



Clinical Trial Details (PDF Generation Date :- Thu, 28 Oct 2021 04:37:16 GMT)

CTRI Number	CTRI/2015/06/005847 [Registered on: 03/06/2015] - Trial Registered Retrospectively	
Last Modified On	25/11/2019	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Other (Specify) [Implementation science and health system]	
Study Design	Cluster Randomized Trial	
Public Title of Study	Assess effectiveness of a new mobile phone application towards improving community based maternal, newborn and child health services in tribal areas of Gujarat	
Scientific Title of Study	Use of mHealth Solutions to Improve Delivery of Proven Maternal, and Newborn Care Interventions through Community Based Accredited Social Health Activists (ASHAs) by Enhancing Their Motivation and Strengthening Supervision in Tribal Areas of Gujarat, India: A Cluster Randomized trial	
Secondary IDs if Any	Secondary ID	Identifier
	Nil	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
	Name	Dr Pankaj Shah
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Department of maternal, newborn, child and adolescent health, World Health Organization			
	> Financial support: Indian Council of Medical Research, P.O. Box No. 4911 Ansari Nagar New Delhi - 110029 India. Technical partner: ICMR and WHO, P.O. Box No. 4911 Ansari Nagar New Delhi - 110029 India. Implementation partner: The Department of Health and Family Welfare, Government of Gujarat, Block 5, Dr Jivraj Mehta Bhavan, Gandhinagar, Gujarat, India 382010.			
	> John D and Catherine T MacArthur Foundation			
Primary Sponsor	Primary Sponsor Details			
	Name	Indian Council of Medical Research		
	Address	P.O. Box No. 4911 Ansari Nagar New Delhi - 110029 India		
	Type of Sponsor	Government funding agency		
Details of Secondary Sponsor	Name	Address		
	Department of maternal newborn child and adolescent health World Health Organization	World Health Organization Avenue Appia 20 1211 Geneva 27 Switzerland		
	John D and Catherine T MacArthur Foundation	India Habitat Centre Zone VA, First Floor Lodhi Road New Delhi 110 003 India		
	NIL	NIL		
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Dr Pankaj Shah	SEWA Rural	Community Health Department Jhagadia District Bharuch Bharuch GUJARAT	9426120316 02645220313 pankaj8892@yahoo.co. in
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Multi-institutional ethics committee	Approved	16/02/2014	No
	SEWA Rural Institutional Ethics Committee	Approved	29/01/2016	No
	WHO Research Ethics Review Committee	Approved	07/12/2015	No
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Healthy Human Volunteers		Maternal, newborn and child mortality, malnutrition and other complications	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	ImTeCHO (Innovative Mobile-phone Technology for Community Health Operations) mobile and web application	Intervention (called "ImTeCHO") is a platform based on mobile phone technology to improve coverage of proven community based maternal, newborn and child health (MNCH) services through improving performance of	



ASHAs and PHC staff by providing support, supervision and motivation. The intervention has four components: 1. Use of ImTeCHO mobile and web based application by ASHAs, medical officers and PHC staff Every ASHA will be given a low cost phone which will be General Packet Radio Service (GPRS) enabled. ASHA will fill out forms on her mobile during home visits. Data will be sent using GPRS network to a server where data will be stored. 1.1 Mobile phone as job aid to ASHA to increase coverage MNCH care - Schedule reminder to ASHAs to make home visit - Home visit forms having checklist to remind scheduled tasks - Multimedia to improve counseling - Checklists to assess and address barriers to behavior change of families (e.g. birth preparedness, complication readiness) - Checklist to remind tasks to be performed during VHND 1.2 Mobile phone as job aid to ASHA and ANM to facilitate care for mother, newborn and child with complications - Diagnostic tool: Checklist and In-built algorithms to identify mother or newborn with complications and automatic risk stratification - Tool to facilitate referral to functional referral facility (for calling 108/emergency transport etc) - Notification alert for ANM once complicated case is identified by ASHA - Manage morbidity by displaying customized management guidelines to help ASHA manage complicated cases at home who refuse get referred to health facility 1.3 Web interface and mobile phone to provide tools to medical officer and PHC staff to facilitate monitoring and supporting program - Daily follow-up of selected high risk cases - Performance monitoring - Monthly reports - Supply management - Calculation and timely payment of incentive to ASHAs - Announcements - Motivating ASHAs as the



		<p>system will display a message about incentive earned after delivery of a service 2. Helpline to provide care for complicated cases over telephone. 3. mHealth facilitators from SEWA Rural will be first contact for ASHAs and PHC staff to report and solve any problem with the ImTeCHO application and other related issues. The mHealth facilitators will monitor adherence to the intervention through use of set of process indicators. 4. Training of ASHAs and PHC staff for use of application and refresher training 5. Head quarter project team at SEWA Rural and district health societies which will supervise and support the project team along with coordinate with the government health staff. Ongoing software updates will be done based on ongoing feedback and report of bugs or errors. The project team might intervene in case of rare emergency situation.</p>
<p>Comparator Agent</p>	<p>Control group</p>	<p>The control area will continue to receive usual health services from government and other providers. All ASHAs in control and intervention area will be trained to get up-to-date to provide recommended maternal, newborn and child care. ASHAs will receive refreshers' training based on ASHA module-6 and 7 which provides skills for the maternal care services that she is expected to deliver including counselling pregnant women, ensuring complete antenatal care through home visits and enabling care at monthly Village Health and Nutrition Days (VHND), assisting households to make birth plan and supporting households for safe delivery. Regarding newborn care, ASHAs will be trained to undertake at least 6 post-partum visits, counsel and problem solve on breastfeeding, keep the baby warm and identify and do basic management of LBW (Low Birth Weight) and pre-term baby, perform examinations needed</p>



		for identification/first contract care for sepsis and asphyxia.
Inclusion Criteria	Inclusion Criteria	
	Age From	31.00 Day(s)
	Age To	9.00 Month(s)
	Gender	Both
	Details	As this is a cluster randomized trial, there are two categories for inclusion and exclusion criteria. For selecting clusters: All clusters (PHCs) belonging to Valia, Netrang (except those where ImTeCHO is being implemented already as part of another project), Dediypada, Nandod, Garudeshwar and Tilakwada blocks in Gujarat with 100% rural population and scheduled tribe population of more than 45% will be eligible to be included. For enrolling respondents for endline survey: • For coverage of maternal, and newborn health services: All woman who are native of study village and is mother of an infant who is one to four months old at the time of survey will be considered as respondents for evaluation. All native women who resided most of the time (at least five months) in study cluster during antenatal period will be included. All women must be in the study cluster at the time of birth in case of home deliveries and in case of institutional deliveries if the she went to hospital from study cluster and came back to same study cluster immediately after delivery, and who provided consent for the evaluation will be included. All women who resided in study cluster for most of time during first month after delivery will be included. • For coverage of child health services: All woman who are native of study cluster and is mother of an infant who is six to eight months old at the time of survey will be considered as respondents for evaluation.
Exclusion Criteria	Exclusion Criteria	
	Details	For selecting clusters: Those PHCs will be excluded where all medical officer posts, and 20% post for ASHAs are vacant at the time of initiation of study. Those PHCs will be excluded whose more than 10% villages have no mobile signal most of the time. Although ImTeCHO mobile application can function without GPRS signal, lack of such signal in large areas of intervention will affect components of intervention to significant extent. PHCs where internet cannot be accessed reliably by medical officer and PHC staff to view web interface and an alternative arrangement is not possible will be excluded too as web interface is important part of the ImTeCHO intervention. For enrolling respondents for endline survey, following respondents will be excluded: 1. Mothers who had twins/multiple births 2. Infants who died before survey 3. Not willing to provide consent
Method of Generating Random Sequence	Stratified randomization	
Method of Concealment	Not Applicable	
Blinding/Masking	Open Label	
Primary Outcome	Outcome	Timepoints
	Primary outcome 1 Proportion of neonates/mothers who received at least two postnatal home visits within first week of delivery by ASHA Primary outcome 2	At baseline (May to July, 2015) and endline (February, to July 2017)



	Modified ASHA-centric Composite Coverage Index	
Secondary Outcome	Outcome	Timepoints
	Proportion of mothers who were visited at home by ASHA at least three times during last pregnancy including at least one visit during last trimester	At baseline and endline
	Proportion of mothers who received satisfactory ANC counseling (at least 5 of below) a. Birth planning and complication readiness, b. Conveyed expected date of delivery, c. Danger signs of pregnancy, d. examination by ANM/doctor, e. Institutional delivery, f. Early essential newborn care, g. Contacting ASHA if danger sign appears	At endline
	Proportion of neonates/mothers who were visited by ASHA at home within 24 hours of delivery (in case of home delivery) or within 24 hours of return to home from hospital in case of hospital delivery	At baseline and endline
	Proportion of neonates/mothers who received at least two postnatal home visits within first week of delivery by ASHA	At baseline and endline
	Proportion of neonates/mothers who received the recommended number of postnatal home visits and at recommended times within first month of delivery by ASHA. Recommended postnatal visits are defined as at least five home visits within first month of delivery including at least two home visits within first week of delivery	At baseline and endline
	Proportion of mothers who received satisfactory education/counseling (at least five of following) about caring for newborn baby from ASHA during her home visits after last delivery a. Exclusive breast feeding b. Proper attachment for breast feeding c. Keeping baby warm by covering in cloth d. Delaying first bath e. Kangaroo mother care f. Caring for umbilical cord g. Washing hands before handling baby h. Vaccination i. Danger signs of newborn	At endline
	Proportion of neonates who were satisfactorily examined (at least three of following) by ASHA during her home visits after last delivery a. Took temperature of newborn b. Took weight of newborn c. Examined skin and umbilicus d. Washed her hands before examining e. Observed breast feeding the baby in her presence	At endline



Proportion of mothers who were counselled by ASHA for young child within last three months a. Initiate complementary food at six months b. Adding oil, sugar and jiggery to food c. Informed status of child on WHO growth chart (green, yellow or red) within last 3 months	At endline
Proportion of mothers who were counselled for seeking care for young child within last 3 months a. To attend VHND b. To contact ASHA in case the child suffers from diarrhea, fever or pneumonia	At endline
Proportion of mothers who had first antenatal examination within first trimester	At baseline and endline
Proportion of mothers who had 4 or more ANC examination by ANM/doctor including at least one examination in last trimester	At baseline and endline
Proportion of mothers who had full antenatal checkup (at least three antenatal examination, one Inj.TT and 100 IFA tablets)	At baseline and endline
Proportion of mothers who were able to state at least three danger signs of pregnancy	At endline
Proportion of mothers who received at least one dose of Inj.TT during last pregnancy	At baseline and endline
Proportion of mothers who consumed at least 100 Iron-Folic Acid (IFA) tablets during last pregnancy	At baseline and endline
Proportion of mothers who delivered at a facility	At baseline and endline
Proportion of mothers who practiced following newborn care immediately after delivery a. Early initiation (within 1 hour) of breastfeeding b. Colostrums was fed c. Bathing delayed after first day d. No prelacteal feed administered	At endline
Proportion of mothers who were able to state at least three danger signs of newborn	At endline
Proportion of mother/family who practiced following at home during first month after delivery Kangaroo mother care for low birth weight baby Did not apply anything on cord Washed hands before handling baby	At endline
Proportion of mothers who practiced exclusive breast feeding until just under 6 months of age	At baseline and endline
Proportion of children who were weighted at least once during last 3 months	At baseline
Proportion of children who received solid, semi-solid or soft foods during previous day	At baseline and endline
Proportion of children who were fed solid, semisolid or soft food at least twice within last 24 hours (Minimum meal frequency)	At endline
Proportion of children who were fed solid,	At endline



semisolid or soft food with added oil, jiggery or sugar at least once during previous day	
Proportion of mother who knew status of child on WHO growth chart	At endline
Proportion of children who visited ANM or doctor at least once within last 3 months (at VHND or any health facility)	At endline
Proportion of mothers who knew that she can contact ASHA for help in case child suffers from diarrhea, fever or pneumonia	At endline
Proportion of children who received all three doses of pentavalent/DPT3 vaccines	At baseline and endline
Proportion of mothers who sought help from ASHA for antenatal complication	At endline
Proportion of mothers who sought help from ASHA for postnatal complication	At endline
Proportion of mothers who suffered from at least one serious complications during last pregnancy or within six weeks of last delivery and sought care from a qualified health personnel	At endline
Proportion of neonate who suffered from at least one complication within one month of last delivery and sought help from ASHA	At baseline and endline
Proportion of neonate who suffered from at least one complication within one month of last delivery and sought help from qualified health provider	At endline
Proportion of mothers who provided Kangaroo Mother Care (KMC) to their low birth weight babies within first month of last delivery	At endline
Proportion of respondents who were harmed by any medicine given by ASHA	At Endline
Proportion of children who suffered from diarrhea within last two weeks and received ORS from ASHA	At baseline and endline
Proportion of children who suffered from diarrhea within last two weeks and received ORS	At baseline and endline
Proportion of children who suffered from diarrhea within last two weeks and received ORS and continued breast feeding	At endline
Proportion of children who suffered from ARI/fever within last two weeks and sought care from ASHA	At baseline and endline
Process indicators for intervention area only -ASHA login rate -ASHA Task completion rate -Number of pregnancy registration forms filled using mobile phones against expected number of registration -Proportion of live and still births reported on the day of outcome -VHND attendance rate -Number of complicated maternal (severe anaemia), newborn (LBW) and child (severe underweight) cases identified against expected -Medical officer login and task completion rate -Stock out rate	Ongoing during the study period



important reasons for low coverage is inadequate information to monitor and support ASHAs' activities apart from insufficient skills of ASHAs, quality of training, and complexity of tasks to be performed. Also, large numbers of complicated maternal, newborn and child cases are unable to go to a health facility. The non-availability of real time information about such cases to Auxiliary Nurse Midwife (ANMs) and medical officers has limited their ability to respond; hence, such complicated cases at home tend not to receive any care.

Proposed intervention is an innovative strategy to overcome above problems by using mobile phone technology (called mHealth solutions) to empower ASHAs and PHC staff. The mHealth intervention is named *ImTeCHO* which stands for "Innovative Mobile-phone Technology for Community Health Operations". "Techo" in Gujarati means "support"; hence, *ImTeCHO* means "I am support". mHealth intervention, *ImTeCHO* will be used in 3 ways: (1) Mobile phone as a job aid to ASHAs to increase coverage of MNCH care (2) Mobile phone as a job aid to ASHAs and ANMs to facilitate referral and care for mothers, newborns and children with complications (3) Web interface to provide timely information to medical officers for monitoring and supporting program, including accurate and timely reporting of births and deaths. Proposed *ImTeCHO* intervention will integrate checklist (to insure standardization of services) with other features that mobile technology offers such as ability to transfer data instantly and apply algorithm automatically to data entered along with features to ensure check-and-balance for truthfulness and accuracy of collected information. All this will be possible by using a low-cost phone costing approximately Rs.5,000 (US \$ 80). Rather than creating a new model, *ImTeCHO* intervention will use mHealth solutions to improve implementation of existing responsibilities of ASHAs. *ImTeCHO* intervention will be implemented within government's existing primary health care system which will be actively facilitated by SEWA Rural. The duration of study will be 36 months.

The study will test the effectiveness of intervention to improve: (1) Coverage of maternal, newborn and child health-care services to be provided by ASHA, (2) Coverage of care received by complicated maternal, newborn and child cases and (3) Supervision and support to ASHA program. This will be a two-arm cluster randomized trial which will be conducted in six high focus, tribal blocks (Population: 450,000) of Bharuch and Narmada districts in Gujarat with 11 Primary Health Centers in each arm. Approximately 33,000 pregnant women, newborn babies and young children will be directly benefitted. Primary outcome of interests will be measured by conducting household surveys at baseline, and post-intervention.

Results of this study will have significant implications on policy. At the end of the study, exact road map for implementation of *ImTeCHO* in larger system will be ready as following deliverables will be produced: training modules for using mobile phones, implementation plan for introducing mHealth solutions for MNCH care in larger system, a comprehensive report and creation of a demonstration site. Proposed intervention including mobile phone application and web interface can complement existing online Mother and Child Tracking System (MCTS) in use and further enhance inherent usefulness of Mother and Child Tracking System (MCTS). Apart from facilitating provision of services, the intervention will provide timely, reliable and accurate information for birth and death reporting. Lessons learned from this study will be helpful to guide use of mobile phone technology in other disease areas.

This study will be conducted by Society for Education, Welfare and Awareness (SEWA) Rural, Jhagadia. SEWA Rural and Argusoft India Ltd have developed *ImTeCHO* intervention. The Department of Health & Family Welfare, Government of Gujarat and SEWA Rural will implement the intervention. SEWA Rural will evaluate the intervention with help of experts from ICMR and WHO.

The trial was registered on 3 June, 2015. The first enrollment was done on 26 August, 2015. Therefore, this is a prospectively registered trial. However, the message on the CTRI website states that the trial was registered retrospectively. This has happened because of a human error in stating the date of first enrollment when the trial was registered by the investigators. However, the date of first enrollment is now corrected on the CTRI website and this is in fact a prospectively registered trial.