Original Paper

Improving the Capacity of Health System and Community for Sickle Cell Disease Screening and Management Among Tribal Population in India: Protocol of an Intervention Study

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ABSTRACT: Sickle cell disease (SCD) is one of the major public health problems in the world. In India, the burden of SCD is comparatively high in socio-economically disadvantaged tribal communities. Though efficacious interventions are available to manage SCD, they are not reaching to these communities and no comprehensive programme is in place in the health care system. Therefore, the Indian Council of Medical Research has initiated a nation-wide study to develop an effective intervention model for SCD patients in tribal areas through the government health care system. This intervention includes increasing awareness and preparing the communities for accessing the government health care system for SCD care, and improving the capacity of the primary health care systems including the training of the health care providers on prevention and management of SCD. The study adopted a quasi-experimental design with pre-vs. post-intervention comparisons of outcome variables within the interventional groups and with the control group. The study will be implemented in 6 districts which are endemic for SCD, spread across different geographical zones of India. In each district, four primary health centre (PHC) areas which are predominantly inhabited by tribal population will be selected. Of these four PHC areas, two will be selected randomly for implementing the intervention and the remaining two will be the control area. Information necessary for development and implementation of the intervention will be gathered during formative research, by using both quantitative and qualitative research methods. Intervention with an inclusive partnership and community mobilization will be implemented. The major steps in the implementation of intervention are partnership building with various health and non-health partners including the community. Capacity building and strengthening is another important component to enable the primary health facilities to screen and manage SCD patients. Primarily, sub-health centres and primary healthcare centres will be equipped with appropriate SCD screening techniques. All doctors in the system will be trained in advanced treatment and management issues. To improve the community's awareness and readiness, community mobilization activities will be conducted. An impact evaluation will be carried out at the end of the intervention by comparing the improvement of SCD management in intervention PHCs to that of the control PHCs. However, the process evaluation and necessary mid-term corrections will be made throughout the intervention period. Thus, an intervention model in terms of its suitability, replicability and sustainability for the tribal population will be developed and tested. The findings of this study are more suitable to use during advocacy and to replicate the model by the state health departments. This study develops and places an appropriate referral system for SCD patients at the PHC level. Improving the community's access to health care, improving the quality of care in government health centres and raising awareness among tribal communities are crucial to achieving through innovation. Taken together, these innovations would significantly contribute to better access to health care and management of the SCD patients of underserved tribal population.

KEYWORDS: *Sickle cell disease, treatment, control, intervention.*

Introduction

Sickle cell disease (SCD) or sickle cell anaemia (SCA), one of the prevalent haematological genetic disorders, is caused by sickle haemoglobin (Hb S).

About 2.3% of the world population carries this deficient haemoglobin [1].

Each year around 60 million sickle cell carriers and 120 thousand sickle cell homozygotes (SCD patients) are added globally [1].

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The public health implications of SCD are significant and leading to poor quality of life, lower life expectancy and higher rates of infant mortality.

The complications of SCD vary, but the most common acute events are vaso-occlusive pain crisis, caused by physical and adhesive entrapment of red cells containing Hb S in the microcirculation, acute chest syndrome and lung injury syndrome [2,3].

With increasing age, chronic end-organ complications begin to appear, and they include chronic renal failure [4], haemorrhagic and non-haemorrhagic stroke [5], avascular necrosis of bone and pulmonary hypertension [6].

Thus, the clinical manifestations of SCD vary from mild to severe forms that are associated with a high mortality rate.

Since, the identification of this disorder in tribal population of Nilgiri Hills of Tamil Nadu in 1952 by Lahmann and Cutbush, SCD has been reported in India among numerous ethnic groups [7] with the prevalence of Hb S in the heterozygous form up to 40% [8].

However, it is most prevalent among scheduled tribes who are geographically isolated and socio-economically disadvantaged [9].

Tribal population constitutes 8.6% of India's total population and is spread over the length and breadth of the country.

Due to their habitation in remote and hilly terrains, they are often unable to access government health care and usually depend on traditional healers.

Though the government has established different levels of health care facilities, major challenges in accessing health care are lack of accessibility owing to the geographical location (inaccessible locations) and lack of roads and transport, lack of awareness and financial constraints of people, lack of quality and trust regarding public health care facilities, etc. [10].

In India, SCD has a high prevalence among the tribal population and poses a considerable health burden. There may be more than 120,000 patients with SCD, and it has also been estimated that 44,000 children are born per year with SCA in India [11].

The highest rates of SCD-related mortality occur in the first five years of life. About 20% of children with the SCD die at the age of two years and 30% of children with SCD among the tribal community die before they reach adulthood [12].

Despite the problem, the awareness of the disease is very low among people and health care providers.

Although considerable work has been done on SCD in India, the majority of this work has been limited to population screening and some are extended to molecular typing.

The knowledge has been limited to publications, which did not reach clinicians or health care providers and thus, have limited impact on patient care and policy.

As mentioned, the majority of the SCD patients are from the poor tribal population.

They are not sufficiently managed and are often unable to access the health care facilities of the government system.

Many patients in tribal areas depend on local traditional healers or seek symptomatic treatment from local unqualified practitioners.

Currently, some SCD patients are cared for in tertiary hospitals as well as some private hospitals in urban centres.

In India, there are no structured, functional referral system and standard treatment guidelines for managing SCD. Government of India has developed broader guidelines for prevention and control of haemoglobinopathies [13].

However, there are several implementation gaps and these guidelines and corresponding programmes did not draw much attention of many state health departments.

In order to address these challenges, innovations in implementation research have to focus on improving tribal population's access to health care through improving the infrastructure and quality of care in government health centres and by raising awareness among tribal communities.

Taken together, these innovations would significantly contribute to better access to health care and benefit the SCD patients.

Therefore, the Indian Council of Medical Research has initiated a nation-wide study to develop an intervention to develop a model of screening and management of SCD in the primary health care system of the country.

This intervention includes increasing awareness and preparing the communities for accessing the government health care system for SCD care and improving the capacity of the primary health care systems including the training of the health care workers on prevention and management of SCD.

Aim of the Study

Aim of this study is to develop effective intervention model for the SCD patients for accessing government health care system and improving capacity building in terms of knowledge and skill of the health care workers and infrastructure at different levels of the health system for prevention and management of SCD among the tribal population.

Phases of the Study

The study will be carried out in two phases namely, (1) formative research and (2) intervention and evaluation.

Phase-wise objectives

Phase 1 (Formative Research)

Community-related

-Understanding the community's perceptions (including knowledge and behavior) on SCD;

-Assessment of the disease burden through a rapid survey;

-Understanding the clinical epidemiology /profile of the patients-clinical features, their frequency and risk/precipitating factors, etc. that are necessary for the management;

-Understanding the ethnomedicinal practices and management of illness by the people and the traditional healers;

-Identifying facilitators and barriers (of the individual/household level and community-level) in accessing the SCD screening and management and other similar programmes of the government health system;

-Identifying facilities and other conditions in the community for implementing the intervention by the government health system.

Health system-related

-Assessment of capacity (skills and infrastructure) and treatment modalities in practice and other management issues existing in the government health system-(i) existing programme on SCD, if any and (ii) existing information, education and communication (IEC)/communication strategies, if any;

-Understanding health personnel's perceptions, knowledge and attitude on prevention and management of SCD;

-Identifying supply-side barriers/bottlenecks in implementing SCD screening and management programme, including issues related to manpower and supplies;

-Identifying facilities and other facilitators in the health system for implementing the intervention.

Phase 2 (Intervention and Evaluation)

-Intervention development and implementation;

-Development of intervention for screening and management of SCD patients, through principles-(i) partnership with other government departments, non-governmental organizations (NGOs), community-based organizations (CBOs), etc. and (ii) community mobilization;

-Implementing the intervention by the government health system through the partnership approach;

-Improving the skills and facilities of the public health facilities/personnel for the screening and management of SCD;

-Implementing the screening and management activities (including counselling) of SCD by the health system;

-Enabling and making communities accept the screening;

-Facilitating the care-seeking behaviour of patients (for home-based care) through health workers or community members;

-Developing a system of reference for SCD patients from sub health centre level onwards;

-Developing community engagement /participation to mobilize the community for the success of the intervention;

-Development and implementation of the registry.

Evaluation

a) Assessing the impact of the intervention in terms of:

-Changes in the perception, knowledge and attitude of people as well as the health system personnel;

-Acceptability of the programme by the people;

-Bringing SCD patients under treatment/care coverage;

-Improvement in quality of life/reduction in the pain/crisis, etc.

Preventive behaviour of the people

b) Identifying the difficulties and barriers/bottlenecks of government health services in delivering health services to the population

c) Examining the intervention model in terms of its suitability, replicability and sustainability for the tribal population.

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Study Area

The study will be implemented in 6 districts which are endemic for SCD, spread across different geographical zones of the country. Demographic details and SCD-related information of these districts are provided in Table 1.

Table 1. Details of study areas.

State	District	Population	% of tribal population	PHC	Population	% of tribal population	Prevalence of sickle cell disease or related information
Madhya Pradesh (Central India)	Annupur	749,237	51%	Amarkantak	34,731	58.6%	0.7-1% prevalence of homozygotes
				Benibari	47,425	81.1%	
				Ghata	13,496	88.7%	
				Koylari	18,447	90.2%	
Karnataka (Southern India)	Mysuru	3,038,382	12.9%	Annur	35,410	28.9%	7.4% of both hetero-zygotes and homozygotes
				D.B. Kuppe	6,820	42.7%	
				B. Matakere	9,978	51.2%	
				N. Beltooru	24,531	27.8%	
Assam (North east India)	Udalguri	831,668	82.3%	Bamunjuli	18,449	94%	0.7 to 2% of homo-zygotes
				Paneri	20,536	92%	
				Bhergaon	23,450	95%	
				Dimakuchi	14,789	92%	
Orissa (Eastern India)	Kandhamal	733,110	52.0%	Kalinga	11,549	51%	17% and 2% of hetero-zygotes and homozygotes, respectively
				Khairipada	42,332	53%	
				Simanbadi	21,416	69%	
				Bamanigaon	21,565	74%	
Gujarat (Western India)	Chotaudeypur	1,072,368	77.6%	Dolariya	23,534	98.5%	0.1 to 1% of homozygotes
				Dungarbhit	20,974	95.8%	
				Malaja	25,527	90.0%	
				Raysingpura	23,606	96.3%	
Andhra Pradesh (Southern India)	Visakhapatnam	3,060,914	24.08%	Ananthagiri	21,996	88%	0.7 % to 1.0% of homo-zygotes
				Lungaparthi	12,735	75%	
				Gannela	32,000	96%	
				Madagada	23,540	96%	

Methodology

Study Design

The study adopted a quasi-experimental design with pre-vs. post-intervention comparisons of outcome variables within the interventional groups and with the control group.

Phase 1 (Formative Research)

In each district, four primary health Centre (PHC) areas, which are predominantly inhabited by tribal population will be identified for this study.

Of these four PHC areas, two will be selected randomly for implementing the intervention and the remaining two PHC areas will be the control area.

However, the randomization will be done after completion of the formative phase.

The intervention will be implemented in all villages of two selected PHC areas.

However, the formative research and evaluation surveys will be carried out in sampled villages of all the four PHC areas.

The criterion for selection of villages under each PHC area for sampling purpose:

1. Village in which the PHC is located (PHC villages);
2. Villages where sub-health centres (SHC) are located (SHC villages);
3. Villages where no government health care facility is available (No HF villages).

Both quantitative and qualitative research methods will be used.

Quantitative data on the estimation of the burden of the disease at each site will be assessed through rapid screening of children of below 5 years of age.

Further information will be collected from positive (SCD) cases to understand the clinical epidemiology, profile of the patients, clinical features, their frequency and risk factors, etc. that are necessary for management.

Besides, a household quantitative survey will be carried out to elicit the community's knowledge and perceptions of SCD, and the utilization of government health care services.

The knowledge and perception will include-specific symptoms of SCD, precipitating factors, ethnomedicinal practices, treatment-seeking behavior, therapeutic itinerary, etc.

This survey will also identify enablers and barriers of screening for SCD in the community.

Availability of amenities in the community for implementing the intervention programme will be assessed.

For household quantitative survey, the sample size was estimated by using the formula, $\frac{\left\{Z_{1-\alpha}\sqrt{2\bar{P}(1-\bar{P})}+Z_{1-\beta}\sqrt{[P_1(1-P_1)]+[P_2(1-P_2)]}\right\}^2}{(P_1-P_2)^2}$ [14].

With an assumed community's awareness of sickle cell disease (p) as 5%; and with an expectation of increasing this to 10% through intervention, with 95% confidence, and 80% power, the sample size would be 343 per each arm.

By considering the design effect of (DEFF) of 2.0, as cluster sampling is adopted, the sample size would be 686 for each arm.

By considering 15% of non-response rate, the sample size for each arm would be 789 per arm.

It is rounded to 800.

For both intervention and control arms, the sample would be 1600 per district.

For attaining this sample of 1600 households (400 households per a PHC area), the above-mentioned categories of villages will be selected in 1: 2: 5 ratio, i.e. 8 villages per each PHC area (one PHC village, two SHC villages and five no HF villages).

And 50 households in each village will be selected, randomly. In each village, these 50 households will be sampled in 4 directions of 6-8 random points.

For rapid screening, the above-mentioned categories of villages will be sampled in 1: 1: 3 ratio, i.e. five villages per each PHC area.

And 10 children (only one child per household) will be selected randomly.

These 50 randomly sampled children per PHC area will be screened (a total of 200 children per district) initially by solubility test.

The samples positive for solubility test will further be confirmed by high-performance liquid chromatography (HPLC) at the molecular genetics laboratory of one of the study sites, i.e., ICMR-Regional Medical Research Centre, Bhubaneswar.

Qualitative methods will be used for identifying barriers and facilitators, in accessing the healthcare services and for understanding the community perspective towards SCD disease and the patients.

Also, the supply side facilities and bottlenecks regarding delivering health care services in general and services pertained to screening and management of SCD in specific, will be enquired.

These methods include in-depth interviews, key-informant interviews, focus group discussions and structured observation.

In health facilities, the capacity in terms of knowledge, skills and infrastructure will be assessed and the treatment modalities in practice and other management issues existing in the government health system will be analyzed.

Programmes related to SCD screening and management and implementation of communication strategies of the government health care providers will be assessed.

An understanding of the health personnel's perceptions and knowledge on prevention and management of SCD will also be analyzed.

Identification of barriers in implementing SCD screening and management programme and facilities and other facilitators in the health system for implementing the intervention programme will be assessed through the study tools like in-depth interviews with health care providers, observation, facility checklist and record review for certain services.

To summarize the methodology of the formative research, a methodology matrix is developed showing the sources of information and data collection techniques, along with indicators/parameters for each objective of the formative research phase.

The methodology matrix is given as Supplementary Appendix 1. The timeline for project management is shown as Supplementary Appendix 2. Based on the matrix, survey tools are developed. The list of surveys to be conducted during the formative research phase is given as Supplementary Appendix 3. The survey tools (draft questionnaires, guides/checklists) are also annexed (Supplementary Appendixes 4-11).

Data Management and Analysis

Quantitative and qualitative data will be analyzed by SPSS and Atlas/ti, respectively.

The quantitative data will be computerized and analyzed through SPSS.

To summarize the quantitative data, descriptive statistics will be used.

To examine the associations between various dependent and independent variables multiple linear and logistic regressions will be carried out.

The qualitative data management and analysis will be done with the help of Atlas/ti (Scientific Software Development, Berlin, Germany), a software package for qualitative data analysis.

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This computer-based software will be employed for selecting relevant quotations from the text, coding, annotating, and comparing the quotations.

Phase 2 (Intervention and Evaluation)

Based on the formative research, an intervention with an inclusive partnership strategy will be implemented.

The intervention will be implemented in randomly selected 2 PHCs of the 4 PHCs selected in each district.

An impact evaluation will be carried out at the end of the intervention; however, the process evaluation and necessary mid-term corrections will be made throughout the intervention period.

In addition to process and outcome/impact evaluation, an evaluation to assess its feasibility and effectiveness will also be carried out.

A detailed plan of intervention will be finalized after analyzing the data of formative research.

Following are the important components of the intervention.

Inclusive partnership strategy

It will involve a diverse and inclusive representation of tribal communities and personnel from health care, local administration, non-governmental organizations in project design and implementation.

The public health system and community will have a key role in the implementation of the intervention.

The researchers will train and help in capacity building of the health care facilities, which further will be helping in the implementation of the strategy.

Capacity building and strengthening of the health system

The intervention will be implemented in 2 PHC areas in which the screening and management of symptomatically positive SCD patients will be done after the symptomatic survey on SCD.

Possible positive patients will be referred to respective sub-health centres for screening for SCD using solubility test.

Registry of the positive patients will be done at the sub-health centres.

Parallelly, the health workers at sub-health centres will be trained for using the sickle cell solubility test kit for screening for SCD.

This will be implemented at different levels.

The patients, who are positive in the solubility test will be referred to PHC for confirmation of SCD and treatment.

Training on sickle cell disease screening will be given to all health care personnel in sub-health centres and other health care workers under the government system.

The PHC personnel will also be trained for confirmatory tests for SCD (using cellulose acetate haemoglobin electrophoresis).

The positive patients identified in PHCs, are further taken care for the management of the disease through counselling of the patient's family for making them understand the symptoms and risk of SCD, as well as by referral.

The treatment and management components to be incorporated in the intervention are listed (Supplementary Appendix 12).

Based on these, the required skills and equipment required at health facilities will be identified (Supplementary Appendix 13).

Improving the community's awareness and community mobilization

At the community level, various IEC campaigns will be organized.

Specific communication strategies will be developed as part of the intervention.

The improved awareness of the sickle cell disease along with the improved health systems capacity may lead to treatment-seeking and management of the disease by appropriate intervention for SCD including timely treatment.

The positive patients will be provided with a Wong-baker faces pain rating charts and also diary for management of pain and also for timely medication.

The sub-health centres and PHCs will be strengthened for the management of pneumococcal prophylaxis with appropriate drugs.

Steps will be taken for the smooth implementation of the screening and management activities like counselling for prevention of SCD through interpersonal communication, focus group discussions, theme-based dance forms and other health educational programmes, awareness campaigns during community festivals/fairs and also if possible, through community radio.

Involvement of tribal headmen, traditional healers, village panchayats,

Self-help groups, Village Health Nutrition and Sanitation Committees (VHNSC), etc. will be used to reach the tribal population in intervention PHC areas.

Traditional healers (like *gunea*, *baidya*, *ojha*, etc.) will be involved to facilitate the programs

and enabling communities to accept the screening.

Evaluation

Impact of the intervention in terms of changes in the perception, knowledge and attitude of people as well as the health system personnel through surveys will be assessed.

The SCD patient-related data will be captured through the registry on beneficiaries, their treatment, and other indicators collected during and after treatment.

Improvement of quality of life and reduction in the pain and crisis will be assessed through effective pain and treatment diary.

Also, the preventive behavior of people will be assessed. Most of the above indicators will be used to assess the impact of the intervention, by comparing the improvement in intervention PHCs with those of control PHCs.

Availability of diagnostic and management services in government health care system and strengthening of PHCs and district hospital for emergency cases of stroke and services for chronic transfusion to prevent secondary stroke will be assessed.

Examining the intervention model in terms of its suitability, replicability and sustainability for the tribal population will be carried out.

Ethical consideration

Ethical clearance was approved by the institutional ethics committees of the respective author's (Principal Investigator's) institute.

Each of the 6 committees approved the study for the corresponding district.

All the study participants will be informed about the purpose of the study and their consent will be taken before conducting interviews /discussion.

The purpose of the study will also be explained to the community leaders and other partners, and their consent and cooperation will be sought.

Discussion

SCD has been recognized as a public health problem by several key agencies like the United Nations and the World Health Organization [15].

Though evidence of successful medical and behavioral interventions is available to effectively control and manage SCD globally, not many efforts are made in India at the health system level to implement these interventions.

The national programme is at the documentation stage and could not draw the attention of the state health departments and hence not in place in local health care systems [13].

Successful interventions should be incorporated into existing health care systems by linking primary health care facilities to specialized SCD centres in tertiary health care institutions [16].

Based on the available experiences, clear implementation guidelines are to be developed for use by the health systems.

The current intervention will develop an appropriate referral system at the primary health care level. Early detection of the SCD will be part of the project.

Newborn screening will possibly be carried out.

New-born screening and subsequent care of these paediatric patients reduce mortality and morbidity during the first 5 years of life [17,18].

The suggested management guidelines will be popularized amongst the health care providers at primary health care level while strengthening the capacity of the health systems [13].

Community mobilization and awareness programmes will be important activities of the intervention.

Lack of understanding of the causes of this disease, its management and treatment-seeking will be addressed during these programmes.

People should be aware of the screening and management of the disease and should have the right information on the resources available for diagnosis, treatment, and prevention.

Pre-marriage counselling may lead to fewer children being born with the Hb S. Sickle cell parent screening will aim to identify women /couples at risk of pregnancy with Hb S and provide adequate referral and counselling.

In India, about 70,000 high-risk couples of eligible age group need to be counselled for management and prevention of SCD.

However, this number is likely to go up due to population growth.

As part of this intervention, the primary health care system will be strengthened to screen and manage SCD patients.

In the primary health care system, the community level health institutions-sub-health centres and frontline health workers-will be made aware of the disease and identify the SCD patients, specifically the children based on the symptoms.

They will be trained to screen using simple techniques like the solubility test.

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Health workers will be able to guide people for screening or referral and support the known patients.

These cases of SCD diagnosed by the community-level health workers are to be confirmed subsequently in the primary health centre.

Hence, the primary health centres will be equipped with electrophoresis facility and required training will be given.

The doctors at primary health care centres will be trained in the treatment of SCDs.

Though efficacious therapies are available, they are not reaching these people and are available in few urban-based tertiary hospitals.

Simple therapies like using hydroxyurea are available and will be used in the primary health care level to manage painful crisis among SCD patients.

It is proven to be safe and efficacious [19-21].

Pneumococcal vaccination and penicillin prophylaxis have reduced the risk of mortality among SCD children and mortality from pneumococcal infection is rare due to these interventions [22].

Over the past few years, progress has been made in several respects: long-term treatment with hydroxyurea has decreased the rate of painful crises and improved the quality of life of SCD patients [23], imaging studies helped in the prompt management of life-threatening complications, such as stroke and the chest syndrome; regular blood-transfusion programmes associated with iron chelation prevented complications [24].

However, these advances are in practice in developed countries, and yet to be incorporated in the health care system of developing countries like India.

The tertiary care facilities such as district-level and medical college hospitals are capable of treating serious episodes of crisis and other complications of SCD.

Several treatment modalities are emerging for the management of crisis and improving the quality of life among SCD patients [19].

An appropriate referral system will be an important component of the present intervention.

By the end of the intervention, it is expected that the health system will be ready to adopt these strategies.

Thus, strengthening health systems will focus on improving the capacity of the health care facilities.

Simultaneously, the awareness and perceived felt need of the tribal community will be generated.

The traditional healers and the community leaders can play a crucial role in these efforts of generating awareness, felt needs and acceptance of the services.

The school health programme is another platform in tribal areas and will be used for the generation of awareness.

The role of peripheral health workers is crucial right from initial screening to facilitating the patients for seeking the treatment and further management.

Sensitive and human-centric approaches will be used in this intervention while generating awareness and counselling to address the possible threat of fear of being diagnosed or being stigmatized.

The community's access to health care, improving the quality of care in government health centres, raising awareness among tribal communities will be achieved through innovations.

Taken together, these innovations would significantly contribute to better access to health care by the poor, underserved tribal populations.

The implementation research, aiming the transition of evidence-based interventions into the programme and routine practice, can improve the lives of SCD patients in specific and tribal population in general.

Implementation study accelerates the correct intervention adoption or formulates guideline for care providers and systems of care, with a clear focus on the outcomes [25].

It further helps in identifying and helping to address mismatches between the health system and the communities [26].

However, the proposed kind of intervention is complex and not linear with several stages in different directions with different partners and actors.

Hence, the best practice is to develop intervention very systematically [27].

Also, these complex interventions work well if the processes are tailored to the local context [28].

It is proposed to make intervention plans by the local partners and the communities, and the local primary health centres and its sub-health centres will implement the intervention.

The researchers limit their involvement during the intervention.

This study consists of two phases of which the first phase is the formative phase.

Formative phase gathers required information for developing, implementing and evaluating the intervention.

Besides, the theoretical understanding of the core concepts of intervention is also important.

This intervention is being primarily developed on concepts of partnership and community mobilization.

These concepts have been recognized long back and spurred on by WHO's Health for All-a primary health care movement initiative in the 1970s [29].

It was noted that effective partnership among various disciplines and sections of the society will lead to essential, sound, accessible, appropriately delivered, coordinated, and affordable health care [29].

Partnerships in contemporary public health are complex and their centrality is the people's involvement.

However, the partnership involves individuals and organizations of differential culture, power, status, values and priorities.

For a successful partnership, these differentials are to be known and objective of the partnership that each partner share to achieve it is to be explicitly made clear.

Though the community mobilization became popular through the primary health care movement [29], it is seen now as a strategy to improve health outcomes, specifically through public health interventions.

Community mobilization approach is problem focused and seeks active participation of the target population initially to develop an understanding of the problem and its causes.

And they continue to work with other partners of the intervention to address the problem and initiate the change.

Theoretically, community mobilization is premised on the principles of equity, empowerment, inclusion in decision-making, social justice, attention to the community, respect for diversity and collaboration [30].

The present intervention will adopt the quasi-experimental design, which is suitable when randomization is not feasible due to ethical and operational barriers [31].

Though the findings of studies with this design are more suitable for handing over the model to the health services to replicate the model in a larger real-world setting, the major limitation of this design is researchers have lesser control over some confounding factors.

The current intervention is planned to conduct in a real-world setting of two PHC areas of each district.

And the design is to include both intervention and control areas as well as before and after-intervention comparisons of outcomes.

This is the strength of this study.

And these results are more suitable to use during advocacy and to replicate by the state health departments.

Also, more evidence will be available on how improvement occurred in the outcome variables.

Supplementary files

All appendixes are given as supplementary data here:
https://www.chsjournal.org/CHSJ/resources/CHSJ.46.03.08-NTF-SCD-Protocol_suppl-file.pdf

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Conflict of interests

None to declare.

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