	28±41.55	47.49±41.66	0.016

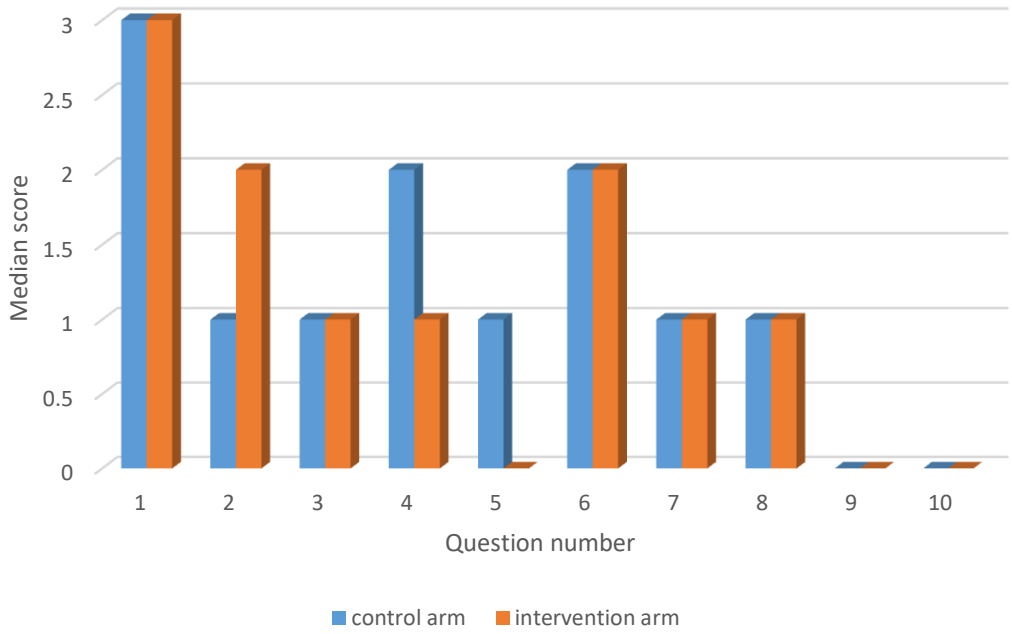
Patients were assessed based on self-efficacy questionnaire at the time of enrolment, after traditional discharge teaching and traditional discharge teaching along with simulation-based education in control group and intervention group respectively, then followed by assessment at 3 months follow up using same self-efficacy questionnaire. The response was recorded on a likert scale (0-4) for each question. Analysis was done using median and interquartile range (IQR) for both groups and comparison between two groups along with p value calculation was done Man Whitney U test.

1. **<u>Comparison of confidence and competence in managing seizures at home using self-efficacy in intervention and control arm at baseline</u>**

Table 5: Comparison of Self-efficacy in intervention and control arm at baseline

Question	Intervention arm Median (IQR)	Control arm Median (IQR)	P-value
1.How sure are you that you know when your child is having a seizure?	3(3-4)	3(2-4)	0.28
2.How sure are you that you can manage your child's seizure at home rather than driving your child to the emergency department?	2(1-3)	1(1-2)	0.032
3.How sure are you that you know when to drive your child to the emergency department when they are having a seizure?	1(0-2)	1(1-2)	0.278
4.How sure are you that you can protect your child from harm when having a seizure?	1(0-2)	2(1-3)	<0.01
5.How sure are you that you can place your child in the recovery position during a seizure?	0(0-2)	1(0-2)	0.12
6.How sure are you that you will carry the rescue medications on you at all times?	2(0-4)	2(1-3)	0.850
7.How sure are you that you can draw up the correct dose of rescue medication when your child is having a seizure?	1(0-3)	1(0-2)	0.890
8.How sure are you that you can follow the directions for administering the rescue medication correctly?	1(0-2)	1(0-2)	0.930
9.How sure are you that you know the common/emergent side effects of your child's rescue medications?	0(0-0)	0(0-1)	<0.01
10.How sure are you that you can assess your child's breathing during a seizure?	0(0-0)	0(0-1)	0.096

Figure : 6 Median score of each arm in self-efficacy queastionnare at baseline



There is no significant difference in median response between two arms in most of the questions at baseline, but there is significant difference in both the groups in question 2, in which intervention arm caregivers had a median response of 2 with IQR of 1-3 and control arm had median of 1 with IQR of 1-2 and a p value of 0.032(<0.05). Similarly in question 9, intervention group had median response of 0 with IQR of 0-0 whereas control arm had median response of 0 with IQR of 0-1, with a significant difference (p value<0.01). In question 4, control arm had a median response of 1 with IQR 1-2 and intervention arm had median of 1 with IQR 0-2. There is a significant difference between both groups in this question with a p value <0.01.

2. Comparison of confidence and competence in managing seizures at home using self-efficacy in intervention and control arm between both the arms after intervention and traditional discharge teaching respectively

Immediately after SBE and traditional discharge teaching and only traditional discharge teaching in intervention and control group respectively comparison of confidence and competence in managing seizures using self -efficacy questionnaire was done. There was a significant difference in median and IQR between two groups with a p value of <0.01.

Table 6: Comparison of Self-efficacy questionnaire in intervention and control arm between both the arms after intervention and traditional discharge teaching respectively

Question	Intervention arm Median (IQR)	Control arm Median (IQR)	P-value
1.How sure are you that you know when your child is having a seizure?	4(3-4)	3(3-4)	<0.01
2.How sure are you that you can manage your child's seizure at home rather than driving your child to the emergency department?	3(2-3)	2(2-3)	<0.01
3.How sure are you that you know when to drive your child to the emergency department when they are having a seizure?	3(2-3)	2(2-3)	<0.01
4.How sure are you that you can protect your child from harm when having a seizure?	3(3-4)	3(2-3)	<0.01
5.How sure are you that you can place your child in the recovery position during a seizure?	4(3-4)	3(2-3)	<0.01
6.How sure are you that you will carry the rescue medications on you at all times?	4(3-4)	3(3-4)	<0.01
7.How sure are you that you can draw up the correct dose of rescue medication when your child is having a seizure?	3(3-3)	2(2-3)	<0.01
8.How sure are you that you can follow the directions for administering the rescue medication correctly?	3(3-3)	2(2-3)	<0.01
9.How sure are you that you know the common/emergent side effects of your child's rescue medications?	2(2-3)	2(2-2)	<0.01
10.How sure are you that you can assess your child's breathing during a seizure?	2(2-3)	2(1-2)	<0.01

Figure 7: Median response of intervention and control arm in self-efficacy questionnare post intervention

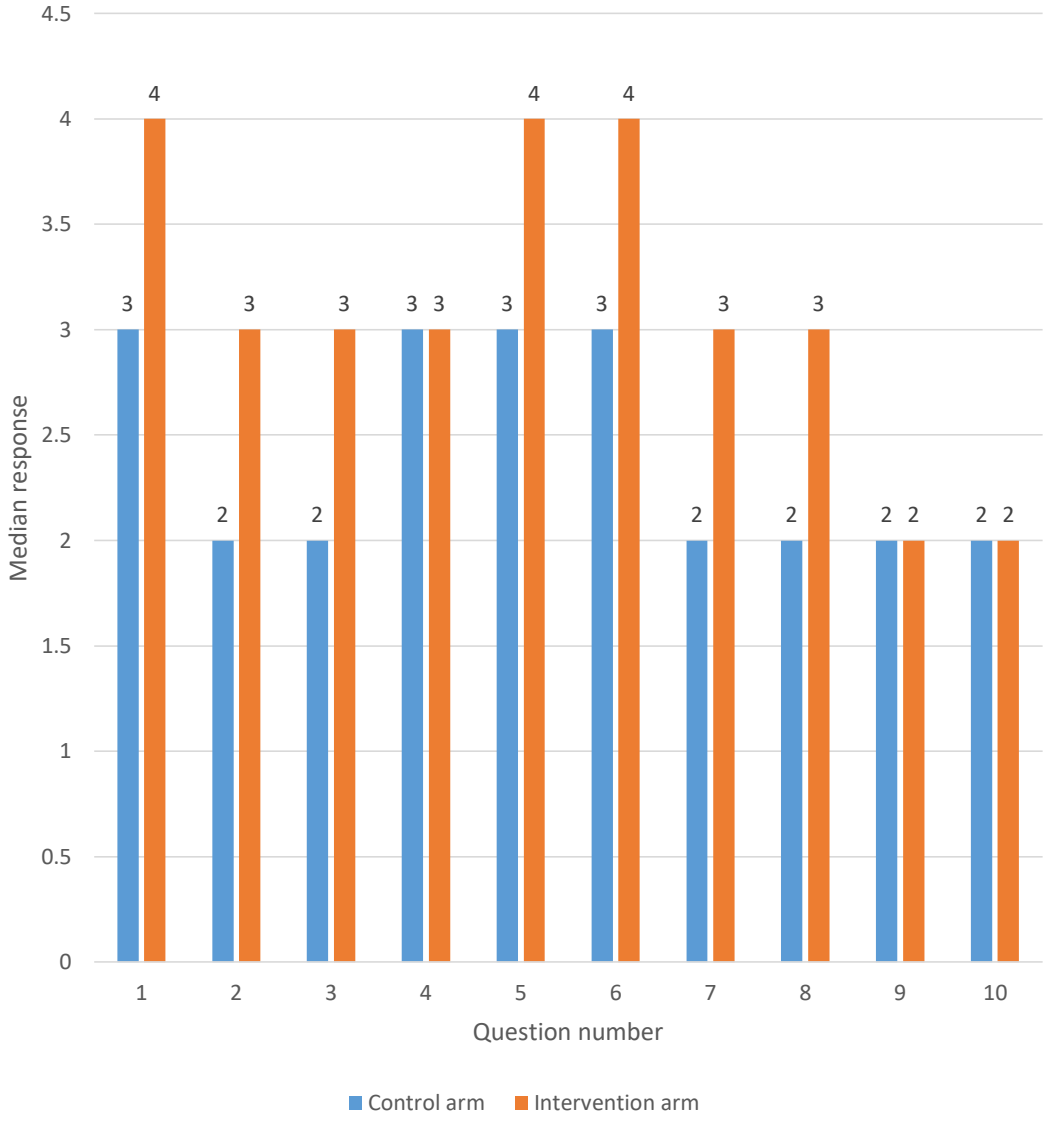


Table 7: Comparing intra arm self-efficacy questionnaire after intervention and traditional discharge teaching

Question	Control arm Median (IQR)		Intervention arm Median (IQR)	
	Pre test	Post test	Pre test	Post test
1.How sure are you that you know when your child is having a seizure?	3(2-4)	3(3-4)	3(3-4)	4(3-4)
2.How sure are you that you can manage your child's seizure at home rather than driving your child to the emergency department?	1(1-2)	2(2-3)	2(1-3)	3(2-3)
3.How sure are you that you know when to drive your child to the emergency department when they are having a seizure?	1(1-2)	2(2-3)	1(0-2)	3(2-3)
4.How sure are you that you can protect your child from harm when having a seizure?	2(1-3)	3(2-3)	1(0-2)	3(3-4)
5.How sure are you that you can place your child in the recovery position during a seizure?	1(0-2)	3(2-3)	0(0-2)	4(3-4)
6.How sure are you that you will carry the rescue medications on you at all times?	2(1-3)	3(3-4)	2(0-4)	4(3-4)
7.How sure are you that you can draw up the correct dose of rescue medication when your child is having a seizure?	1(0-2)	2(2-3)	1(0-3)	3(3-3)
8.How sure are you that you can follow the directions for administering the rescue medication correctly?	1(0-2)	2(2-3)	1(0-2)	3(3-3)
9.How sure are you that you know the common/emergent side effects of your child's rescue medications?	0(0-1)	2(2-2)	0(0-0)	2(2-3)
10.How sure are you that you can assess your child's breathing during a seizure?	0(0-1)	2(1-2)	0(0-0)	2(2-3)

3. Comparison in retention of knowledge using self-efficacy questionnaire in both the arms at 3 months follow up.

Comparison of confidence and competence in managing seizures using self -efficacy questionnaire was done Immediately after SBE and traditional discharge teaching and only traditional discharge teaching in intervention and control group respectively. There was a significant difference in median and IQR between two groups with a p value of <0.01

Table 8: Comparison of Self efficacy questionnaire at 3 months follow up in intervention arm and control arm.

Question	Intervention arm Median (IQR)	Control arm Median (IQR)	P-value
1.How sure are you that you know when your child is having a seizure?	4(3-4)	3(3-4)	0.025
2.How sure are you that you can manage your child's seizure at home rather than driving your child to the emergency department?	3(2-3)	2(1-3)	<0.01
3.How sure are you that you know when to drive your child to the emergency department when they are having a seizure?	3(2-3)	2(1-2)	<0.01
4.How sure are you that you can protect your child from harm when having a seizure?	4(3-4)	2(2-3)	<0.01
5.How sure are you that you can place your child in the recovery position during a seizure?	4(3-4)	2(2-3)	<0.01
6.How sure are you that you will carry the rescue medications on you at all times?	4(3-4)	2(1-3)	<0.01
7.How sure are you that you can draw up the correct dose of rescue medication when your child is having a seizure?	3(3-3)	1(1-2)	<0.01
8.How sure are you that you can follow the directions for administering the rescue medication correctly?	3(3-3)	1(1-2)	<0.01
9.How sure are you that you know the common/emergent side effects of your child's rescue medications?	2(2-2)	1(1-2)	<0.01
10.How sure are you that you can assess your child's breathing during a seizure?	2(2-3)	1(1-2)	<0.01

Figure 8 : Median score of control and intervention arm in self-efficacy questionnare at 3 months follow up

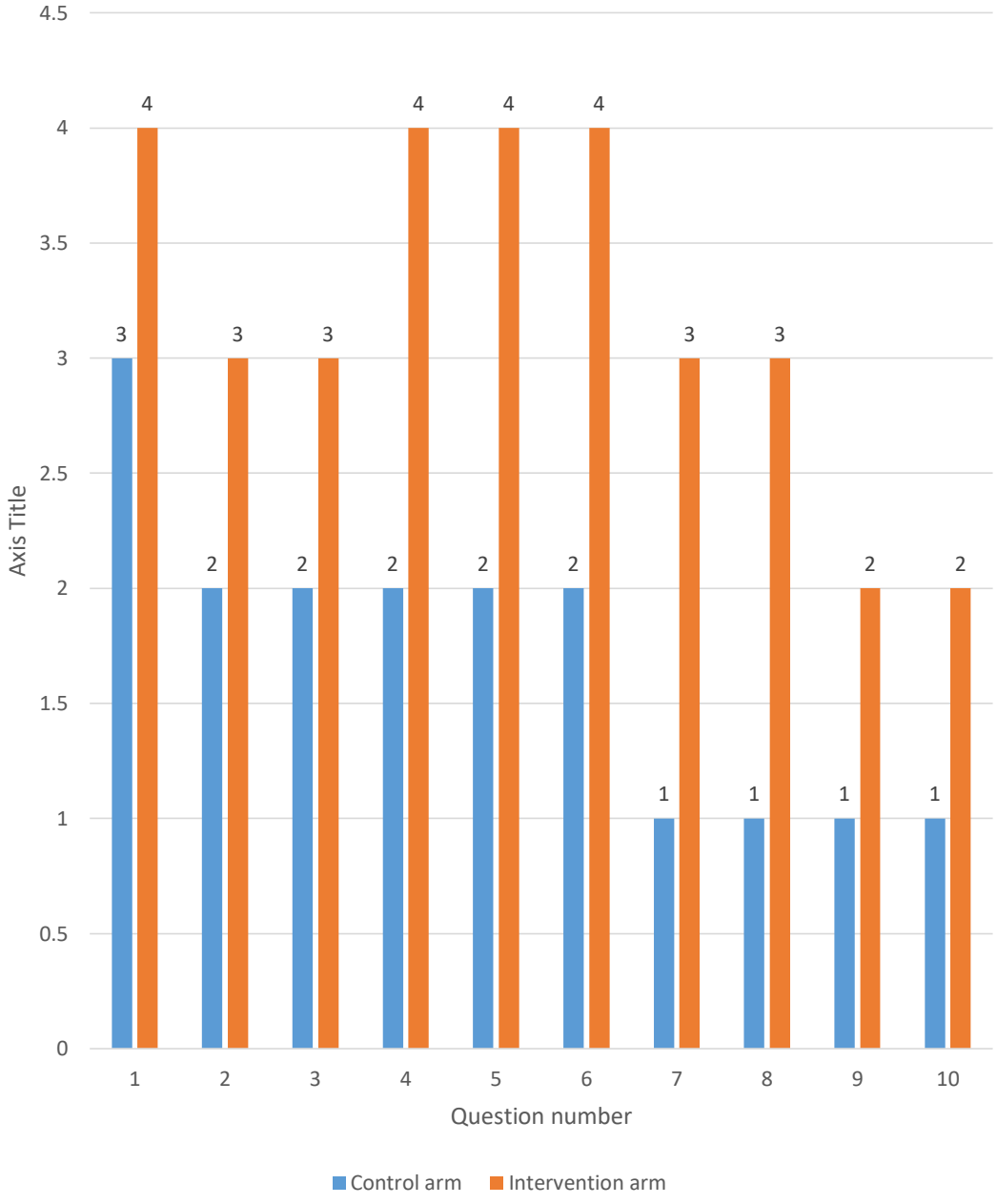


Figure 9: Comparing self efficacy questionnaire in control and intervention arm at all intervals (Question 1-5)

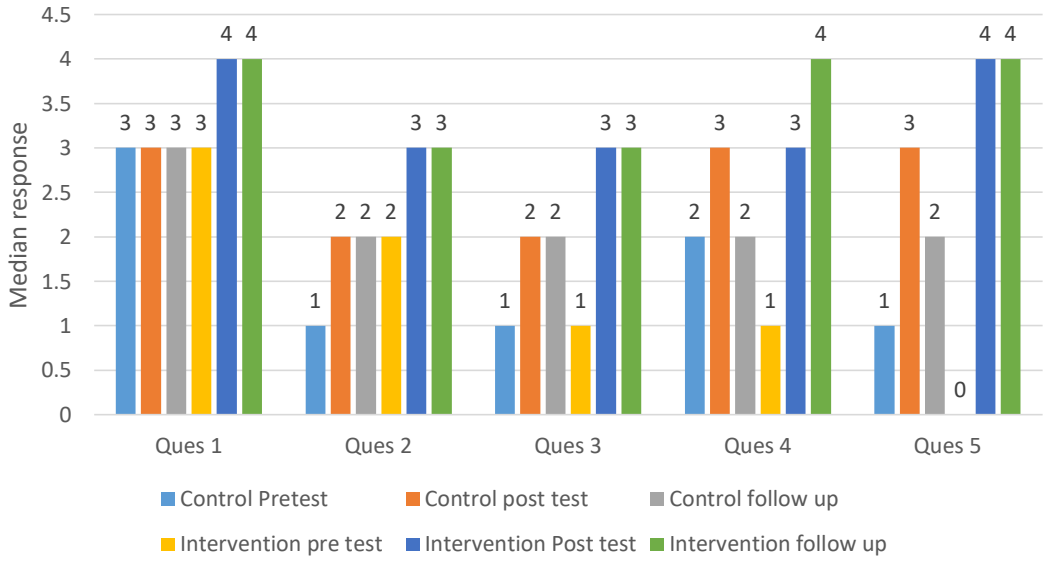
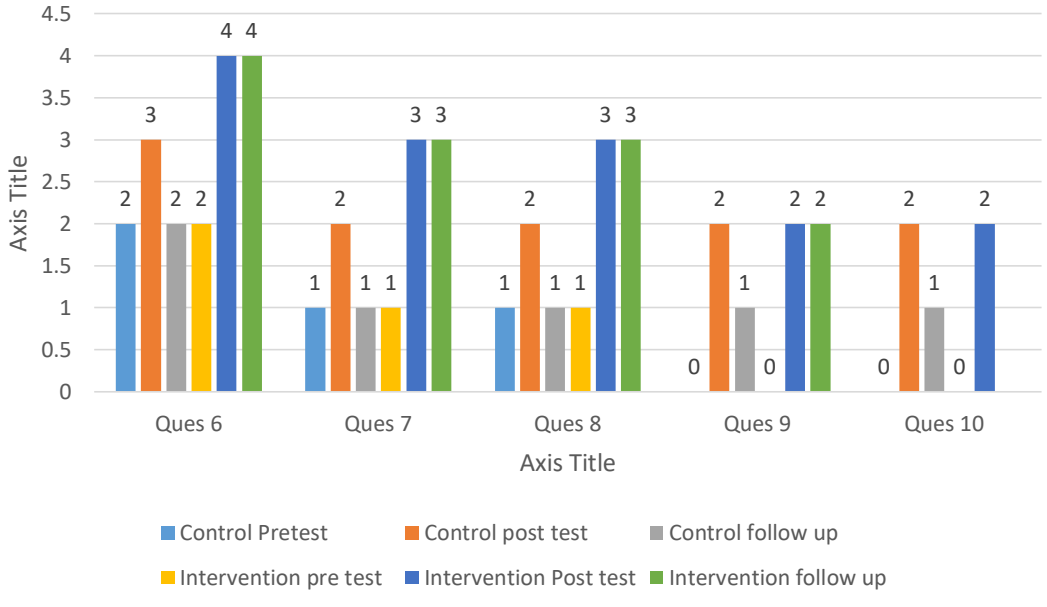


Figure 10: Comparing self efficacy questionnaire in control and intervention arm at all intervals (Question 6-10)

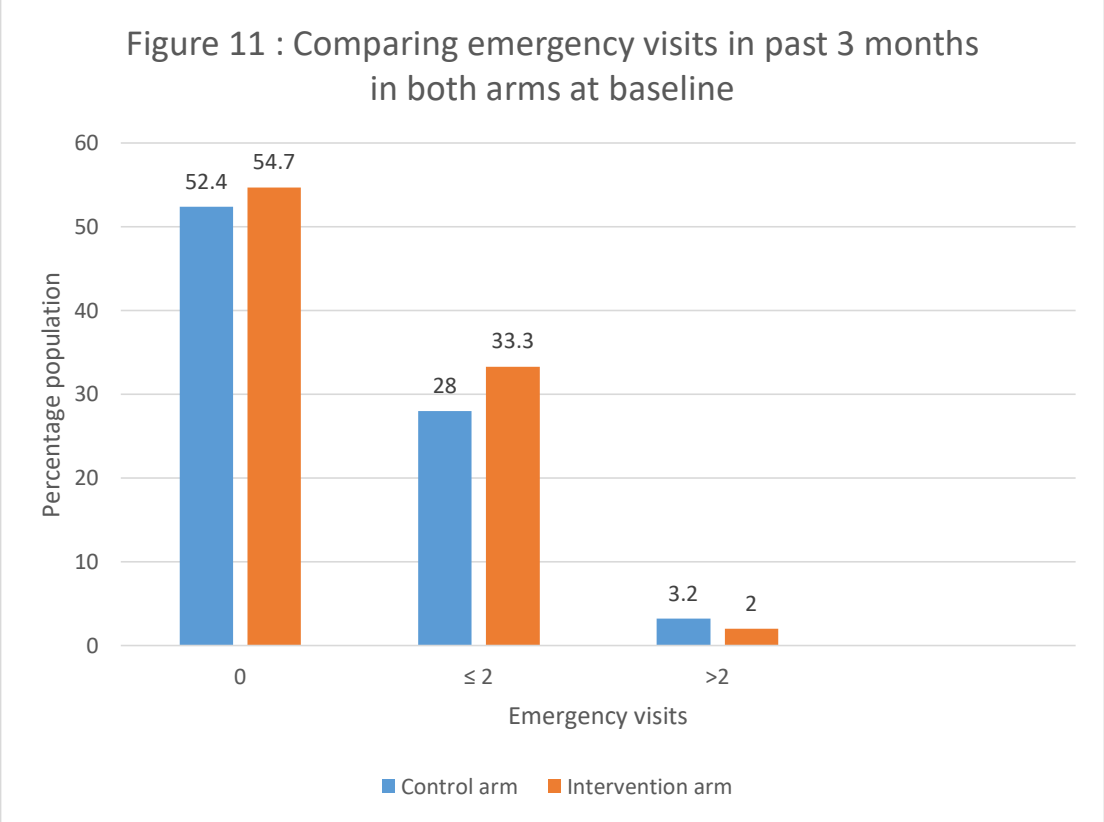


4. Comparison of emergency visits in past 3 months in both arms at baseline

There was no significant difference in number of emergency visits in past 3 months according to baseline data expressed by p value of 0.411.

Table 9: Comparing emergency visits in past 3 months in both arms at baseline

Number of visits	Control N (%)	Intervention N (%)	P value
0	33(52.4%)	33(54.7%)	0.411
≤ 2	28(44.4%)	17(33.3%)	
>2	2(3.2%)	1(2%)	

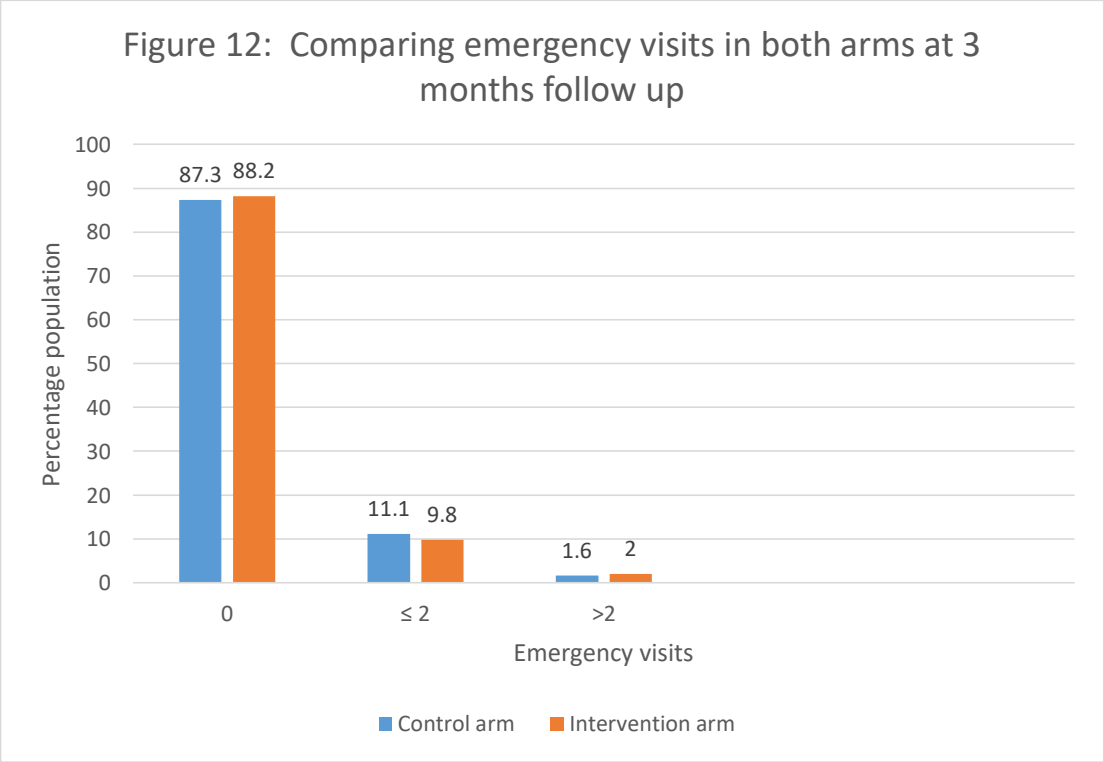


5. Comparison of emergency visits in both arms at 3 months follow up

At 3 months follow up, after intervention and traditional discharge teaching in intervention and control group respectively, number of emergency visits were assessed in both groups and compared. There was no significant difference among both the groups (p value = 0.965).

Table 10: Comparing emergency visits in both arms at 3 months follow up

Number of visits	Control N(%)	Intervention N(%)	P value
0	55(87.3%)	45(88.2%)	0.965
≤ 2	7(11.1%)	5(9.8%)	
>2	1(1.6%)	1(2%)	



DISCUSSION

This study assessed the changes in the confidence and competence of caregivers in management of seizures at home after simulation-based intervention. The study was performed at Department of Pediatrics, Pediatric Ward and Pediatric OPD, AIIMS Jodhpur. Education was provided to two arms, in one using traditional written discharge instructions which were verbally explained and given to caregivers and in another group using simulation-based teaching along with traditional written discharge instructions. A total of 114 caregivers were enrolled in the study. They were randomly assigned to each arm (control, n=63; intervention, n=51).

In baseline demographics there was a significant difference between age of the patient, duration of disease in patient and caregiver age. The difference in age of the patient does not have an impact on the results as questionnaire was meant for their caregivers. Although there was a difference in the age of caregivers as well, however, contrary to our prediction, older adults show similar rates of learning as indexed by a configural learning score compared to young adults. These results suggest that the ability to acquire knowledge incidentally about configural response relationships is largely unaffected by cognitive aging (26).

The results of our study showed an increase in confidence and competence of caregivers in managing seizures after simulation-based training. In all the aspects evaluated by the questionnaire there was significant difference between the intervention and control arm. Although there was a chance that participants in both the arms might have some difference in previous knowledge about seizure management, which was eliminated by randomization. Analysis showed no significant difference in the baseline knowledge between the two arms as shown by p value <0.05 in most questions. In the pretest questionnaire control arm had least score in question 9 and 10 which assess the knowledge of caregiver about common/emergent side effects of rescue medications and their confidence in assessing their child's breathing during a seizure respectively, which was also same for the intervention arm, while highest score for both arms was in question 1 assessing their ability to recognize seizure. In post-test questionnaire control arm had least score in question 10 and highest in question 1 and question 6 that is confidence of carrying the rescue medications at all times, in comparison to intervention arm which had least score in post-test

questionnaire in 9 and 10 and highest score in question 1, 5(placing their child in recovery position) and 6. In medical literature, there are many studies done using simulation done on health care practitioner but there are very less such studies on caregivers that too of patients with seizures. As compared to study by Siaglet et al (2) where the results showed in the control and experimental groups, pretest mean item scores on the self-efficacy questionnaire were lowest for knowledge of rescue medication side effects (question 9) and highest for carrying rescue medications at all times (question 6). On the post-test, self-efficacy questionnaire mean scores for participants in the control group were lowest for managing the seizure at home (question 2) and highest for following directions for administration of rescue medications (question 8). In the experimental group, mean item scores on the post-test self-efficacy were lowest for question 2 and highest for knowing when to drive the child to the emergency department (question 3) (2).

A comparison between control and intervention arm after traditional teaching and intervention showed significant improvement in intervention arm reflected by an increase in the median response in questions and p value of <0.05 in all the questions of self-efficacy questionnaire. This observation was congruent with the results of study done by Siaglet et al (2). While intervention arm had more improvement, control arm also had significant improvement from baseline, which can be explained by the fact that there was minimal baseline knowledge about seizure management in both the groups which was supplemented by the discharge instructions explained to them. These results were congruent with study by Gholami, et. al in 2016 which concluded; supportive educational program can increase in maternal awareness about how to care, causes for recurrence, and measures taken in emergency stages of epilepsy through gradual strengthening of the sense of self-reliance and problem-solving abilities to promote mothers' self-efficacy (27).

When compared at 3 months follow up there was significant difference between the retention of knowledge and confidence of caregivers in both arms, as intervention arm was more confident in managing seizures at home, keeping the child in recovery position while protecting from harm and regarding the use of rescue medications. These results are also congruent with study by Siaglet et al (2).

Although there was no significant difference in the decrease in number of emergency visits in both the groups at follow up. But there was significant proportion of increase

in the number of patients who had no emergency visits at follow up in both the arms, which could be explained by the fact that both arms received knowledge about the use of rescue medications and management of seizures at home in some way, which was lacking in both arms at baseline. It has been proven that parents are more satisfied when services are provided in a family-centered manner. Satisfaction with service is important because it has been shown to increase adherence to treatment recommendations and to lead to fewer parental feelings of distress and depression and improved well-being (28).

Only a small number of studies were identified that address "head-to-head" comparative effectiveness of SBE with traditional clinical education or a pre-intervention baseline. There is no doubt that SBE is superior to traditional clinical education for acquisition of a wide range of medical skills in health care practitioners (29). However, to our knowledge, the present study was among the few studies to examine its efficacy for supporting PFCC, in this case traditional seizure teaching in this population of caregivers. The significantly higher scores related to seizure management behaviors demonstrated by caregivers who received the simulation-based education were congruent with the teaching focus. The development, implementation, and evaluation of simulation-based education for patients, caregivers, and families is a new and growing field. A unique aspect of educating non-healthcare caregivers is fostering PFCC through simulation-based training.

Scenario simulation teaching has both advantages and limitations. Clinical scenarios allow learners to have training in advance to narrow the gap between theory and practice. However, simulation-based education cannot completely replace real clinical practice. After the learners make a decision according to the scenario, the instructors have to discuss the correct management strategy and provide timely feedback (23).

The present study had several limitations. The first was the small sample size and the unequal number of participants in each arm. As it was a study with simple randomization and allocation was according to enrollment, unequal size could be explained. The second limitation rests in the intervention tool. The tool used was pediasim-Manikin which is routinely used for training in pediatric emergency procedures, but it does not have an in-built simulation for seizures, for which local modification was done, so it served as a low fidelity simulation. The third limitation was the lack of control of traditional seizure teaching. The final limitation resides in

the sustainability of our findings over time by having participants be evaluated over time intervals.

CONCLUSION

The present study studied the impact of simulation-based education for improving caregiver competence and confidence with seizure management. Our findings suggest a significant increase in caregiver competence and confidence in managing seizures when traditional seizure discharge teaching administered is supplemented with simulation-based education. It showed that retention of knowledge is better in intervention arm. Even though in this study there was no much difference in reduction of emergency visits at follow-up in both arms, but could be explained by the short time to follow-up and could be improved by deliberate practice using simulation.

Additionally, more well-designed RCTs are needed to better assess the effects of SBE in caregivers, and the follow-up time should be much longer. These findings are instructive for clinical practice.

SUMMARY

Background: Most of the paediatric seizures occur in the outpatient setting, where family members act as primary caregivers; proper intervention by them can lead to better management, decreased morbidity and decreased chances of progressing to status epileptics. Traditionally, during discharge only verbal teaching is done about seizure management. Simulation-based education (SBE) on paediatric seizure management was shown to be useful for paramedics and medical staff working in emergency departments. However, there is only one study on the effect of simulation-based education on confidence and competence of primary caregivers to manage seizures at home, that too in a developed country.

Methodology: This is a double-arm randomized controlled trial done in our tertiary care centre. Total 114 Participants were enrolled and assigned to a control arm(n=63) receiving traditional seizure discharge teaching alone and an intervention arm(n=51) receiving the traditional discharge teaching and SBE after randomization. Participants in both groups completed a self-efficacy questionnaire after enrolment, post-intervention, and three months after the intervention. The aim was to study the effect of SBE on the confidence and competence of caregivers in managing seizures at home. The secondary objectives are to compare the retention of knowledge after three months and the reduction in emergency visits in both arms.

Results: There was significant increase in the confidence of caregivers after SBE showed by a p value <0.01in all questions of self-efficacy questionnaire. Also, there was significant increased retention of knowledge tested by self-efficacy questionnaire at 3 months follow-up with p value<0.05. But there was no significant difference in the number of emergency visits on follow up (p value:0.96).

Conclusion: Simulation-based education can be used to train caregivers to manage seizures at home as it increases their confidence in managing seizures and retention of knowledge.

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Annexure-I

All India Institute of Medical Sciences, Jodhpur

CONSENT FORM

Title: Impact of simulation-based intervention on domestic care of seizures in children by primary caregivers- a randomized control study

Investigators:

Dr. Sanjana; Junior Resident, Department of Pediatrics

Dr. Kuldeep Singh, Professor and Head, Department of Pediatrics

I…….. (father/mother/guardian) of …….....UHID No…… have been explained about the nature of the study in my own language. I have read and understood this consent form and the information provided to me. I was free to ask any questions and they have been answered. I have been explained about the risks and benefits to my child associated with participation in the study and I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my baby's future treatment in the hospital. I am also aware that the investigators may terminate participation of my child in the study at any time, for any reason, without my consent. I have decided for the participation of my child in the research study. I am aware, that if I have any questions during this study, I should contact at one of the addresses listed above. By signing this consent from, I attest that the information given in this document has been clearly explained to me and apparently understood by me. So, I hereby give consent for inclusion of my child in the above explained study program.

Signature of the patient: **Signature of the guardian:**

Signature of witness-1: **Signature of witness-2:**

Name: Name:

Signature of investigator: Date:

अनुबंध 1

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर

सहमति पत्र

शीर्षक**:** सिमुलेशन आधारित प्रशिक्षण का अभिभावकों द्वारा घरेलू मिरगी रोकथाम पर प्रभाव – एक यादृच्छिक नियंत्रण अध्ययन

जांचकर्ता:

Dr. Sanjana; Junior Resident, Department of Pediatrics

Dr. Kuldeep Singh, Professor and Head, Department of Pediatrics

मुझे…… .. (पिता / माता / अभिभावक) ……। UHID No …… मेरी अपनी भाषा में अध्ययन के स्वरूप के बारे में बताया गया है।मैंने इस सहमति पत्र और मुझे प्रदान की गई जानकारी को पढ़ और समझ लिया है।मैं किसी भी प्रश्न को पूछने के लिए स्वतंत्र था और उनका उत्तर दिया गया है। मुझे अध्ययन में भाग लेने से जुड़े अपने बच्चे को होने वाले जोखिमों और लाभों के बारे में समझाया गया है और मुझे इस तथ्य की जानकारी है कि मैं बिना किसी कारण के किसी भी समय अध्ययन से बाहर निकल सकता हूं और इस से मेरे बच्चे के भविष्य में इलाज पर कोई असर नहीं पड़ेगा । मुझे यह भी पता है कि जांचकर्ता मेरी सहमति के बिना, किसी भी समय, किसी भी कारण से अध्ययन में मेरे बच्चे की भागीदारी को समाप्त कर सकते हैं। मैंने शोध अध्ययन में अपने बच्चे की भागीदारी के लिए निर्णय लिया है। मुझे पता है, कि अगर इस अध्ययन के दौरान मेरे कोई प्रश्न हैं, तो मुझे ऊपर सूचीबद्ध एक पतेपर संपर्क करनाचाहिए।इस सहमति पर हस्ताक्षर करने से, मैं इस बात पर ध्यान देता हूं कि इस दस्तावेज़ में दी गई जानकारी मुझे स्पष्ट रूप से बताई गई है और मेरे द्वारा स्पष्ट रूप से समझी गई है। इसलिए, मैं उपरोक्त वर्णित अध्ययन कार्यक्रम में अपने बच्चे को शामिल करने के लिए सहमति देता हूं।

हस्ताक्षर:

गवाह -1 काहस्ताक्षर: गवाह -2 केहस्ताक्षर:

नाम:

अन्वेषककाहस्ताक्षर: दिनांक:

Annexure-II

All India Institute of Medical Sciences, Jodhpur

Patient Information Sheet

Title: "**Impact of simulation-based intervention on domestic care of seizures in children by primary caregivers- a randomized control study"**

Introduction: This statement describes the purpose, procedures, benefits, risks and discomforts of the study and your right to withdraw from the study at any point of time.

Purpose:

1. To study the effect of simulation-based teaching intervention on the confidence and competence of caregivers in managing seizures at home.

Study Procedure: Your relevant clinical history will be recorded, you will be asked to fill self-efficacy questionnaire during enrollment, after which u will be randomly allocated to two groups. Based on that you will be either given traditional discharge teaching or simulation-based education along with traditional discharge teaching and you will be asked to fill the self-efficacy questionnaire post intervention and at 3 months post intervention.

Benefits: No monetary benefits will be given to you. However, any new information that can come to light regarding any findings in the study will help in further management of the disease and help all other ailing patients suffering from this problem.

Confidentiality: Records of your study participation will be kept confidential, under safe custody. Any publication of data will not identify you by name. By signing the consent form you authorize the sharing of your study related medical records to the regulatory authorities and the Institutional Ethical Committee.

Information regarding withdrawal: You have the right to withdraw yourself from the study at any time during the course of the study.

Contact for additional information: Any time during or after the study, you can obtain further information about the study from Dr. Sanjana, All India Institute of Medical Science, Jodhpur, and Rajasthan.

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर

रोगी सूचना पत्र

शीर्षक:"प्राथमिक देखभालकर्ताओं द्वारा बच्चों में मिर्गी की घरेलू देखभाल पर सिमुलेशन-आधारित हस्तक्षेप का प्रभाव- एक यादृच्छिक नियंत्रणअध्ययन।"

परिचय: यह कथनअध्ययन के उद्देश्य, प्रक्रियाओं, लाभों, जोखिमों और असुविधाओं और किसी भी समयअध्ययन से हटने के आपके अधिकार का वर्णन करताहै।

उद्देश्य:

1. घर पर मिर्गी को प्रबंधित करने में देखभाल करने वालों के आत्मविश्वास और क्षमता पर सिमुलेशन-आधारित शिक्षण हस्तक्षेप के प्रभाव का अध्ययन करना।

अध्ययनप्रक्रिया: आपका प्रासंगिक नैदानिक इतिहास दर्ज किया जाएगा, आपको नामांकन के दौरान स्व-प्रभाव कारिता प्रश्नावली भरने के लिए कहा जाएगा, जिसके बाद आपको दो समूहों में यादृच्छिक रूप से आवंटित किया जाएगा।इसके आधार पर आपको पारंपरिक डिस्चार्ज शिक्षण या तो पारंपरिक डिस्चार्ज शिक्षण के साथ सिमुलेशन आधारित शिक्षा दी जाएगी और आपको स्व-प्रभाव कारिता प्रश्नावली हस्तक्षेप के बाद और 3 महीने के बाद भरने के लिए कहा जाएगा।

लाभ:कोई मौद्रिक लाभ आपको नहीं दिया जाएगा।हालांकि, किसी भी नई जानकारी जो अध्ययन में किसी भी निष्कर्ष के बारे में प्रकाश में आ सकती है, बीमारी के आगे प्रबंधन में मदद करेगी और इस समस्या से पीड़ित अन्य सभी बीमार रोगियों की मदद करेगी

गोपनीयता:सुरक्षित अभिरक्षा के तहत, आपके अध्ययन की भागी दारी के रिकॉर्ड को गोपनीय रखा जाएगा। डेटा का कोई भी प्रकाशन आपको नाम से नहीं पहचानेगा। सहमति पत्र पर हस्ताक्षर कर के आप नियामक अधिकारियों और संस्थागत नैतिक समिति को अपने अध्ययन से संबंधित मेडिकल रिकॉर्ड को साझा करने कोअधिकृत करते हैं।

वापसी के बारे में जानकारी: आपको अध्ययन के दौरान किसी भी समय अध्ययन से खुद को वापस लेने का अधिकार है।

अतिरिक्त जानकारी के लिए संपर्क करें: अध्ययन के दौरान या बाद में किसी भी समय, आप डॉ संजना, अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर, राजस्थान से अध्ययन के बारे में अधिक जानकारी प्राप्त कर सकते हैं।

ANNEXURE III

All India Institute of Medical Sciences, Jodhpur

Case Record Form

Sr. No. AIIMS/JDH/____/_____

Date:

1. Name of patient:
2. Age/sex of patient:
3. Details of caregiver:

	Caregiver 1	Caregiver 2	Caregiver 3	Caregiver4
Name				
Age/sex				
Relation to patient				
Education status				
Occupation				

4. Total duration of disease:
5. Age at onset of disease:
6. Treatment receiving:
7. Frequency of use of rescue medicines:
8. Any history of status epilepticus episodes:
9. Emergency department visits in last 3 months:
10. Clinical features at presentation:

Address: Contact number:

Any past episodes of seizures Y/N

PAST HISTORY: Any past hospitalizations Y/N

TREATMENT HISTORY: For __ Years

FAMILY HISTORY OF EPILEPSY Y/N

ANNEXURE IV

KidSIM-ASPIRE Parent Seizure Self-Efficacy Questionnaire

Kindly answer the following questions related to disease of your child and your knowledge about it. Select one of the following options:

0-Not confident at all,

2-somewhat confident,

4- Very confident

1. How sure are you that you know when your child is having a seizure?

0. ☐ 1. ☐ 2. ☐ 3. ☐ 4. ☐

2. How sure are you that you can manage your child's seizure at home rather than driving your child to the emergency department?

0. ☐ 1. ☐ 2. ☐ 3. ☐ 4. ☐

3. How sure are you that you know when to drive your child to the emergency department when they are having a seizure?

0. ☐ 1. ☐ 2. ☐ 3. ☐ 4. ☐

4. How sure you that you can protect your child from are harm when having a seizure?

0. ☐ 1. ☐ 2. ☐ 3. ☐ 4. ☐

5. How sure are you that you can place your child in the recovery position during a seizure?

0. ☐ 1. ☐ 2. ☐ 3. ☐ 4. ☐

6. How sure are you that you will carry the rescue medications on you at all times?

0. ☐ 1. ☐ 2. ☐ 3. ☐ 4. ☐

7. How sure are you that you can draw up the correct dose of rescue medication when your child is having a seizure?

0. ☐ 1. ☐ 2. ☐ 3. ☐ 4. ☐

8. How sure are you that you can follow the directions for administering the rescue medication correctly?

0. ☐ 1. ☐ 2. ☐ 3. ☐ 4. ☐

9. How sure are you that you know the common/emergent side effects of your child's rescue medications?

0. ☐ 1. ☐ 2. ☐ 3. ☐ 4. ☐

10. How sure are you that you can assess your child's breathing during a seizure?

0. ☐ 1. ☐ 2. ☐ 3. ☐ 4. ☐

अनुबंध 4

KidSIM- प्रश्नावली

अपने बच्चे की बीमारी और इसके बारे में आपके ज्ञान से संबंधित निम्नलिखित सवालों के जवाब दें। निम्न विकल्पों में से एक का चयन करें जहां

0- बिल्कुल भी विश्वास नहीं है,

2-कुछ हद तक विश्वास है,

4- पूर्ण विश्वास है

1. जब आपके बच्चे को दौरा होता है तो आप कितने यकीन से उस दौरे को पहचान सकते हैं?

0. ☐ 1. ☐ 2.☐ ☐ ☐

2. आप कितने विश्वास के साथ दौरे के समय बच्चे को अस्पताल लiने की बजाय घर पर ही मिर्गी का उपचार कर सकते हैं?

0. ☐ 1. ☐ 2.☐ ☐ ☐

3.जब आपके बच्चे को दौरा आता है तो आपको कितने विश्वास के साथ पता है की कब उसे अस्पताल लाना है?

0. ☐ 1. ☐ 2.☐ ☐ ☐

4.दौरे के दौरान होने वाली हानि या चोट से अपने बचे को बचाने में आप कितने सक्षम हैं?

0. ☐ 1. ☐ 2.☐ ☐ ☐

5. दौरे के दौरान आप अपने बचे को रिकवरी पोजीशन (सही अवस्था) में लiने में कितने सक्षम हैं?

0. ☐ 1. ☐ 2.☐ ☐ ☐

6. आप कितने विश्वास के साथ कह सकते हैं की आप हर समय अपने साथ दौरे की बचाव की दवाएं रखेंगे ?

0. ☐ 1. ☐ 2.☐ ☐ ☐

7. आप कितने विश्वास से बच्चे को दौरे के दौरान सही मात्रा में बचाव की दवाई दे सकते हैं?

0. ☐ 1. ☐ 2. ☐ ☐ ☐

8. आप कितने विश्वास के साथ कह सकते हैं की आप दौरे की बचाव दवाएं देने के निर्देशों का सही पालन करते हैं?

0. ☐ 1. ☐ 2. ☐ ☐ ☐

9. आप कितने विश्वास से कह सकते हैं की आपको बच्चे की दौरे की इमरजेंसी दवाओं के साइड इफेक्ट्स की जानकारी है?

0. ☐ 1. ☐ 2. ☐ ☐ ☐

10. जब आपके बच्चे को दौरा पड़ रहा है उस समय बच्चा साँस ले रहा है या नहीं ये आप कितने विश्वास से कह सकते हैं?

0. ☐ 1. ☐ 2. ☐ ☐ ☐

ANNEXURE V

Discharge instructions for caregivers of patients with seizure

At the time of seizure:

1. Keep child on a flat surface with safe surroundings.
2. Remove anything like sharp/ hard objects which might hurt the child.
3. Stay calm and don't try to restrain any movement.
4. Record the timing of seizure, any provoking factor, type and duration of seizure.
5. Place your child in recovery position.
6. Don't try to give any oral medication, water or food until seizure subsides and child is completely conscious.
7. Don't try to put your hand/ any object in child mouth and don't try to hold his/her tongue.
8. Assess breathing pattern/skin colour/ pulse of child.
9. If seizure lasting for more than 2 minutes use rescue medication.
10. Draw correct dose and administer half dose in each nostril.
11. When to call ambulance: persistent seizure >5 mins, recurrent seizure episodes, change in type of seizure trouble breathing, not regaining consciousness, any injury sustained during seizure.

General instructions:

1. Don't let the child remain unaccompanied or let him/her participate in activities like adventure sports, swimming or driving
2. Give anti- seizure medication regularly
3. Don't change dose or brand of medication without consulting physician
4. Always keep rescue medication with you
5. Common Side effects of rescue medicine: Nose or throat irritation, light-headedness, headache, blurring of vision, slurred speech, runny nose
6. Symptoms of overdose: confusion, lack of coordination, loss of consciousness, excessive drowsiness, muscle weakness

अनुबंध 5

दौरे के रोगियों की देखभाल करने वालों के लिए छुट्टी निर्देश

दौरे के समय:

1. बच्चे को सुरक्षित वातावरण में समतल सतह पर रखें।

2. बच्चे को चोट पहुँचाने वाली नुकीली/कठोर वस्तु जैसी कोई भी चीज़ हटा दें।

3. शांत रहें और किसी भी गतिविधि को रोकने की कोशिश न करें।

4. जब्ती का समय, कोई उत्तेजक कारक, जब्ती का प्रकार और अवधि रिकॉर्ड करें।

5. अपने बच्चे को सही अवस्था में रखें।

6. जब तक दौरा कम न हो जाए और बच्चा पूरी तरह से होश में न आ जाए, तब तक कोई भी मौखिक दवा, पानी या भोजन देने की कोशिश न करें।

7. बच्चे के मुंह में अपना हाथ/कोई वस्तु डालने की कोशिश न करें और उसकी जीभ को पकड़ने की कोशिश न करें।

8. बच्चे के सांस लेने के पैटर्न/त्वचा के रंग/नाड़ी का आकलन करें।

9. यदि 2 मिनट से अधिक समय तक दौरे पड़ते हैं तो बचाव दवा का उपयोग करें।

10. सही खुराक लें और प्रत्येक नथुने में आधी खुराक डालें।

11. एम्बुलेंस को कब कॉल करें: लगातार दौरे> 5 मिनट, बार-बार दौरे पड़ने, दौरे के प्रकार में बदलाव, सांस लेने में परेशानी, होश में न आना, दौरे के दौरान लगी कोई चोट।

<u>सामान्य निर्देश:</u>

1. बच्चे को अकेले न रहने दें या उसे साहसिक खेल, तैराकी या ड्राइविंग जैसी गतिविधियों में भाग लेने न दें।

2. दवा नियमित रूप से दें

3. चिकित्सक की सलाह के बिना दवा की खुराक या ब्रांड में बदलाव न करें

4. बचाव दवा हमेशा अपने पास रखें

5. बचाव दवा के सामान्य दुष्प्रभाव: नाक या गले में जलन, हल्का सिर दर्द, सिरदर्द, दृष्टि का धुंधलापन, नाक बहना

6. ओवरडोज के लक्षण: भ्रम, चेतना की हानि, अत्यधिक उनींदापन, मांसपेशियों में कमजोरी

ANNEXURE VI

EHTICAL CLEARANCE CERTIFICATE

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2021/3562 Date: 12/03/2021

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2021/3397**

Project title: **"Impact of simulation-based intervention on domestic care of seizures in children by primary caregivers: a randomized control study"**

Nature of Project:	**Research Project Submitted for Expedited Review**
Submitted as:	**M.D. Dissertation**
Student Name:	**Dr.Sanjana**
Guide:	**Dr. Kuldeep Singh**
Co-Guide:	**Dr. Bharat Choudhary & Dr. Manoj Kumar Gupta**

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.
- In case of any issue related to compensation, the responsibility lies with the Investigator and Co-Investigators.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the PI may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation.

If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member Secretary

Member secretary
Institutional Ethics Committee
AIIMS Jodhpur

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