



DEVELOP, VALIDATE AND EVALUATE EFFICACY OF MOBILE APPLICATION FOR SCREENING AND IDENTIFYING AUTISTIC SPECTRUM DISORDER (ASD) AMONG CHILDREN AGED FROM 16 TO 30 MONTHS BY FRONTLINE HEALTH WORKERS - PILOT STUDY

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ABSTRACT

Background: Identifying developmental delay can be a significant obstacle due to the absence of appropriate screening tests that effectively capture differences and incorporate cultural beliefs when explaining disabilities. This creates a major challenge in accurately identifying and addressing developmental delays, which can ultimately hinder the ability of individuals to receive the necessary interventions and support they require. **Aim:** Aim of the research work is to Develop Validate and Evaluate the effectiveness of Mobile application for Screening and Identifying Autistic Spectrum Disorder (ASD) among Children aged from 16 to 30 months by Frontline Health workers in view of early referral and interventional services. **Material and Method:** A randomized controlled study will be conducted for children between the ages of 16 to 30 months in the adopted villages of the community departments of the Wardha district. To collect quantitative data, frontline healthcare workers will undergo training to administer Mobile Application based Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA) through a mobile application to the experimental group, while a paper-based version of the M-CHAT-R will be used for the control group. The screened children will undergo a gold standard diagnostic tool to confirm the diagnosis. The effectiveness of the Mobile Application based Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA) will be assessed based on the number of false positive and True negative cases. **Results:** The analysis of the study's findings will be conducted by analyzing both the baseline and end-line data. This will be accomplished by utilizing descriptive and inferential statistical techniques, including the Chi-square test. Through the application of these methods, the study's outcomes will be accurately measured and interpreted, providing insight into the effectiveness of the mobile application for screening and identifying ASD in young children. The data analysis will be conducted with a high level of rigor and attention to detail, ensuring that the results obtained are reliable and robust. **Conclusion:** The implementation of a mobile application for screening and identifying Autistic Spectrum Disorders (ASD) by frontline health workers will significantly increase accessibility and coverage, leading to improved healthcare system for early identification of developmental delays. This innovative solution has the potential to reduce the burden on healthcare delivery systems, while simultaneously enhancing the quality of life for children with ASD. Early identification and intervention will enable children to receive the necessary support and resources for a more effective and minimal assistive life. Therefore, this work is of utmost importance in advancing the field of healthcare and improving the lives of those with developmental delays.

KEYWORDS : Autistic spectrum disorder, MCHAT-R, Mobile Application based Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA), Frontline health workers

INTRODUCTION

Autistic Spectrum Disorder (ASD) is a neurodevelopmental disorder that affects communication, social interaction, and behavior. It is estimated that one in 54 children is diagnosed with ASD, making it one of the most prevalent developmental disorders in the world [1]. The early identification and intervention for ASD can significantly improve the outcomes and quality of life for individuals with ASD. However, the identification of ASD in young children can be challenging due to the variability in symptoms and the lack of reliable screening tools.

The American Academy of Paediatrics (AAP) recommends the use of standardized screening tools for ASD during routine well-child visits at 18 and 24 months of age [2]. The Modified Checklist for Autism in Toddlers, revised (M-CHAT-R) is one of the most widely used screening tools for ASD in young children. The M-CHAT-R is a 20-item questionnaire that is completed by parents or caregivers and can be administered in a variety of settings, including primary care clinics, childcare centers, and preschools [3].

Despite the availability of standardized screening tools like M-CHAT-R, the identification of ASD in young children remains a significant challenge. One of the primary barriers to early identification is the lack of accessibility to reliable screening tools, particularly in low- and middle-income countries (LMICs) where resources and trained professionals are often limited [4]. In addition, cultural beliefs and stigma around developmental disabilities can also be a barrier to early identification and intervention [5].

Mobile health (mHealth) technologies have the potential to overcome some of these barriers to early identification and intervention for ASD. Mobile applications (apps) can be easily accessed and used by parents, caregivers, and frontline health workers, and can provide a standardized and reliable screening tool for ASD. In addition, mobile apps can be used to provide education and resources for parents and caregivers, as well as facilitate early referral and intervention for children with ASD.

Several studies have investigated the use of mobile apps for screening

and identifying ASD in young children. One study evaluated the feasibility and acceptability of using a mobile app to administer the M-CHAT-R in a community-based setting in rural Bangladesh [4]. The study found that the mobile app was easy to use and acceptable to parents and caregivers and could potentially improve access to early identification and intervention for ASD in LMICs. Another study developed a mobile app that incorporated video-based screening for ASD, which showed high sensitivity and specificity for identifying ASD in young children [6].

Despite the potential benefits of using mobile apps for screening and identifying ASD in young children, there is a lack of research on the effectiveness of mobile apps in improving early identification and intervention for ASD. In addition, there is a need for the development and validation of mobile apps that are culturally sensitive and appropriate for use in diverse populations [7].

Operational Definition

Mobile Application: A Mobile App which will be developed to identify and screen Autistic Spectrum disorders (ASD), based on Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA)

Frontline health workers: In this study it means, accredited social health care workers (ASHA) and Frontline Health workers, working in selected areas where data collection will be done.

Rational of the Study

The rationale for this study is to address the significant challenge of early identification of Autistic Spectrum Disorder (ASD) in young children, particularly in low- and middle-income countries (LMICs) where resources and trained professionals are often limited. Despite the availability of standardized screening tools like the Modified Checklist for Autism in Toddlers, revised (M-CHAT-R), there is a lack of accessibility to reliable screening tools in LMICs. Mobile health (mHealth) technologies, such as mobile applications (apps), have the potential to overcome this barrier by providing a standardized and

reliable screening tool for ASD that can be easily accessed and used by parents, caregivers, and frontline health workers.

The aim of this research is to develop, validate, and evaluate the effectiveness of a mobile app for screening and identifying ASD among children aged 16 to 30 months by frontline health workers in view of early referral and interventional services. A randomized controlled study will be carried out in adopted villages from community departments of Wardha district. The study will compare the use of a Mobile Application based Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA) administered by frontline health workers with the paper-based M-CHAT-R screening tool used in the control group.

The results of this study can contribute to the development of culturally sensitive and appropriate mobile apps for ASD screening in diverse populations, as well as improve access to early identification and intervention for ASD in LMICs. Additionally, this study can provide evidence on the effectiveness of mobile app-based screening tools for ASD, which can inform policy and practice for the implementation of mHealth technologies in health care systems.

Several studies have investigated the feasibility and acceptability of using mobile apps for screening and identifying ASD in young children [8,9]. However, there is a lack of research on the effectiveness of mobile apps in improving early identification and intervention for ASD [7]. Therefore, this study aims to fill this gap in the literature by evaluating the effectiveness of a Mobile Application based Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA) for ASD in young children.

PHASE I:-

- Generation and validation of the newly developed Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA)
- Developing Mobile application based on Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA)

Research Question (RQ1)

Whether the generated Mobile Application based Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA) on for early identification and referral services of ASD among 16 to 30 months, is valid and reliable?

Aim:

To develop, validate and pilot the Mobile Application based Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA) for early identification and screening of Autistic spectrum disorders among children aged 16 to 30 months.

Objectives

- 1) To assess the validity of Mobile Application based Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA)
- 2) To assess the reliability of newly developed Mobile Application based Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA).
- 3) To evaluate the efficacy of Mobile Application based Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA) through pilot study.

MATERIAL AND METHOD

The research design for this study is a Randomized Parallel Group Active Control Trial, which involves random allocation of participants to either the intervention or the control group, with the intervention group receiving the new Mobile Application based Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA) and the control group receiving the standardised screening method M-CHAT/R. The research approach is interventional, meaning that the study aims to evaluate the effectiveness of the mobile application in screening and identifying ASD among children aged from 16 to 30 months.

Study Setting

The setting for the study will be selected community areas, specifically two villages that will be selected randomly in the district, one intervention and the other control village. The study will be conducted over a period of three months, during which data will be collected and analysed.

Sample Size and Technique

The sampling procedure will involve determining the sample size

based on a pilot study. The sample size and sampling technique will be determined based on the data given by frontline workers, and two villages will be selected randomly in the district, one intervention and the other control village, to participate in the study.

Selection Criteria For Subjects Under Study:

Inclusive Criteria For Samples

- Children aged from 16 to 30 months will be included in the study.
- Children with siblings with developmental disabilities will be included.
- Children born with high-risk pregnancies will be included.
- Children with a history of NICU admission will be included.

Exclusive Criteria For Samples

- Children less than 16 months of age will not be included in the study.
- Children who have already been diagnosed with some developmental disabilities will be excluded.
- Children attending special schools for developmental delays will be excluded from the study.

Data Collection Tool

To gather quantitative data for the study, Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA) will be employed. This tool will be assessed for specificity and sensitivity and after validation it will be translated into the local vernacular language of Marathi and then validated with the assistance of language experts. Once the tool has been validated, it will be incorporated into a mobile application.

Frontline health workers will receive training on how to use the mobile application for screening children for ASD. The tool will be administered to all children, following which a gold-standard diagnostic test will be implemented to assess the effectiveness Mobile Application based Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA). Along with screening information, the data collection tool will include socio-demographic information such as gender, natal history, and NICU stay, as well as other relevant details. Confidentiality of all data collected throughout the study will be maintained.

Randomization

The field practice area for this study encompasses five adopted villages: Salod, Umari Meghe, Nimgaon Sabane, Waigaon (N), and Dahegaon Station. From these five villages, two will be selected at random to participate in the study. One of the villages will be designated as the intervention arm, where the Mobile Application based Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA) will be used by frontline health workers for screening and identifying ASD in children aged 16 to 30 months. The other village will serve as the control arm, where the paper-based M-CHAT-R will be used by frontline health workers for screening and identifying ASD in children of the same age group. By using a control group, we can better assess the effectiveness of the mobile application compared to the standard paper-based screening tool.

Baseline Data

The collection of baseline data is an essential component of the study, and it will be gathered from both the intervention and control groups. To identify potential participants, a list of children will be obtained from Anganwadi and Gram Panchayat. The participants will be assessed in their respective settings, and great care will be taken to ensure complete privacy to avoid causing any disturbance or hesitation among the children and their parents.

Intervention Package

The intervention package for this study will involve the use of a Mobile Application based Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA) in young children. used as instrument for screening ASD in children aged 16 to 30 months. The mobile application will be user-friendly and easily accessible for frontline health workers to use in their respective settings. Its effectiveness in detecting ASD in children will be evaluated through a randomized controlled study, which will compare the results of children screened using the Mobile Application based Comprehensive Tool for Screening Autistic Spectrum Disorder (CTSA) to those screened using paper-based M-CHAT-R. The aim is to ensure that the mobile application is an effective and reliable tool for detecting ASD in young children and can be easily integrated into the routine healthcare services provided by frontline health workers.

Implications

This work will assist in improving the knowledge of frontline healthcare workers in handling the technology-based screening tool to assess the children, along with that the knowledge of the parents will also be improved in the observation of their children. Ultimately it will reduce the burden on families, society, and the health care delivery system through early detection and treatment strategies.

Ethical Consideration

We have obtained approval from the Institutional Ethics Committee of DMIMS University for this research project. The committee has reviewed and approved the study design, methodology, and informed consent process to ensure that the study meets ethical standards and protects the rights and welfare of the participants.

Informed Consent

Informed consent is a crucial aspect of any research study involving human participants. In this study, all the participants selected for the study will be explained in detail about the purpose and procedures of the study. The informed consent form will include information about the study's objectives, procedures, potential risks and benefits, and the participants' rights. The participants and their parents or legal guardians will have the opportunity to ask any questions they may have about the study before signing the consent form.

Statistical Analysis

Data will be entered into Microsoft Excel sheet and statistical analysis will be done in STATA 10 software. The Chi-square test, Fischer's exact test for categorical data, and independent t-test for continuous data with normal distribution will be used to assess the relationship between various demographic, clinical, and etiological characteristics, and outcomes. The parameters that will be compared are gestational age, NICU stay, and the educational qualification of parents. The comparison will be done for both electronic and paper-based screening to evaluate the effectiveness of Mobile applications.

RESULTS OF PILOT STUDY

		Frequency	Percent
History of NICU stay	Yes	10	50
	No	10	50
	Total	20	100

Total 20 samples are involved in the study described among following demographic variables, for history of NICU stay yes found with 10(50.0%) & no found with 10(50.0%).

		Frequency	Percent
Period of Gestation	Full term	17	85
	Premature	3	15
	Total	20	100

Total 20 samples are involved in the study described among following demographic variables, for period of gestation full term found with 17(85.0%) & premature found with 3(15.0%).

		Frequency	Percent
Family History of ASD	Yes	17	85
	No	3	15
	Total	20	100

Total 20 samples are involved in the study described among following demographic variables, for family history of ASD yes found with 17(85.0%) & no found with 3(15.0%).

		Frequency	Percent
Family history of any Genetic Disorder	Yes	2	10
	No	18	90
	Total	20	100

Total 20 samples are involved in the study described among following demographic variables, family history of any genetic yes found with 2(10.0%) & no found with 18(90.0%).

		Frequency	Percent
Educational qualification of Mother	Primary	2	10
	High School	18	90
	Total	20	100

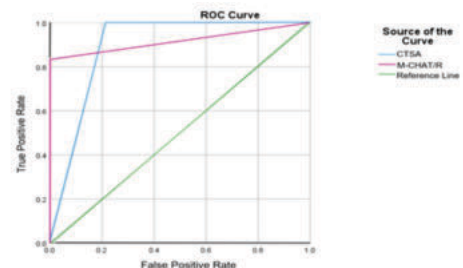
Total 20 samples are involved in the study described among following demographic variables, educational qualification of mother primary found with 2(10.0%) & high school found with 18(90.0%).

		Frequency	Percent
Educational qualification of Father	High School	5	25
	Higher Secondary	8	40
	Degree	6	30
	Post graduate	1	5
	Total	20	100

Total 20 samples are involved in the study described among following demographic variables, educational qualification of father high school found with 5(25.0%), higher school found with 8(40.0%), degree found with 6(30.0%), post graduate school found with 1(5.0%).

Area Under the Curve					
Test Result Variable (s)	Area	Std. Error	Asymptotic Sig.	Asymptotic 95% Confidence Interval	
				Lower Bound	Upper Bound
M-CHAT/R	0.893	0.073	0.006	0.750	1.000
CTSA App	0.917	0.093	0.004	0.735	1.000

Result are tested for the modified method found with AUC=0.893 & M-CHAT/R found with AUC=0.917, this conclude that CTSA app has accuracy 89.3% compared to original with 91.7%.



	M-CHAT/R				CTSA App		
Diagnostic Agreement	0	1	Total	Diagnostic Agreement	0	1	Total
0	14	0	14	0	11	3	14
1	1	5	6	1	0	6	6
Total	15	5	20	Total	11	9	20
Sensitivity	0.933333			Sensitivity	0.99		
Specificity	0.99			Specificity	0.666667		

Sensitivity and Specificity are tested for Diagnostic agreement against M-CHAT/R and CTSA app method, sensitivity found with 0.933333 & specificity found with 0.99 for original method and for modified method sensitivity found with 0.99 & specificity found with 0.666667.

DISCUSSION AND CONCLUSION

Pilot Study was conducted on 20 samples each for both control and experimental group which is approximately 10% of the main study samples. The pilot study period was from January 2023 to February 2023. Sensitivity and Specificity are tested for Diagnostic agreement against M-CHAT/R and CTSA app method, sensitivity found with 0.933333 & specificity found with 0.99 for original method and for modified method sensitivity found with 0.99 & specificity found with 0.666667.

It concludes that newly developed tool is more valid and reliable in screening ASD in children.

REFERENCES

- Centers for Disease Control and Prevention. (2021). Autism Spectrum Disorder (ASD). Retrieved from <https://www.cdc.gov/ncbddd/autism/data.html>
- Johnson, C. P., Myers, S. M., & Council on Children with Disabilities. (2007). Identification and evaluation of children with autism spectrum disorders. *Pediatrics*, 120(5), 1183-1215.
- Robins, D. L., Fein, D., Barton, M. L., & Green, J. A. (2014). The Modified Checklist for Autism in Toddlers, Revised, with Follow-Up (M-CHAT-R/F). Retrieved from <https://mchatscreen.com/wp-content/uploads/2020/06/MCHAT-R-F-with-Scoring-Instructions.pdf>
- Zaidi, S. H. R., Sajed, S., Mukherjee, S., Hasan, M. T., & Ferdous, S. (2019). Feasibility and acceptability of using a mobile application to screen for autism in a community-based setting in Bangladesh. *Frontiers in Public Health*, 7, 123.
- Elsabbagh, M., Divan, G., Koh, Y. J., Kim, Y. S., Kauchali, S., Marcini, C., Fombonne, E. (2012). Global prevalence of autism and other pervasive developmental disorders. *Autism Research*, 5(3), 160-179.
- Sacrey, L. A., Zwaigenbaum, L., Bryson, S., Brian, J., Smith, I. M., Roberts, W., & Roncadin, C. (2018). Can parents' concerns predict autism spectrum disorder? A prospective study of high-risk siblings from 6 to 36 months of age. *Journal of the American Academy of Child & Adolescent Psychiatry*, 57(8), 556-563.
- Elsabbagh, M., Divan, G., Koh, Y. J., Kim, Y. S., Kauchali, S., Marcini, C., ... & Fombonne, E. (2012). Global prevalence of autism and other pervasive developmental disorders. *Autism Research*, 5(3), 160-179. doi: 10.1002/aur.239
- Sacrey, L. A. R., Bryson, S. E., Zwaigenbaum, L., & Brian, J. A. (2018). Infant Eye

- Tracking in Relation to Developmental Outcomes in Infants at High Risk for Autism Spectrum Disorder. *Journal of Autism and Developmental Disorders*, 48(3), 832-846. doi: 10.1007/s10803-017-3370-9
9. Zaidi, Z. F., Habib, H. A., Mohsena, M., Chowdhury, M. A. K., Sikder, M. T., Tarar, S. H., & Hasan, M. T. (2019). Community validation of autism screening instrument in Bangladesh using a mobile health technology-based approach. *Autism Research*, 12(2), 261-270. doi: 10.1002/aur.2019
 10. Johnson CP, Myers SM, Council on Children with Disabilities. Identification and evaluation of children with autism spectrum disorders. *Pediatrics*. 2007 Nov;120(5):1183-215.
 11. Zaidi SH, Yousafzai AK, Salat MS, Shafiq Y, Zaidi S, Hameed S, et al. Feasibility and acceptability of using a mobile application for autism screening in areas of Pakistan with limited access to resources: a pilot study. *JMIR mHealth and uHealth*. 2019 Jun 25;7(6):e15172.
 12. Sacrey LA, Zwaigenbaum L, Bryson S, Brian J, Smith IM, Roberts W, et al. Can parents' concerns predict autism spectrum disorder? A prospective study of high-risk siblings from 6 to 36 months of age. *Journal of the American Academy of Child & Adolescent Psychiatry*. 2018 Jul 1;57(7):495-503.