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STUDY PROTOCOL

Title

Integrated multisectoral strategy to improve girls' and women's nutrition before conception, during pregnancy and after birth in India (Swabhimaan): a prospective, non-randomized controlled evaluation

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ABSTRACT

Introduction

Swabhimaan is community-based programme to improve adolescent girls' and women's nutrition in rural areas of three Indian states- Bihar, Chhattisgarh and Odisha with high prevalence of undernutrition among women, high fertility and high proportion of young mothers.

Methods and analysis

Swabhimaan has a nested prospective, non-randomized controlled evaluation. Five intervention sites receive community-led interventions through national government's livelihood mission supported women's self-help group federations (or Village Organisations) since 2017 and five control sites will initiate these activities 36 months later, in 2020. The evaluation includes baseline (2016-17), midline (2018-19) and endline (2020-21) surveys. Baseline survey covered 6352 adolescent girls, 2573 pregnant women and 8755 mothers of children under two. The final impact analysis will be by intention-to-treat, comparing primary and secondary outcomes in five intervention areas and five

control areas. This analysis will be carried out at an individual level, adjusting for clustering at the level of the village and Village Organisation, using linear and logistic random effects models in STATA 14. The expected outcomes are: (1) a 15% reduction in the proportion of adolescent girls with a Body Mass Index (BMI) <18.5; (2) a 15% reduction in the proportion of mothers of children under two with a BMI<18.5; (3) and a 0.4cm improvement in mean mid-upper arm circumference among pregnant women; and (4) improvements of between 5% and 20% in the coverage of key nutrition interventions over three years.

Ethics

All procedures involving human subjects were approved by the Institutional Ethics Committee of the All India Institute of Medical Sciences (AIIMS), Bihar, Chhattisgarh and Odisha and in compliance with guidelines laid down in the Declaration of Helsinki.

Evaluation registration

The evaluation is registered with the Registry for International Development Impact Evaluation (RIDIE-STUDY-ID-58261b2f46876) and the Indian Council of Medical Research, National Clinical Trials Registry of India (CTRI/2016/11/007482)

Key words

Adolescent girls, nutrition, agriculture, multi-sector, women collectives, India

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The study will provide evidence on effectiveness of a community-led model in delivering a comprehensive package of 18 nutrition services, on improving nutrition status of adolescent girls, pregnant women and mothers of children under two in resource-poor settings.
- The model is based on sustainable government resources with only one of the three states receiving additional non-government funding to test the model.
- The pace of implementation will vary considerably across three states due to variable governance, availability of resources, maturity of self-help groups and intensity of non-government engagement which is likely to impact the study outcomes.

- While the design includes a comparator site, introduction of new government schemes that can have variable influence in intervention and control sites are not ruled out.
- The evaluation is led by an independent third party with no role in implementation of the model.

INTRODUCTION

There is compelling evidence on the importance of women's nutrition prior to and during pregnancy, to ensure optimal foetal growth and development and for the health and wellbeing of the mother [1]. Globally, over 800,000 neonatal deaths and 20% of stunting in children less than five years of age is attributable to poor nutrition in utero, including protein-energy and micronutrient deficiencies [2]. Nearly 4.5 million Indian women become pregnant in adolescence, 58% have anaemia and 23% are thin. It is unsurprising that over 50 million children under-five (38%) are stunted [3,4]. India has both policies and programs in place to deliver and monitor globally-recommended preconception and antenatal nutrition interventions. Most recently, India's National Nutrition Mission or Poshan Abhiyaan (2018-22) aims to reduce the proportion of children born with low birthweight from 19% to 11% and under-five children stunted from 38% to 13% respectively, by 2022. It also aims to reduce anaemia among adolescent girls and pregnant women, which is over 50%, by 3% per annum. This is to be achieved through coordinated efforts across 11 different ministries that together can make all essential nutrition services available to women and children through integration of their ongoing vertical programmes and schemes [5]. Despite these policies and programmes, in 2015-16 the coverage of at least four antenatal care visits was just over 50%, only a third of pregnant women consumed Iron Folic Acid (IFA) tablets for at least 100 days during pregnancy, and less than 40% used the maternity benefit scheme [3]. Challenge lies in lack of effective operational models to deliver a comprehensive package of essential nutrition interventions for adolescent girls and women, models that can overcome both systemic challenges and those around user service uptake.

Evidence from randomized controlled trials within and outside India suggests that working with women's groups as a platform for promoting health interventions and increasing service uptake is a feasible approach in low-resource settings [6,7,8,9,10]. This is provided the necessary requisites, such as high-quality facilitators for establishing and maintaining the group, high coverage of intervention, sufficient time for implementation of the intervention, concomitant supply strengthening interventions and appropriate safeguards against harm such as conflict with service providers and domestic

violence, are met. However, none of these trials investigated nutrition outcomes for adolescent girls or women.

In view of the undisputed role of income poverty in the aetiology of undernutrition, there is a need to integrate women-centric poverty alleviation in nutrition programs and vice-versa. Notable global examples where women's collectives have been engaged with to deliver services and promote health and nutrition behaviours in underserved communities, along with economic empowerment include a community conditional cash transfer programme in Indonesia, as well as livelihood and food security programmes in Bangladesh (Shouhardo, Jibaon-o-Jibika) and Nepal (Suaahara) [11,12]. Indian experiences include Kudumbashree (Kerala), the Society for Elimination of Rural Poverty Project (Andhra Pradesh and Telangana), Self Employed Women's Association (rural areas of several states), Community Health Care Management Initiative (West Bengal), Jamkhed (Maharashtra), and urban health models by the Urban Health Resource Centre and Mahila Abhivrudhi Society, Andhra Pradesh. Women's groups are trained on promotion of the health and nutrition interventions, the scope and duration of training varying with the type of programme. The promoting agency, which is mostly a non-government organisation or federated structure, provides capacity building and supervisory support. Most programmes strengthen the health services delivery system in addition to intervening with community groups [13,14].

Women's SHGs and their federations supported by the Deendayal Antyodaya Yojana -National Rural Livelihoods Mission (DAY-NRLM)'s Government of India's flagship poverty alleviation program, remain an untapped platform for improving reach and use of essential nutrition interventions, particularly for women residing in income-constrained settings [15]. A 2016 scoping study from UNICEF India suggested that DAY-NRLM village organisations have the potential to manage grants for improving last mile delivery of essential nutrition services for women, provided they are enabled, supervised and incentivised [16]. DAY-NRLM is also one of the nodal agencies for implementation of the Poshan Abhiyaan. Capitalising on this, the Swabhimaan programme is a four-year initiative launched in 2016 to improve adolescent girls' and women's nutrition.

Swabhimaan is a package of community-led interventions delivered by DAY-NRLM-supported federations of women self-help groups (SHGs) comprising Village Organizations (VOs) and the higher order Cluster-Level Federations (CLFs), to improve the nutrition status of adolescent girls and women in three Indian states: Bihar, Chhattisgarh and Odisha. The objectives of the program are:

1. To improve the food and nutrient intake of adolescent girls and women
2. To prevent micronutrient deficiencies and nutritional anaemia
3. To increase access to services during fixed day, Village Health Sanitation and Nutrition Days (VHSNDs) and provide special care to nutritionally 'at risk' women, defined as those with mid-upper arm circumference (MUAC) <23 cm or Body Mass Index (BMI)<18.5 kg/m^2
4. To increase access to education about water, sanitation and hygiene (WASH) and access to WASH commodities

To prevent early, poorly spaced and repeated pregnancies

METHODS AND ANALYSIS

This protocol describes the intervention and evaluation methods for the Swabhimaan program, which aims to improve the nutrition status of adolescent girls and women in three Indian states: Bihar, Chhattisgarh and Odisha.

Intervention target groups

The primary target groups for the program are adolescent girls, newlywed women and couples, pregnant women, and mothers of children under two years of age. Swabhimaan also reaches out to husbands, mothers-in-law and farmer producer groups.

Intervention processes

Swabhimaan's technical package of 18 nutrition-specific and nutrition-sensitive interventions includes interventions to improve the adequacy of food consumed in terms of both quantity and quality, the prevention of micronutrient deficiencies including anaemia, access to basic health services, and special care of nutritionally "at risk" women, identified as those with MUAC <23 cm or Body Mass Index (BMI)<18.5 kg/m^2, where latter is available, improving hygiene and access to water and sanitation services and preventing early, too many and too soon pregnancies (Table 1).

172 **Table 1 Nutrition-specific and nutrition-sensitive interventions package, Swabhimaan**

	Relevant target group		
	Preconception	**Pregnancy**	**Lactation**
Improve food and nutrient intake			
1. Access to generalized household ration through Public Distribution System (PDS), a food subsidy scheme	*	*	*
2. Balanced energy protein supplementation through access to supplementary rations	*	*	*
3. Access to knowledge and choices about how to increase maternal dietary diversity	*	*	*
4. Access to knowledge and support for nutrition-sensitive agriculture at home (kitchen garden) and community based food insecurity coping strategies.	*	*	*
Prevent micronutrient deficiencies and anaemia			
5. IFA supplementation	*	*	*
6. Universal use of iodized salt	*	*	*
7. Calcium supplementation and deworming	x	*	*
8. Access to information and commodities like insecticide treated bed-nets for malaria prevention	*	*	*
9. Access to information on preventing tobacco and alcohol use in pregnancy	x	*	*
Increase access to health services and special care to nutritionally "at risk" women			
10. Early registration in outreach services	*	*	X
11. Recording and monitoring of nutritional status and special community-based at-nutritional risk package	x	*	X

12. Quality reproductive health, antenatal and postnatal care	*	*	*
13. Access to knowledge and entitlements for promotion of institutional deliveries and maternity benefits	x	*	*
Increase access to education and commodities for WASH			
14. Sanitation and hygiene (including menstrual hygiene) education	*	*	*
15. Access to safe drinking water and sanitation commodities	*	*	*
Prevent early, poorly spaced or unwanted pregnancies			
16. Promotion of secondary education and education for delaying the age at marriage to legal age	*	x	X
17. Access to information and family planning commodities for delaying age at first pregnancy and prevention of repeated pregnancies	*	*	*
18. Women's collective voice and empowerment for decision-making to prevent child marriage, violence against women, child spacing and other gender-related issues	*	*	*

In intervention sites, these interventions are delivered through a combination of community- and systems-led efforts, while control sites receive only systems strengthening. Community-led interventions are delivered through trained community cadre who are members of VOs, namely Poshan Sakhis (lit. 'Nutrition sister/friend') or Community Resource Persons (CRPs) and Krishi Mitras (lit. farmer friends) or Village Resource Persons (VRPs). The community cadre are part of the DAY-NRLM and SRLM implementation structure. In Bihar, a separate cadre of Kishori Sakhis (lit. 'Adolescent sister/friend') for reaching out and serving adolescent girls has been created (Table 2).

Table 2 Geographic scope and service providers for community-led interventions under Swabhimaan

	Bihar	Chhattisgarh	Odisha	Total
Revenue villages	77	111	168	356
CLF and related (Tier -3)	5	4	12	21
VOs (Tier 2)	72	80	79	231
Poshan Sakhis or CRPs of Tier 2	72	100	79	251
Kishori Sakhis of Tier 2	72	-	-	72
SHGs (Tier-1)	1985	1488	702	4175
VRPs/Krishi mitras	115	80	39	234

Poshan Sakhis and Kishori Sakhis undergo three days of pre-service training on integrated nutrition microplanning, which includes a theoretical orientation and practical on consultative identification and prioritization of nutrition and related problems among target groups in their village/s, developing an annual plan of activities including a budget to address these problems, the use of MUAC tapes, recording and using MUAC measurements for screening nutritionally "at risk" adolescent girls and women. As no standard MUAC cut-offs are available for screening adolescent girls at risk of undernutrition and <21 cm as well as <22 cm have been reported in research, a stricter cut-off of <19 cm is being used to identify those, most at risk [17,18,19]. In addition, clinical examination for signs of anaemia is also done. Post-training, they co-facilitate the development of the integrated nutrition microplan with the block coordinator/ supervisor through a 12-day process, which can spread over almost two months. The process entails microplanning at VO level, its validation by reaching out to the most vulnerable communities and village clusters, then consolidation of all VO plans at CLF and block levels. Poshan Sakhis and Kishori Sakhis are then trained over three days on use of participatory learning and action (PLA) to facilitate monthly women's group and adolescent girls' group meetings. Poshan Sakhis and Kishori Sakhis lead activities in their village/s as per decided

activities in the microplan. More cost-intensive and complex grant management activities are led by CLFs (Table 3).

Table 3 Community led interventions under Swabhimaan

Responsible agency / Service provider	Intervention	Frequency
VO		
Social action committee	Selection of Poshan Sakhi (1 per VO)	One time
Poshan sakhi/CRP	Integrated nutrition microplanning (12 days over 2 months)	Once, followed by annual review
	Maitri bethak (lit. friendly meeting) of women open to non-group members using Participatory Learning and Action	Monthly
	One additional monthly home visit/group meeting of nutritionally "at risk" women	Monthly
Krishi mitra/ VRP	Maitri kishan bethak (lit. friendly farmers meeting) on nutrition-sensitive agriculture Participatory Learning and Action	Monthly
	Home-based Poshan beds/backyard poultry	Monthly
CLF		
Social action committee	Families with women and children at risk of undernutrition linked to agri-poultry linkage and social protection schemes	Monthly
	Loans for secondary education	Monthly
	Creating farmer training school sites	Monthly
	Training for Poshan sakhi and Krishi mitras	Quarterly
	Newly wed couples meetings	Biannual
	Entitlement camps and health checkups for SHG	Biannual

	members	
	Review of integrated nutrition plan	Annual

The CRPs receive INR 450 (USD 7) for developing the poshan microplan and thereafter a similar incentive every month for completed activities. CLFs also receive grants including: INR 500 (~USD 7) for meetings with newlywed couples; INR 500 for each 'welcome kit' given to newlywed couples with essential items like IFA, contraceptives, sanitary napkins; INR 1500 (~USD 22) for review of each VO's integrated nutrition microplan; and INR 5000 (~USD 77) for developing farmer training school sites which are model nutri-farms for training farmer producer group members interested in nutri-sensitive agriculture.

The system strengthening activities include five components:

1) strengthening VHSNDs to improve access to antenatal care, family planning and micronutrient supplementation through quarterly trainings of health service providers, monthly review of nutrition indicators, and the identification of women at risk of undernutrition (MUAC <23cm) for special supplementary food and counselling;

2) Strengthening adolescent health days to improve access to adolescent health and nutrition services via quarterly trainings of health service providers;

3) an extended VHSND once every six months for newlyweds and women, including individual counselling and information about entitlement camps;

4) annual training and follow-up meetings with service providers from food security, Integrated Child Development Services (ICDS), water and sanitation departments to help them improve the delivery of entitlements and services;

5) ensuring regular review meetings with representation across government departments involved in service delivery (Table 4).

Table 4 Service providers engaged in system strengthening interventions under Swabhimaan

	Bihar	Chhattisgarh	Odisha	Total
ASHA	252	471	212	935

AWW	261	358	304	923
ANMs	49	58	33	140
Lady Supervisors	9	7	12	28
Fair Price Shop owners	109	78	46	233

* Auxiliary Nurse Midwife (ANM), Accredited Social Health Activist (ASHA) and Anganwadi Worker (AWW)

Thus, in addition to DAY-NRLM, system strengthening activities engage four other government departments: Department of Woman and Child Development for increasing ICDS reach and quality, Department of Health and Family Welfare for VHSND strengthening, Department of Water and Sanitation for improving water quality and achieving open defecation free villages and districts, and finally Department of Civil and Food Supply for increasing coverage of food subsidy schemes.

Study design

The Swabhimaan evaluation is a prospective, non-randomized controlled study with baseline, midline and endline cross-sectional surveys. Across Bihar, Chhattisgarh and Odisha, five areas (intervention arm) have been purposively allocated to community-led interventions delivered through VOs and CLFs since 2017, and five remaining areas (control arm) will initiate these activities 36 months later, in 2020. Both intervention and control sites are located in the poorest areas (also referred to as resource blocks) identified by DAY-NRLM in four districts: Purnea in Bihar, Bastar in Chhattisgarh, and Angul and Koraput in Odisha. In Bihar, within Kasba and Jalalgarh blocks located in Purnea district, we allocated two clusters of villages to the intervention and one to act as control. In Chhattisgarh, we allocated Bastar block in Bastar district to intervention and Bakawand block to control. In Odisha, 12 gram panchayats (an administrative structure comprising around five villages) within Koraput block in the district of Koraput and Pallahara block in the district of Angul both serve as intervention areas, and 14 remaining gram panchayats serve as control. The unit of assignment to intervention and control is an area comprising a defined number of villages. There are a total of five intervention and five control areas across three states, as follows:

- Bihar: two intervention areas (42 villages across two blocks); two control area (31 villages across two blocks)
- Chhattisgarh: one intervention area (40 villages); one control area (40 villages)
- Odisha: two intervention areas (80 villages across two blocks); two control areas (80 villages across two blocks)

Study hypotheses and outcomes

We hypothesize that, over an intervention period of three years, Swabhimaan's community-led interventions will lead to:

(a) a 15% reduction in the proportion of adolescent girls with a BMI<18.5

(b) a 15% reduction in the proportion of mothers of children under two with a BMI<18.5

(c) a 0.4cm improvement in mean MUAC among pregnant women

These three indicators are considered the evaluation's primary outcomes.

We also hypothesize an improvement of between 5% and 20% in the coverage of 18 key nutrition-specific and -sensitive interventions over three years (Table 5). These constitute the evaluation's secondary outcomes. The International Institute of Population Sciences, Mumbai is Swabhimaan's independent impact evaluation partner.

Table 5 Primary and secondary outcomes for Swabhimaan

PRIMARY OUTCOMES
1. % adolescent girls with BMI <18.5 kg/m^2 2. mean MUAC among pregnant women 3. % mothers of children under 2 with <18.5 kg/m^2
SECONDARY OUTCOMES
ADOLESCENT GIRLS (Girls aged 10-19) – unmarried, not pregnant and not the mother of a child under two
1. Mean dietary diversity score 2. % receiving minimum dietary diversity score (MDD) (5

of10 food groups) 3. % consuming four or more IFA tablets in the month preceding the survey 4. % living in a household with iodized salt 5. % living in food secure households 6. % living in households with a kitchen garden 7. % living in households with a toilet or covered pit latrine 8. % using safe pads or sanitary pads 9. % accessing adolescent health services (Kishori Divas) in six months preceding the survey 10. % who attended at least three Kishori meetings in six months 11. % who attended at least three Kishori meetings in in six months
PREGNANT WOMEN (if she is pregnant, a girl or woman will join this category whether she is an adolescent, newlywed or the mother of any child under two)
1. % of pregnant women in the 2nd and 3rd trimester consuming at least 25 IFA tablets in the month preceding the survey 2. Mean dietary diversity score 3. % receiving minimum dietary diversity (5out of 10 food groups) 4. % living in a household with iodized salt 5. % living in food secure households 6. % living in households with a kitchen garden 7. % living in households with a toilet or covered pit latrine

8. % receiving ICDS entitlement for supplementary food in month preceding the survey 9. % who had one antenatal check-up in the first trimester 10. % weighed at least once in first trimester 11. % who received one dose of albendazole in second trimester 12. % who took two calcium tablets in 2nd trimester 13. % below the age of eighteen 14. % who attended at least three Maitri Bethak meetings in six months 15. % who attended at least three Maitri Bethak meetings in six months 16. % who attended at least three VHSNDs in six months 17. % who attended at least three VHSNDs in six months 18. % using a modern family planning method (in previous delivery); before the current pregnancy 19. % who are members of women's Ag-producer groups and have adopted at least 1 mix micronutrient-rich cropping methods, against previous practice 20. % who are members of women's Ag-producer groups and have adopted at least 1 pesticide-free agri-methods, against previous practice
MOTHERS OF CHILDREN AGED UNDER TWO YEARS
1. Mean dietary diversity score 2. % receiving minimum dietary diversity (5 out of 10 food groups) 3. % living in a household with iodized salt

4. % living in food secure households
5. % living in households with a kitchen garden
6. % living in households with a toilet or covered pit latrine
7. % receiving their minimum PDS entitlement in month preceding survey
8. % receiving ICDS entitlement for supplementary food in month preceding survey
9. % who received at least four ANC overall in last pregnancy
10. % consuming 100 or more IFA tablets during last pregnancy
11. % weighed at least four times in last pregnancy
12. % using a modern family planning method
13. % who accessed at least one of three social protection schemes (JSY, Adarsh Dampati Yojana)
14. % who delivered in a health facility in last pregnancy
15. % who attended at least three Maitri Bethak meetings and three VHSNDs in last year
16. % who attended at least three Maitri Bethak meetings and three VHSNDs in last year
17. % who are members of women's Ag-producer groups and have adopted at least 1 mix micronutrient-rich cropping methods, against previous practice
18. % who are members of women's Ag-producer groups and have adopted at least 1 pesticide-free agri-methods, against previous practice

The theory of change for Swabhimaan is presented in Figure 1.

Figure 1 Theory of change for Swabhimaan: Bihar, Chhattisgarh and Odisha (2016 -2021)

Inclusion and exclusion criteria for cross-sectional surveys

The three evaluation cross-sectional surveys will include all adolescent girls aged 10-19 years, pregnant women, and mothers of children under two residing in the study areas and who agreed to participate.

Sample size calculation

We conducted State-specific sample size calculations to determine the appropriate number of adolescent girls, pregnant women and mothers of children under two to be interviewed in each state to be able to detect differences of 15% in the proportion of adolescent girls with a BMI<18.5, a 15% reduction in the proportion of mothers of children under two with a BMI<18.5, and a 0.4cm improvement in mean MUAC among pregnant women between intervention and control areas at endline, accounting for 5% refusal to participate (Table 6). Overall, we estimated that baseline and endline surveys should include a total of 6638 adolescent girls, 10,160 mothers of children under two and 2992 pregnant women across the three States.

Table 6 State wise estimated total sample in intervention and control areas by target groups

	Bihar	Chhattisgarh	Odisha	Total
Adolescent girls	1750	3294	1594	6638
Pregnant women	748	1122	1122	2992
Lactating mothers	2846	3294	4020	10160
Total	5345	7710	6736	19790

Data collection

We conducted the baseline survey for the evaluation in 2016. In Bihar, a full household listing was conducted to identify adolescent girls aged 10-19 years, pregnant women and mothers of children under two in all programme areas. Simple random sampling using a sample interval was then used to

select respondents in each of these three groups. In Chhattisgarh, 224 villages in two blocks (administrative areas of around 100,000 population) were paired on the basis of population size and whether they had held a monthly Village Health and Nutrition Day for the last three months. Forty such pairs (a total of 80 villages) were then randomly selected for data collection, and all eligible respondents in each of the three target groups in these 80 villages were approached for interview. In Odisha, a set of 12 Gram Panchayats (administrative units of around 5000 population in two blocks have been purposively identified as the intervention areas, and all remaining Gram Panchayats in the two blocks serves as control areas. All eligible respondents in each of the three target groups are to be approached for interview.

Blinding

It is not possible to blind participants to allocation, but data collection teams and analysts are blind to allocation.

Data analysis

In each state, we will assess the comparability of intervention and control areas at baseline by examining area-level and individual level characteristics, including: the number of self-help groups and village organisations in each area, the socio-demographic profile of respondents and their households (caste, literacy and assets) and key evaluation outcomes at baseline.

The final impact analysis will be by intention-to-treat, comparing primary and secondary outcomes in five intervention areas and five control areas. This analysis will be carried out at an individual level, adjusting for clustering at the level of the village and Village Organisation, using linear and logistic random effects models in STATA 14. We will use the difference-in-difference method to compare primary and secondary outcomes between intervention and control areas at endline, adjusting for their baseline values and for other characteristics that differed significantly between the two areas at baseline. We will present analyses both a State level, and conducted a pooled analysis with data from all States.

Process monitoring and progress review

In addition to the impact evaluation described above, we are conducting process monitoring. The process monitoring system is based on the reporting structures within the SRLM (Figure 2).

Figure 2 SRLM organization structure and its adaptation in Swabhimaan, Bihar

SRLM's have a project management units at State, district and block levels (SPMU,DPMU, BPMU). The block Management Information System (MIS) coordinator is the reporting link between the CRPs and their supervisors and the BPMU. In Bihar, a supervisor position has been embedded in the organization structure while in Chhattisgarh and Odisha, supervisory staff is a representative from the SRLM's organogram.

CRPs/ Poshan sakhis collect data and report coverage of community-led interventions on monthly monitoring formats which are available in both web-based and paper formats. Key performance indicators include:

- Target women who attended the VHSND (%)
- Target women who attended the maitri bethak (%)
- At-risk women visited fortnightly in their home visits (%)
- At-risk women attended fortnightly food demonstration and counselling session (%)
- Target newly-wed who attended the couple meeting (reported quarterly)
- Target groups who attended the women only camps (reported biannually)

All CRP reports are collated monthly at the block level. A CLF level review of the progress on performance indicators and the planned activities as per the poshan microplan is planned for every quarter, however, Swabhimaan has mixed experience in achieving this with Chhattisgarh undertaking monthly reviews while other states undertaking annual reviews. DAY-NRLM hosts annual reviews with the respective SRLMs for stock taking and approval for next annual cycle.

Timeline

Baseline was completed in 2016. The first phase of implementation is between 2017 and 2020. Midline and endline for first phase will be completed in 2019 and 2021 respectively.

ETHICS

The baseline survey was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving human subjects were approved by the Institutional Ethics Committee of the All India Institute of Medical Sciences (AIIMS), Bihar, Chhattisgarh and AIIMS, Odisha in July 2016 (Supplementary files 1,2 and 3). Written informed consent was obtained from all subjects. The impact evaluation has been registered with the Registry for International Development Impact Evaluations (RIDIE-STUDY-ID-58261b2f46876) [20] and Indian Council of Medical Research National Clinical Trials Registry of India (CTRI/2016/11/007482).

CONCLUSION AND IMPLICATIONS

Swabhimaan operates in complete alignment with DAY-NRLM's mandate under the joint convergent action plan for Poshan Abhiyaan. In coordination with departments of Woman and Child Development and Health, DAY-NRLM shares responsibility for (1) SHG members mobilizing communities for utilizing entitled services through Department of Health, (2) SHG members participating in Behaviour Change and Communication activities, promoting recommended health, nutrition and WASH behaviours, (3) common use of infrastructure by the three departments such as use of Panchayat halls for SHG and VO meetings and (4) promoting nutri-based livelihoods for women's collectives. These activities are integrated in VO's poshan microplans and system strengthening activities under Swabhimaan.

Swabhimaan operates as three different models in Bihar, Chhattisgarh and Odisha. Bihar is the demonstration and learning site, with financial support for human resources and activities through UNICEF India. In Chhattisgarh and Odisha, the initiative is almost completely led by the respective SRLMs with UNICEF to SRLM cost ratio at 1:5. UNICEF India supports some human resource at state and block levels, but none at the VO level in these two states. By 2020, it is planned to advocate

for increased number of positions at SRLMs to support implementation of the convergent action plan and create a system of CRPs graduating to block level positions in the three states. UNICEF India's support on human resource will gradually lessen. DAY-NRLM has recognized the Chhattisgarh model of Swabhimaan as a best practice for integrating health, nutrition and WASH on the SHG platform and has planned to take elements from the initiative for horizontal expansion to poorest resource blocks in other states. Findings from the Swabhimaan midline survey will inform scale-up plans in other states.

DECLARATIONS

Abbreviations

AIIMS All India Institute of Medical Sciences, ANM Auxiliary Nurse Midwife , ASHA Accredited Social Health Activist, AWW Anganwadi Worker, BMI Body Mass Index, BPMU Block Project Management Unit, CLF Cluster Level Federation, CRP Community Resource Person, DAY-NRLM Deendayal Antyodaya Yojana- National Rural Livelihoods Mission, DPMU District Project Management Unit, ICDS Integrated Child Development Services, IFA Iron Folic Acid, MIS Management Information System, MUAC Mid-upper Arm Circumference, PLA Participatory Learning Action, PDS Public Distribution System, RIDIE Registry for International Development Impact Evaluation , SHG Self-help group, SPMU State Project Management Unit, SRLM State Rural Livelihoods Mission, VHSND Village Health Sanitation and Nutrition Day, VRP Village Resource Person, VO Village Organization, WASH Water Sanitation and Hygiene

Ethics approval and consent to participate

The baseline survey was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving human subjects were approved by the Institutional Ethics Committee of the All India Institute of Medical Sciences (AIIMS), Bihar, Chhattisgarh and AIIMS, Odisha in July 2016. Written informed consent was obtained from all subjects. The impact evaluation has been registered with the Registry for International Development Impact Evaluations (RIDIE-STUDY-ID-58261b2f46876) and Indian Council of Medical Research National Clinical Trials Registry of India (CTRI/2016/11/007482).

Patient and Public Involvement

This research did not have any patients. The public (community) was involved in the design and implementation of the intervention package at the village level but not in the evaluation. Public were not invited to contribute to the writing or editing of this document for readability or accuracy.

Competing interests

None of the authors have any competing interests.

Funding

This research is funded by UNICEF India.

Authors' contributions

VS and ADW provide technical oversight and VS is the national focal point of the initiative. NK is key contact in NRLM and advises on effective utilization of NRLM platforms. VS, AB, SB, NN, AD,RNP, SS, AL and NK were involved in designing Swabhimaan initiative at national and state level. RG, VN and NN contributed to the Participatory Learning Action component of the initiative. DS and US contributed to the agriculture component. SB, RNP, SS, AL, NA, FS, MP, PM are involved in the implementation of the initiative in Bihar, Chhattisgarh and Odisha. BM, SS and AP are government counterparts; BM provides management support in Odisha and Somya and AP in Bihar. AP, HPSS and SU advise on evaluation of the initiative and AP drafted the registered protocol. NA, VB, MR, BS, RRS, SP, LKD were part of evaluation team; NA, VB and MR led baseline evaluation in Bihar, Odisha and Chhattisgarh, respectively. VS, AB and AP drafted the manuscript. All authors reviewed the manuscript.

Acknowledgements

Shivani Dar (UNICEF Bihar) and Anoop Jha (Independent consultant) supported stakeholder coordination in Bihar. Anoop Jha was part of implementation team in Bihar. Shibanand Rath (Ekjut) participated in the designing workshop and made significant contribution to the participatory learning action component of the initiative. CM Singh (AIIMS, Patna, Bihar) managed evaluation teams in Bihar. Aparajita Chattopadhyay, Preeti Dhillon, Prakash H. Fulpagare and Konsam Dinachandra Singh (IIPS) supported quality control in baseline survey and are part of the evaluation team. Sarita Anand (Roshni, Lady Irwin College, New Delhi) leads process documentation of the initiative.

Rachna Sharma (UNICEF India) and Dhruv Sengupta (DAY-NRLM) offer technical advice on specific components related to communication and government coordination, respectively.

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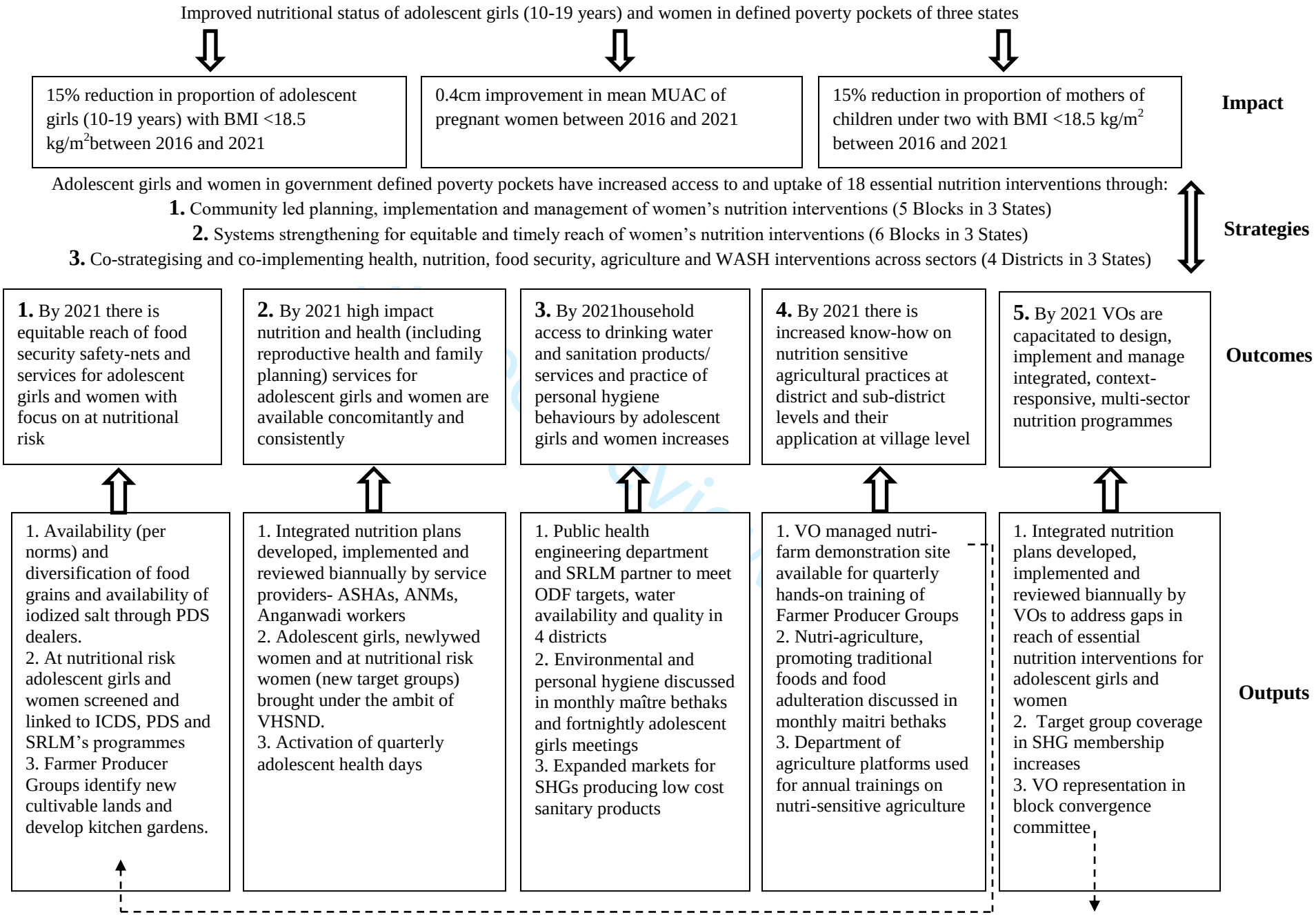
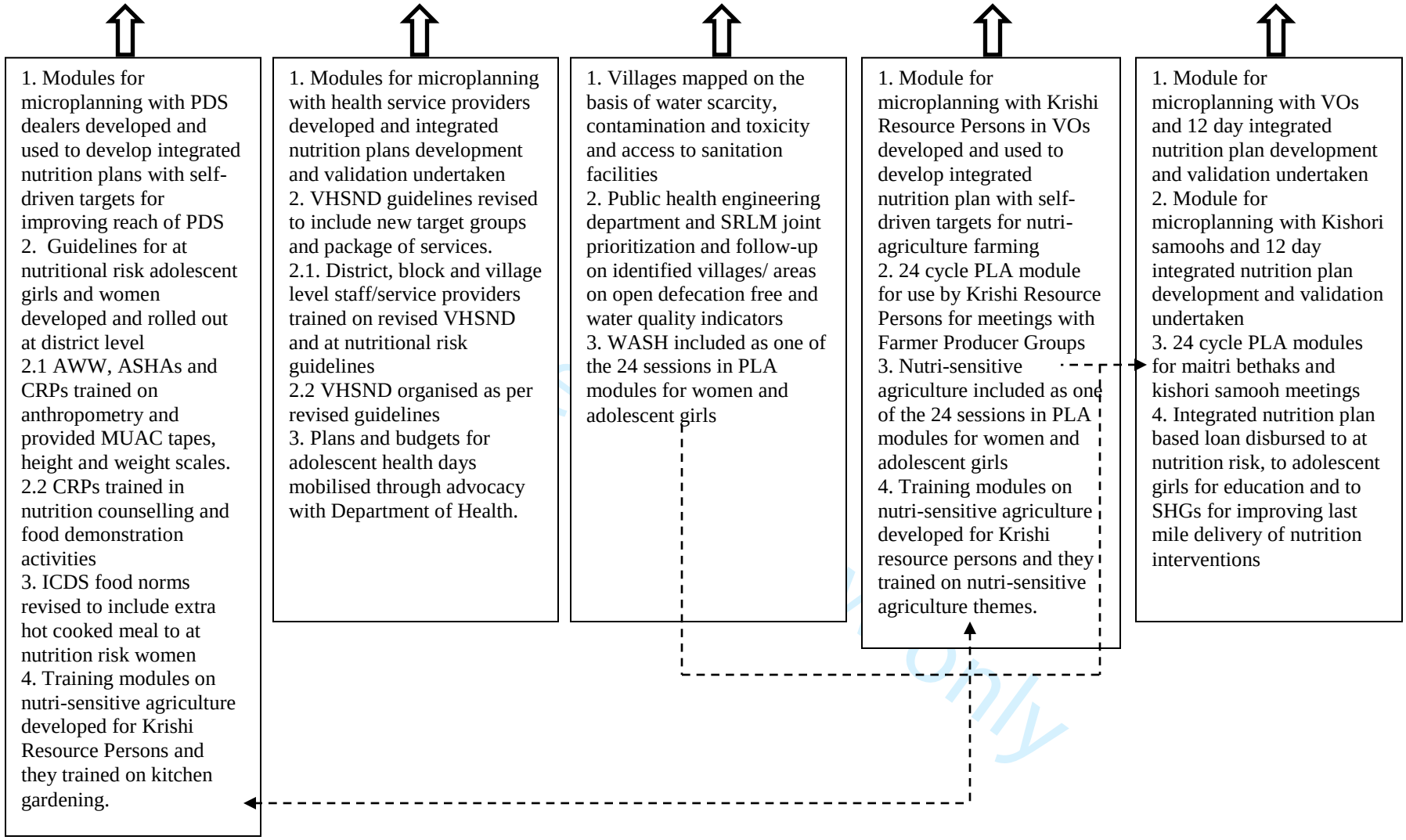
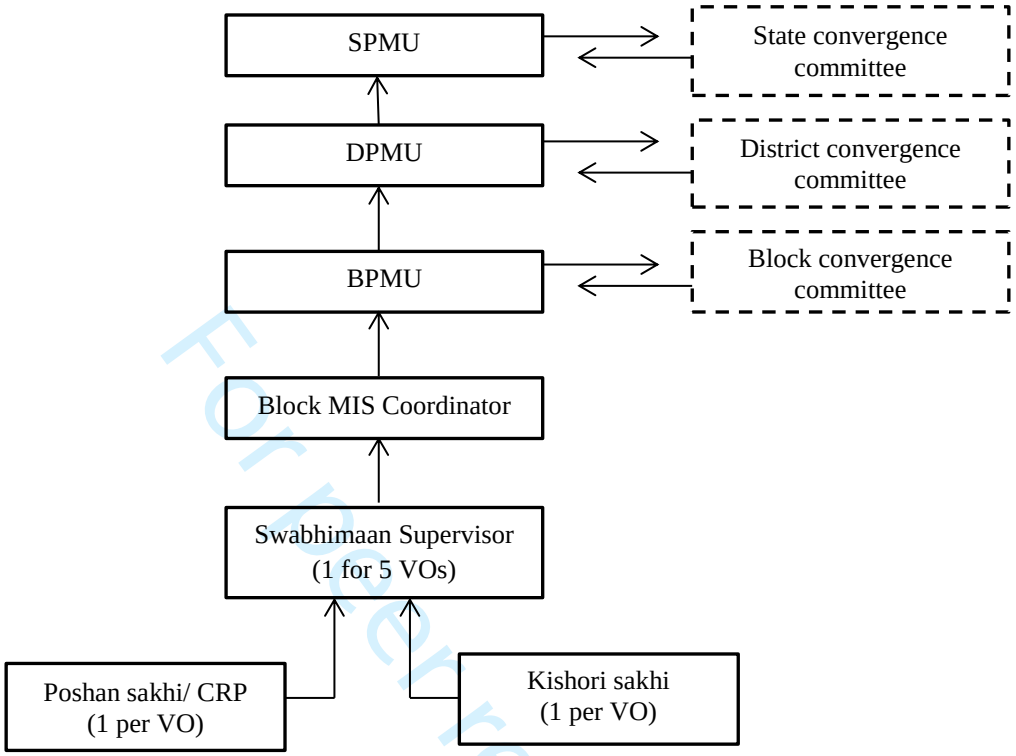
Figure 1 Theory of change for Swabhimaan: Bihar, Chhattisgarh and Odisha (2016 -2021)





Cross-cutting input: Annual planning and review of selected nutrition indicators by a multi-sector nutrition committee at block, district and state levels

Figure 2 SRLM organization structure and its adaptation in Swabhimaan, Bihar



All India Institute of Medical Sciences, Patna

Ethics committee approval letter

Date: 23/01/2016

Dr. Neeraj Agarwal
Prof.& Head
Department of Community & Family Medicine
AIIMS, Patna

Dear Dr. Neeraj Agarwal

Ref: IEC/AIIMS/PAT/52/2016

The Institutional Ethics Committee, All India Institute of Medical Sciences, Patna reviewed & discussed your study documents entitled **"Prospective, controlled, non-randomized evaluation of a programme to improve the nutritional status of women before conception, during pregnancy and after birth in Bihar". (The Swabhimaan Programme)** dated: 19.01.2016 study code: IEC/AIIMS/PAT/52/2016 on 19.01.2016.

The following members of ethics committee were present at the meeting held on 19.01.2016 at 2:00 P.M. at Department of Community and Family Medicine, All India Institute of Medical Sciences, Patna.

S. No.	Name and address of the EC members	Designation
1.	Dr. R.N. Singh, Consultant Orthopaedic Surgeon	Chairman
2.	Dr. P.P. Gupta, HOD, Pharmacology, AIIMS, Patna	Member: Pharmacologist
3.	Dr. Sadhana Sharma, Professor, Biochemistry, AIIMS, Patna	Member: Basic Sciences
4.	Dr. Ramji Singh, Addl. Prof. & Head, Physiology, AIIMS, Patna	Member: Pre-Clinical
5.	Dr. Ravi Kirti, Asst. Prof., General Medicine, AIIMS, Patna	Member: Physician
6.	Dr. Subhash Kumar, Assit. Prof., Radio Diagnosis, AIIMS, Patna	Member: Clinician
7.	Mr. Binay Kumar Pandey, Advocate, Patna High Court	Member: Legal Expert
8.	Mr. Ajit Kumar Chaudhary, Social Worker	Member: Social Worker
9.	Ms. Shahina Khan, Director of Raza International Group of Schools	Member: Philosopher
10.	Dr. C.M. Singh, Addl. Prof., Dept. of C&FM, AIIMS, Patna	Member Secretary

Address: All India Institute of Medical Sciences, District - Patna, State - Bihar, Pin Code – 801507,
E-mail – iecaiimspatna@gmail.com

The IEC approves the study to be conducted in its presented form.

Principal Investigator is responsible for fulfilling the following requirements:

- All Co-investigator must be kept informed of the status of the project.
- Any, amendment(s) to the protocol or the consent form(s), must be informed and submitted to the IEC for review and approval prior to the activation of the same. The IEC number assigned to the project should be cited in any correspondence.
- Serious Adverse Events (SAE), if any, should be reported to the IEC immediately. New information that becomes available which could change the risk-benefit ratio must be submitted promptly for IEC review.
- Records of documents related to signed consent (by subjects/witnesses) should be maintained properly for the audit by IEC.
- Approved study needs to be reviewed by IEC AIIMS Patna periodically at least once in a year as appropriate.
- After completion of the permitted tenure of the study, submission of the study report to the IEC AIIMS Patna is mandatory.
- A continuing review application must be submitted to the IEC in order to continue the study beyond the approved period. Failure to submit the same will result in the termination of the study.
- IEC AIIMS Patna will maintain the confidentiality of all the approved studies and will share the information with authentic bodies only on justification of the request.

Yours sincerely

Member Secretary
IEC, AIIMS, Patna

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
AIIMS, PATNA

Address: All India Institute of Medical Sciences, District - Patna, State - Bihar, Pin Code – 801507,
E-mail – iecaiimspatna@gmail.com

Institute Ethics Committee
अखिल भारतीय आयुर्विज्ञान संस्थान ,रायपुर (छत्तीसगढ़)
All India Institute of Medical Sciences, Raipur(Chhattisgarh)
Department of Pharmacology
2nd Floor, South Wing
Medical College Complex, Gate No. 5
Tatibandh, GE Road,
Raipur-492 099 (CG)
www.aiimsraipur.edu.in
Ethics Committee Registration No.: ECR/714/Inst/CT/2015

आरोग्यम् सुख सम्पदा

Letter No.: 114/IEC-AIIMSRPR/2016 Date: 02.09.2016

CERTIFICATE OF APPROVAL

To : Dr. Manisha Ruikar (Principal Investigator)
Professor & Head, Department of Community & Family Medicine,
AIIMS Raipur (CG)

Review Date : 06.08.2016

Reference : IEC Proposal No: **AIIMSRPR/IEC/2016/042**

Title : Baseline Survey for Swabhimaan Project, Bastar Block and Bakavand Block, Bastar District (Developed in consultation with UNICEF)

The Institute Ethics Committee, All India Institute of Medical Sciences, Raipur (Chhattisgarh) reviewed and discussed your above referenced research proposal in the meeting held on 06.08.2016.

The following documents were reviewed.

1. Covering Letter
2. Research Project Proposal (Version 2.0)
3. Case Record Form (Version 1.0)
4. Participant information sheet for participants more than 18 years of age (English & Hindi) (Version 1.0)
5. Participant information sheet for participants less than 18 years of age - English & Hindi (Version 1.0)
6. Consent Form for participant more than 18 year of age (English & Hindi) (Version 1.0)
7. Assent Form - English & Hindi (Version 1.0)
8. Undertaking regarding GCP guidelines and reporting of SAE
9. Other documents

Certificate of Approval: Proposal No. AIIMSRPR/IEC/2016/042
Ref: 114/IEC-AIIMSRPR/2016 dated 02.09.2016

a. Duly signed compliance sheet submitted to IEC by PI alongwith following documents :

i. E-comunication by Dr Abner Daniel, Nurition Specialist, Child Development and Nutrition, UNICEF to the Principal Investigator

ii. Letter by Director, National Rural Livelihood Promotion Society to Mision Director, Chhatttisgarh Gramin Ajjevika Samvardaan Samiti

iii. Letter by Mission Director, SRLM, Chhattisgarh to the Chief, Field Office , UNICEF

The following members of Institute Ethics Committee were present at the meeting held on 06.08.2016 at 11:00 AM at Department of Pharmacology, AIIMS Raipur.

Sr. No.	Name of IEC Member	Designation
1	**Dr. Arun T. Dabke** Ex. Vice-chancellor Ayush and Health Science University Raipur (CG)	Chairman
2	**Dr. S. R. Gupta** M.D. (Med.), M.D. Pharmacology Retired Professor & Head Department of Medicine Pt. J. N. M. Medical College, Raipur	Basic Medical Scientist
3	**Dr. P. K. Neema** Professor and Head Department of Anaesthesiology AIIMS Raipur	Clinician
4	**Dr. Sarita Agrawal** Professor and Head Department of Obstetrics and Gynaecology AIIMS Raipur	Clinician
5	**Mrs. Kamla Janswami** Ex-president Lion's Club, Raipur	Lay Person from Community
6	**Ms. Pushpy Michael** Principal Bharatmata Higher Secondary School GE Road, Tatibandh, Raipur Chhattisgarh	Social Scientist
7	**Dr. Nitin Gaikwad** Associate Professor Department of Pharmacology AIIMS Raipur	Member Secretary
Outside Legal Expert		
8	**Advocate Shekhar Amin**	Legal Expert

Certificate of Approval: Proposal No. AIIMSRPR/IEC/2016/042
Ref: 114/IEC-AIIMSRPR/2016 dated 02.09.2016

Clear statement of decision reached:

At Institute Ethics Committee meeting held on 06.08.2016, the committee reviewed the research project and study related documents and discussed the ethical issues involved.

A letter to this effect was sent to you seeking certain clarifications / modifications vide letter no. 104/IEC-AIIMSRPR/2016, dated 19.08.2016. In response to this, you have submitted required clarifications / modifications vide letter no. CFM/MR/Project/348/2016 dated 24.08.2016 (IEC inward letter no. 2016/84 dated 25.08.2016). Therefore, the research project and study related documents are approved with respect to ethical issues.

Hence, at the convened meeting of IEC-AIIMS Raipur on 02.09.2016, IEC decided to **approve** the above referenced research project.

As Principal Investigator, you are responsible for fulfilling the following requirements of approval:

1. This is approval is valid for entire duration of the study (i.e. Six months). The review application must be submitted to the IEC-AIIMS Raipur in order to continue the study beyond the approved period.
2. All the co-investigators must be kept informed of the status of the project.
3. Changes, amendments, and addendum to the protocol or the consent form, must be submitted to the IEC-AIIMS Raipur for re-review and approval prior to the activation of the changes.
4. Any change of study site, change of investigator/s, termination of study (with reason to do so) should also be informed to IEC-AIIMS Raipur.
5. The IEC proposal number assigned to the project should be cited in any correspondence.
6. Any Serious Adverse Event (SAE) occurring during the course of the study should be reported to the IEC-AIIMS Raipur.
7. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for IEC review.
8. Only approved consent forms are to be used in the enrolment of participants. All consent forms signed by subjects and/or witnesses should be retained on file. The

Certificate of Approval: Proposal No. AIIMSRPR/IEC/2016/042
Ref: 114/IEC-AIIMSRPR/2016 dated 02.09.2016

IEC may conduct audits of all study records, and consent documentation may be part of such audits.

9. The study progress report should be made available for the IEC review on every 6 month.
10. The final report of the study must be submitted to IEC-AIIMS Raipur after the completion of the study.

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

Sincerely,

Dr. Arun T. Dabke
Chairman
Institute Ethics Committee
All India Institute of Medical Sciences
Raipur 492 099 (C.G.)

02/09/2016

Dr. Nitin Gaikwad
Member Secretary
Institute Ethics Committee
All India Institute of Medical Sciences
Raipur 492 099 (C.G.)

INSTITUTIONAL ETHICS COMMITTEE

(ECR/534/Inst/OD/2014)

All India Institute of Medical Sciences Bhubaneswar,
Village Sijua, Patrapada, PO Dumduma, Bhubaneswar
751019, Odisha
Email: iec.aiimsbbsr@gmail.com
Phone:

54 (1)

To: Dr. Vikas Bhatia (Principal Investigator)

Date: 10.05.16

Re: IEC Proposal: T/EM -F/CMFM/16/02

Title: **Swabhiman- a nutritional intervention program in Odisha. Pre-implementation status assessment.**

I am pleased to inform you that at the convened meeting of 07.05.2016, the IEC voted to approve an amendment and to re-approve (renewal approval of the protocol and the consent form(s) is for 12 months) the above referenced protocol. As Principal Investigator, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators must be kept informed of the status of the project.
2. Changes, amendments, and addenda to the protocol or the consent form must be submitted to the IEC for re-review and approval prior to the activation of the changes. The IEC number assigned to the project should be cited in any correspondence.
3. Adverse events should be reported to the IRB. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for IEC review. The IEC and outside agencies must review the information to determine if the protocol should be modified, discontinued, or continued as originally approved.
4. Only approved consent forms are to be used in the enrolment of participants. All consent forms signed by subjects and/or witnesses should be retained on file. The IEC may conduct audits of all study records, and consent documentation may be part of such audits.
5. IEC AIIMS needs review of an approved study not less than once per 12-month period. **Therefore, a continuing review application must be submitted to the IEC in order to continue the study beyond the approved period.** Failure to submit a continuing review application in a timely fashion will result in termination of the study, at which point new participants may not be enrolled and currently enrolled participants must be taken off the study.
6. Principal investigator should initiate the project only after obtaining administrative permission from Director/Dean, AIIMS, Bhubaneswar.

Sincerely,

Chairman, IEC

(Chairman)

Institutional ethics Committee
AIIMS, Bhubaneswar

Members of the IEC who voted in Favour of the Proposal

Dr. Debasish Hota, Dr. Manaswini Mangaraj, Dr Amit Ghosh, Dr. Swagata Tripathy, Dr. K C Mishra, Dr. Somnath Mukherjee.

(2)

अखिल भारतीय आयुर्विज्ञान संस्थान, भुबनेश्वर – ७५१ ०१९

RESEARCH CELL

All India Institute of Medical Sciences, Bhubaneswar-751 019

AIIMS-BBSR/RC/EM-F/02/2016/05 Dt: 13/05/2016

Dr. Vikas Bhatia

Professor & Head

Department of Community Medicine & Family Medicine

Subject: Regarding initiation of extramural research project.

Dear Prof. Bhatia,

The research cell is pleased to inform you that your extramural funded project entitled **"Swabhiman- a nutritional intervention program in Odisha, Pre-implementation status assessment"** (bearing provisional project code T/EM-F/CMFM/16/02 and IEC approval letter No T/EM-F/CMFM/16/02 dated 10.05.2016) has been examined and approved by the competent authority.

Kindly note that following the approval, you have been assigned permanent project code: P/EM-F/CMFM/16/02 and the study may be initiated in the institute.

You are requested to provide 6 monthly progress reports (in case study duration is longer than 6 months) and a consolidated summary report within 1 month of end of study to the research cell.

Dept. of CMFM
AIIMS, BBSR
Date of Receipt 14/05/16
Date of Despatched

Thanking You

Yours sincerely

Project

13/05/16

Dr. Dillip Kumar Parida,
Faculty-in-Charge, Research Cell

13/5/16

BMJ Open

Integrated multisectoral strategy to improve girls' and women's nutrition before conception, during pregnancy and after birth in India (Swabhimaan): protocol for a prospective, non-randomized controlled evaluation

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-031632.R1
Article Type:	Protocol
Date Submitted by the Author:	29-Aug-2019
Complete List of Authors:	Sethi, Vani ; UNICEF India, Child Development and Nutrition Bhanot, Arti; Independent consultant; Bhattacharjee, Sourav; UNICEF Odisha, Nutrition Gope, Rajkumar ; Ekjut Sarangi, Debjeet; Living Farms Nath, Vikash; Ekjut Nair, Nirmala; Ekjut, Singh, Usha; Dr Rajendra Prasad Central Agricultural University Daniel, Abner; UNICEF India, Child Development and Nutrition Parhi, Rabi; UNICEF Bihar, Nutrition Sinha, Sonali; UNICEF Odisha Loomba, Avinash; UNICEF Chhattisgarh S, Somya; Bihar Rural Livelihoods Promotion Society Purty, Apollo; Bihar Rural Livelihoods Promotion Society Ali, Naushad; Independent consultant Mohapatra, Babita; Odisha Livelihoods Mission Agarwal, Neeraj; All India Institute of Medical Sciences (AIIMS), Patna Bhatia, Vikas; All India Institute of Medical Sciences Bhubaneswar Ruikar, Manisha; All India Institute of Medical Sciences - Raipur Sahu, Bharati; Independent consultant RS, Reshmi; International Institute for Population Sciences Pedgaonkar, Sarang; International Institute for Population Sciences Dwivedi, Laxmi Kant; International Insititute of Population Sciences, Saiyed, Farhat; UNICEF Chhattisgarh Prajapati, Mahendra; UNICEF Bihar Mishra, Preetu; UNICEF Chhattisgarh Prost, Audrey ; London School of Hygiene and Tropical Medicine, Global Health and Development Kejrewal, Nita; Deendayal Antyodaya Yojana, National Rural Livelihoods Mission Wagt, Arjan; UNICEF India, Child Development and Nutrition Sachdev, Harshpal; Sitaram Bhartia Institute of Science and Research, Department of Paediatrics Unisa, Sayeed; International Institute for Population Sciences, Mathematical Demography and Statistics
Primary Subject Heading:	Public health

Secondary Subject Heading:	Nutrition and metabolism
Keywords:	Adolescent girls, Nutrition < TROPICAL MEDICINE, Agriculture, Mutli-sector, Women collectives, India

STUDY PROTOCOL

Title

Integrated multisectoral strategy to improve girls' and women's nutrition before conception, during pregnancy and after birth in India (Swabhimaan): protocol for a prospective, non-randomized controlled evaluation

Authors

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ABSTRACT

Introduction

Swabhimaan is community-based programme to improve adolescent girls' and women's nutrition in rural areas of three Indian states- Bihar, Chhattisgarh and Odisha with high prevalence of undernutrition. .

Methods and analysis

Swabhimaan has a nested prospective, non-randomized controlled evaluation. Since 2017, five intervention sites receive community-led interventions through national government's livelihood mission supported women's self-help group federations and five control sites will initiate these activities 36 months later, in 2020. Community-led activities aim to improve coverage of 18 interventions including adequacy of food consumed, prevention of micronutrient deficiencies, access to basic health services, and special care of nutritionally at risk girls and women, improving hygiene and access to water and sanitation services and access to family planning services. The evaluation

includes baseline (2016-17), midline (2018-19) and endline (2020-21) surveys covering 6352 adolescent girls, 2573 pregnant women and 8755 mothers of children under two. The final impact analysis will be by intention-to-treat, comparing primary and secondary outcomes in five intervention areas and five control areas. The primary outcomes are: (1) a 15% reduction in the proportion of adolescent girls with a Body Mass Index (BMI) <18.5 kg/m^2; (2) a 15% reduction in the proportion of mothers of children under two with a BMI<18.5 kg/m^2 and (3) and a 0.4cm improvement in mean mid-upper arm circumference among pregnant women

Ethics and dissemination

All procedures involving human subjects were approved by the Institutional Ethics Committee of the All India Institute of Medical Sciences (AIIMS), Bihar, Chhattisgarh and Odisha and in compliance with guidelines laid down in the Declaration of Helsinki. Evidence will inform maternal and preconception nutrition policy at national and state level.

Evaluation registration

The evaluation is registered with the Registry for International Development Impact Evaluation (RIDIE-STUDY-ID-58261b2f46876) and the Indian Council of Medical Research, National Clinical Trials Registry of India (CTRI/2016/11/007482)

Key words

Adolescent girls, nutrition, agriculture, multi-sector, women collectives, India

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The study will provide evidence on effectiveness of a community-led model in delivering a comprehensive package of 18 nutrition services, on improving nutrition status of adolescent girls, pregnant women and mothers of children under two in resource-poor settings.
- The model is based on sustainable government resources with only one of the three states receiving additional non-government funding to test the model.
- The pace of implementation will vary considerably across three states due to variable governance, availability of resources, maturity of self-help groups and intensity of non-government engagement which is likely to impact the study outcomes.

- While the design includes a comparator site, introduction of new government schemes that can have variable influence in intervention and control sites are not ruled out.
- The evaluation is led by an independent third party with no role in implementation of the model.

INTRODUCTION

There is compelling evidence on the importance of women's nutrition prior to and during pregnancy, to ensure optimal foetal growth and development and for the health and wellbeing of the mother [1]. Globally, over 800,000 neonatal deaths and 20% of stunting in children less than five years of age is attributable to poor nutrition in utero, including protein-energy and micronutrient deficiencies [2]. Nearly 4.5 million Indian women become pregnant in adolescence, 58% have anaemia and 23% are thin. It is unsurprising that over 50 million children under-five (38%) are stunted [3,4]. India has both policies and programmes in place to deliver and monitor globally-recommended preconception and antenatal nutrition interventions. Most recently, India's National Nutrition Mission or Poshan Abhiyaan (2018-22) aims to reduce the proportion of children born with low birthweight from 19% to 11% and under-five children stunted from 38% to 13% respectively, by 2022. It also aims to reduce anaemia among adolescent girls and pregnant women, which is over 50%, by 3% per annum. This is to be achieved through coordinated efforts across 11 different ministries that together can make all essential nutrition services available to women and children through integration of their ongoing vertical programmes and schemes [5]. Despite these policies and programmes, in 2015-16 the coverage of at least four antenatal care visits was just over 50%, only a third of pregnant women consumed Iron Folic Acid (IFA) tablets for at least 100 days during pregnancy, and less than 40% used the maternity benefit scheme [3]. Challenge lies in lack of effective operational models to deliver a comprehensive package of essential nutrition interventions for adolescent girls and women, models that can overcome both systemic challenges and those around user service uptake.

Evidence from randomized controlled trials within and outside India suggests that working with women's groups as a platform for promoting health interventions and increasing service uptake is a feasible approach in low-resource settings [6,7,8,9,10]. This is provided the necessary requisites, such as high-quality facilitators for establishing and maintaining the group, high coverage of intervention, sufficient time for implementation of the intervention, concomitant supply strengthening interventions and appropriate safeguards against harm such as conflict with service providers and domestic

violence, are met. However, none of these trials investigated nutrition outcomes for adolescent girls or women.

In view of the undisputed role of income poverty in the aetiology of undernutrition, there is a need to integrate women-centric poverty alleviation in nutrition programmes and vice-versa. Notable global examples where women's collectives have been engaged with to deliver services and promote health and nutrition behaviours in underserved communities, along with economic empowerment include a community conditional cash transfer programme in Indonesia, as well as livelihood and food security programmes in Bangladesh (Shouhardo, Jibaon-o-Jibika) and Nepal (Suaahara) [11,12]. Indian experiences include Kudumbashree (Kerala), the Society for Elimination of Rural Poverty Project (Andhra Pradesh and Telangana), Self Employed Women's Association (rural areas of several states), Community Health Care Management Initiative (West Bengal), Jamkhed (Maharashtra), and urban health models by the Urban Health Resource Centre and Mahila Abhivrudhi Society, Andhra Pradesh. Women's groups are trained on promotion of the health and nutrition interventions, the scope and duration of training varying with the type of programme. The promoting agency, which is mostly a non-government organisation or federated structure of community based groups, provides capacity building and supervisory support. Most programmes strengthen the health services delivery system in addition to intervening with community groups [13,14].

Women's SHGs and their federations supported by the Deendayal Antyodaya Yojana -National Rural Livelihoods Mission (DAY-NRLM)'s Government of India's flagship poverty alleviation programme, remain an untapped platform for improving reach and use of essential nutrition interventions, particularly for women residing in income-constrained settings [15]. A 2016 scoping study from UNICEF India suggested that DAY-NRLM village organisations have the potential to manage grants for improving last mile delivery of essential nutrition services for women, provided they are enabled, supervised and incentivised [16]. DAY-NRLM is also one of the nodal agencies for implementation of the Poshan Abhiyaan. Capitalising on this, the Swabhimaan programme is a four-year initiative launched in 2016 to improve adolescent girls' and women's nutrition.

Swabhimaan is a package of community-led interventions delivered by DAY-NRLM-supported federations of women self-help groups (SHGs) comprising Village Organizations (VOs) and the higher order Cluster-Level Federations (CLFs), to improve the nutrition status of adolescent girls and women in three Indian states: Bihar, Chhattisgarh and Odisha. The objectives of the programme are:

1. To improve the food and nutrient intake of adolescent girls and women
2. To prevent micronutrient deficiencies and nutritional anaemia
3. To increase access to services during fixed day, Village Health Sanitation and Nutrition Days (VHSNDs) and provide special care to nutritionally 'at risk' women, defined as those with mid-upper arm circumference (MUAC) <23 cm or Body Mass Index (BMI)<18.5 kg/m^2
4. To increase access to education about water, sanitation and hygiene (WASH) and access to WASH commodities
5. To prevent early, poorly spaced and repeated pregnancies

METHODS AND ANALYSIS

This protocol describes the intervention and evaluation methods for the Swabhimaan programme, which aims to improve the nutrition status of adolescent girls and women in three Indian states: Bihar, Chhattisgarh and Odisha.

Target groups

The primary target groups for the programme are adolescent girls, newlywed women and couples, pregnant women, and mothers of children under two years of age. Swabhimaan also reaches out to husbands, mothers-in-law and farmer producer groups.

Evaluation design

The Swabhimaan evaluation is a prospective, non-randomized controlled study with baseline, midline and endline cross-sectional surveys. Across Bihar, Chhattisgarh and Odisha, five sites covering 162 villages (intervention arm) have been purposively allocated to community-led interventions delivered through VOs and CLFs since 2017, and five sites covering 151 villages (control arm) will initiate these activities 36 months later, in 2020. Both intervention and control sites are located in the poorest areas (also referred to as resource blocks) identified by DAY-NRLM in four districts: Purnea in Bihar,

Bastar in Chhattisgarh, and Angul and Koraput in Odisha. In Bihar, within Kasba and Jalalgarh blocks located in Purnea district, we allocated 42 villages to the intervention and 31villages to control arm. In Chhattisgarh, we allocated 40 villages in Bastar block in Bastar district to intervention and 40 villages in Bakawand block to control. In Odisha, 80 villages within Koraput block in the district of Koraput and Pallahara block in the district of Angul both serve as intervention areas, and 80 more serve as control. The unit of assignment to intervention and control was a cluster of villages in Bihar and Chhattisgarh and a gram panchayat (administrative units of around 5000 population) in Odisha which was in alignment with NRLM identified administrative boundaries for managing the livelihoods programme in these states (Figure 1).

Figure 1. Evaluation design

Study hypotheses and outcomes

We hypothesize that, over an intervention period of three years, Swabhimaan's community-led interventions will lead to:

(a) a 15% reduction in the proportion of adolescent girls with a BMI<18.5

(b) a 15% reduction in the proportion of mothers of children under two with a BMI<18.5

(c) a 0.4cm improvement in mean MUAC among pregnant women

These three indicators are considered the evaluation's primary outcomes. The targets for reduction in proportion of adolescent girls and pregnant women with BMI<18.5 kg/m^2 was based on population based survey data for the selected districts while that for MUAC in pregnancy was based on a rapid assessment undertaken in the intervention sites and the reductions noted in previous research on women's nutritional status [17,18]. We also hypothesize an improvement of between 5% and 20% in the coverage of 18 key nutrition-specific and -sensitive interventions over three years (Table 1). These constitute the evaluation's secondary outcomes.

Table 1 Primary and secondary outcomes for Swabhimaan

PRIMARY OUTCOMES
1. % adolescent girls with BMI <18.5 kg/m^2
2. mean MUAC among pregnant women

3. % mothers of children under 2 with <18.5 kg/m^2
SECONDARY OUTCOMES
ADOLESCENT GIRLS (Girls aged 10-19) – unmarried, not pregnant and not the mother of a child under two
1. Mean dietary diversity score 2. % receiving minimum dietary diversity score (MDD) (5 of10 food groups) 3. % consuming four or more IFA tablets in the month preceding the survey 4. % living in a household with iodized salt 5. % living in food secure households 6. % living in households with a kitchen garden 7. % living in households with a toilet or covered pit latrine 8. % using safe pads or sanitary pads 9. % accessing adolescent health services (Kishori Divas) in six months preceding the survey 10. % who attended at least three Kishori meetings in six months 11. % who attended at least three Kishori meetings in in six months
PREGNANT WOMEN (if she is pregnant, a girl or woman will join this category whether she is an adolescent, newlywed or the mother of any child under two)
1. % of pregnant women in the 2nd and 3rd trimester consuming at least 25 IFA tablets in the month preceding the survey 2. Mean dietary diversity score 3. % receiving minimum dietary diversity (5out of 10 food groups) 4. % living in a household with iodized salt 5. % living in food secure households 6. % living in households with a kitchen garden 7. % living in households with a toilet or covered pit latrine 8. % receiving ICDS entitlement for supplementary food in month preceding the survey 9. % who had one antenatal check-up in the first trimester

10. % weighed at least once in first trimester
11. % who received one dose of albendazole in second trimester
12. % who took two calcium tablets in 2nd trimester
13. % below the age of eighteen
14. % who attended at least three Maitri Bethak meetings in six months
15. % who attended at least three Maitri Bethak meetings in six months
16. % who attended at least three VHSNDs in six months
17. % who attended at least three VHSNDs in six months
18. % using a modern family planning method (in previous delivery); before the current pregnancy
19. % who are members of women's Ag-producer groups and have adopted at least 1 mix micronutrient-rich cropping methods, against previous practice
20. % who are members of women's Ag-producer groups and have adopted at least 1 pesticide-free agri-methods, against previous practice

MOTHERS OF CHILDREN AGED UNDER TWO YEARS

1. Mean dietary diversity score
2. % receiving minimum dietary diversity (5 out of 10 food groups)
3. % living in a household with iodized salt
4. % living in food secure households
5. % living in households with a kitchen garden
6. % living in households with a toilet or covered pit latrine
7. % receiving their minimum PDS entitlement in month preceding survey
8. % receiving ICDS entitlement for supplementary food in month preceding survey
9. % who received at least four ANC overall in last pregnancy
10. % consuming 100 or more IFA tablets during last pregnancy
11. % weighed at least four times in last pregnancy
12. % using a modern family planning method

13. % who accessed at least one of three social protection schemes (JSY, Adarsh Dampati Yojana)
14. % who delivered in a health facility in last pregnancy
15. % who attended at least three Maitri Bethak meetings and three VHSNDs in last year
16. % who attended at least three Maitri Bethak meetings and three VHSNDs in last year
17. % who are members of women's Ag-producer groups and have adopted at least 1 mix micronutrient-rich cropping methods, against previous practice
18. % who are members of women's Ag-producer groups and have adopted at least 1 pesticide-free agri-methods, against previous practice

Sample size calculation

We conducted State-specific sample size calculations to determine the appropriate number of adolescent girls, pregnant women and mothers of children under two to be surveyed to be able to detect achievement of hypothesised targets for primary outcomes (Table 2). Sample size accounted for 5% refusal rate and design effect of 1.5. Overall, we estimated that baseline and endline surveys should include a total of 6638 adolescent girls, 10,160 mothers of children under two and 2992 pregnant women across the three States.

Table 2 State wise estimated total sample in intervention and control areas by target groups

	Bihar	Chhattisgarh	Odisha	Total
Adolescent girls	1750	3294	1594	6638
Pregnant women	748	1122	1122	2992
Lactating mothers	2846	3294	4020	10160
Total	5345	7710	6736	19790

Sample selection

We conducted the baseline survey for the evaluation in 2016-17. In Bihar, a census was undertaken and full household listing was conducted to identify adolescent girls aged 10-19 years, pregnant

women and mothers of children under two in all programme areas. Respondents for each of the three target groups were then selected by simple random sampling. In Chhattisgarh, all villages in designated programme site were paired on the basis of population size and whether they had held a monthly VHSND for the last three months. Forty such pairs were then randomly selected for data collection, and all eligible respondents in each of the three target groups in these 80 villages were surveyed. In Odisha, all eligible target groups in 26 purposively identified Gram Panchayats- 12 intervention and 14 control were surveyed.

Tools

Bilingual questionnaire (Bihar: English and Hindi, Chhattisgarh: English and Hindi and Odisha: English and Odia) for all target groups were developed, field tested and standardized for all states. In baseline, information obtained included but was not limited to socio-demographic and household characteristics, educational attainment, diet diversity, household food security, access to services. Anthropometric measurements (weight, height and MUAC) were conducted using standard techniques [19]. Weight to the nearest 0.1 kg was recorded using a SECA electronic weighing scale with minimal clothing. Height was taken barefoot to the nearest 0.1 cm using a stadiometer. MUAC was measured to the nearest 0.1 cm with a non-stretchable measuring tape.

Sample coverage in baseline survey

Sample coverage for both interviews and anthropometric measurements was universal in all states except among mothers of children under two in Bihar where 85% of those sampled could be interviewed and coverage for all anthropometric measurements was 83%.

Intervention

Swabhimaan covers 18 nutrition-specific and nutrition-sensitive interventions (Table 3).

Table 3 Nutrition-specific and nutrition-sensitive interventions package, Swabhimaan

	Relevant target group		
	Preconception	**Pregnancy**	**Lactation**
Improve food and nutrient intake			
1. Access to generalized household ration through	*	*	*

Public Distribution System (PDS), a food subsidy scheme			
2. Balanced energy protein supplementation through access to supplementary rations	*	*	*
3. Access to knowledge and choices about how to increase maternal dietary diversity	*	*	*
4. Access to knowledge and support for nutrition-sensitive agriculture at home (kitchen garden) and community based food insecurity coping strategies.	*	*	*
Prevent micronutrient deficiencies and anaemia			
5. IFA supplementation	*	*	*
6. Universal use of iodized salt	*	*	*
7. Calcium supplementation and deworming	x	*	*
8. Access to information and commodities like insecticide treated bed-nets for malaria prevention	*	*	*
9. Access to information on preventing tobacco and alcohol use in pregnancy	x	*	*
Increase access to health services and special care to nutritionally "at risk" women (MUAC <23 cm)			
10. Early registration in outreach services	*	*	x
11. Recording and monitoring of nutritional status and special community-based at-nutritional risk package	x	*	x
12. Quality reproductive health, antenatal and postnatal care	*	*	*
13. Access to knowledge and entitlements for promotion of institutional deliveries and maternity benefits	x	*	*
Increase access to education and commodities for			

WASH			
14. Sanitation and hygiene (including menstrual hygiene) education	*	*	*
15. Access to safe drinking water and sanitation commodities	*	*	*
Prevent early, poorly spaced or unwanted pregnancies			
16. Promotion of secondary education and education for delaying the age at marriage to legal age	*	x	x
17. Access to information and family planning commodities for delaying age at first pregnancy and prevention of repeated pregnancies	*	*	*
18. Women's collective voice and empowerment for decision-making to prevent child marriage, violence against women, child spacing and other gender-related issues	*	*	*

In intervention sites, these interventions are delivered through a combination of community- and systems-led efforts, while control sites receive only systems strengthening. Community-led interventions are delivered through trained community cadre who are members of VOs, namely Poshan Sakhis (lit. 'Nutrition sister/friend') or Community Resource Persons (CRPs) and Krishi Mitras (lit. farmer friends) or Village Resource Persons (VRPs). The community cadre are part of the DAY-NRLM and SRLM implementation structure. In Bihar, a separate cadre of Kishori Sakhis (lit. 'Adolescent sister/friend') for reaching out and serving adolescent girls has been created (Table 4).

Table 4 Geographic scope and service providers for community-led interventions under Swabhimaan

	Bihar	Chhattisgarh	Odisha	Total
Revenue villages	77	111	168	356

CLF and related (Tier -3)	5	4	12	21
VOs (Tier 2)	72	80	79	231
Poshan Sakhis or CRPs of Tier 2	72	100	79	251
Kishori Sakhis of Tier 2	72	-	-	72
SHGs (Tier-1)	1985	1488	702	4175
VRPs/Krishi mitras	115	80	39	234

Poshan Sakhis and Kishori Sakhis undergo three days of pre-service training on integrated nutrition microplanning, which includes a theoretical orientation and practical on consultative identification and prioritization of nutrition and related problems among target groups in their village/s, developing an annual plan of activities including a budget to address these problems, the use of MUAC tapes, recording and using MUAC measurements for screening nutritionally "at risk" adolescent girls and women. As no standard MUAC cut-offs are available for screening adolescent girls at risk of undernutrition and <21 cm as well as <22 cm have been reported in research, a stricter cut-off of <19 cm is being used to identify those, most at risk [20,21,22]. In addition, clinical examination for signs of anaemia is also done followed by a diagnostic test for blood haemoglobin level by a health service provider at VHSND. Post-training, they co-facilitate the development of the integrated nutrition microplan with the block coordinator/ supervisor through a 12-day process, which can spread over almost two months. The process entails microplanning at VO level, its validation by reaching out to the most vulnerable communities and village clusters, then consolidation of all VO plans at CLF and block levels. Poshan Sakhis and Kishori Sakhis are then trained over three days on use of participatory learning and action (PLA) to facilitate monthly women's group and adolescent girls' group meetings. Poshan Sakhis and Kishori Sakhis lead activities in their village/s as per decided activities in the microplan. More cost-intensive and complex grant management activities are led by CLFs (Table 5).

Table 5 Community led interventions under Swabhimaan

Responsible agency /	Intervention	Frequency

Service provider		
VO		
Social action committee	Selection of Poshan Sakhi (1 per VO)	One time
Poshan sakhi/CRP	Integrated nutrition microplanning (12 days over 2 months)	Once, followed by annual review
	Maitri bethak (lit. friendly meeting) of women open to non-group members using Participatory Learning and Action	Monthly
	One additional monthly home visit/group meeting of nutritionally "at risk" women	Monthly
Krishi mitra/ VRP	Maitri kishan bethak (lit. friendly farmers meeting) on nutrition-sensitive agriculture Participatory Learning and Action	Monthly
	Home-based Poshan beds/backyard poultry	Monthly
CLF		
Social action committee	Families with women and children at risk of undernutrition linked to agri-poultry linkage and social protection schemes	Monthly
	Loans for secondary education	Monthly
	Creating farmer training school sites	Monthly
	Training for Poshan sakhi and Krishi mitras	Quarterly
	Newly wed couples meetings	Biannual
	Entitlement camps and health checkups for SHG members	Biannual
	Review of integrated nutrition plan	Annual

The CRPs receive INR 450 (USD 7) for developing the poshan microplan and thereafter a similar incentive every month for completed activities. CLFs also receive grants including: INR 500 (~USD

7) for meetings with newlywed couples; INR 500 for each 'welcome kit' given to newlywed couples with essential items like IFA, contraceptives, sanitary napkins; INR 1500 (~USD 22) for review of each VO's integrated nutrition microplan; and INR 5000 (~USD 77) for developing farmer training school sites which are model nutri-farms for training farmer producer group members interested in nutri-sensitive agriculture.

The system strengthening activities include five components:

1) strengthening VHSNDs to improve access to antenatal care, family planning and micronutrient supplementation through quarterly trainings of health service providers, monthly review of nutrition indicators, and the identification of women at risk of undernutrition (MUAC <23cm) for special supplementary food and counselling;

2) Strengthening adolescent health days to improve access to adolescent health and nutrition services via quarterly trainings of health service providers;

3) an extended VHSND once every six months for newlyweds and women, including individual counselling and information about entitlement camps;

4) annual training and follow-up meetings with service providers from food security, Integrated Child Development Services (ICDS), water and sanitation departments to help them improve the delivery of entitlements and services;

5) ensuring regular review meetings with representation across government departments involved in service delivery

Thus, in addition to DAY-NRLM, system strengthening activities engage four other government departments: Department of Woman and Child Development for increasing ICDS reach and quality, Department of Health and Family Welfare for VHSND strengthening, Department of Water and Sanitation for improving water quality and achieving open defecation free villages and districts, and finally Department of Civil and Food Supply for increasing coverage of food subsidy schemes.

The theory of change for Swabhimaan is presented in Supplementary File 1.

Blinding

It is not possible to blind participants to allocation, but data collection teams and analysts are blind to allocation.

Data analysis

In each state, we will assess the comparability of intervention and control areas at baseline by examining area-level and individual level characteristics, including: the number of self-help groups and village organisations in each area, the socio-demographic profile of respondents and their households (caste, literacy and assets) and key evaluation outcomes at baseline.

The final impact analysis will be by intention-to-treat, comparing primary and secondary outcomes in five intervention areas and five control areas. This analysis will be carried out at an individual level, adjusting for clustering at the level of the village and VO, using linear and logistic random effects models in STATA 14. We will use the difference-in-difference method to compare primary and secondary outcomes between intervention and control areas at endline, adjusting for their baseline values and for other characteristics that differed significantly between the two areas at baseline. We will present analyses both a State level, and conducted a pooled analysis with data from all States.

Patient and Public Involvement

This research did not have any patients. The public (community) was involved in the design and implementation of the intervention package at the village level but not in the evaluation. Public were not invited to contribute to the writing or editing of this document for readability or accuracy.

Process monitoring and progress review

In addition to the impact evaluation described above, we are conducting process monitoring. The process monitoring system is based on the reporting structures within the SRLM (Figure 2).

Figure 2 SRLM organization structure and its adaptation in Swabhimaan, Bihar

SRLM's have a project management units at State, district and block levels (SPMU,DPMU, BPMU). The block Management Information System (MIS) coordinator is the reporting link between the CRPs and their supervisors and the BPMU. In Bihar, a supervisor position has been embedded in the

organization structure while in Chhattisgarh and Odisha, supervisory staff is a representative from the SRLM's organogram.

CRPs/ Poshan sakhis collect data and report coverage of community-led interventions on monthly monitoring formats which are available in both web-based and paper formats. Key performance indicators include:

- Target women who attended the VHSND (%)
- Target women who attended the maitri bethak (%)
- At-risk women visited fortnightly in their home visits (%)
- At-risk women attended fortnightly food demonstration and counselling session (%)
- Target newly-wed who attended the couple meeting (reported quarterly)
- Target groups who attended the women only camps (reported biannually)

All CRP reports are collated monthly at the block level. A CLF level review of the progress on performance indicators and the planned activities as per the poshan microplan is planned for every quarter, however, Swabhimaan has mixed experience in achieving this with Chhattisgarh undertaking monthly reviews while other states undertaking annual reviews. DAY-NRLM hosts annual reviews with the respective SRLMs for stock taking and approval for next annual cycle.

Timeline

Baseline was completed in 2017. The first phase of implementation is between 2017 and 2020. Midline and endline for first phase will be completed in 2019 and 2021 respectively.

ETHICS AND DISSEMINATION

The baseline survey was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving human subjects were approved by the Institutional Ethics Committee of the All India Institute of Medical Sciences (AIIMS), Bihar, Chhattisgarh and AIIMS, Odisha in July 2016 (Supplementary files 2,3 and 4). Written informed consent was obtained from all

subjects. The impact evaluation has been registered with the Registry for International Development Impact Evaluations (RIDIE-STUDY-ID-58261b2f46876) [23] and Indian Council of Medical Research National Clinical Trials Registry of India (CTRI/2016/11/007482).

Government of India is committed to reviewing its antenatal care guidelines with focus on nutrition in addition to other components of antenatal care in line with new recommendations of the World Health Organization, 2016 [24]. Evidence from the evaluation will inform maternal nutrition policy as well as incorporation of nutrition interventions for adolescent girls and newly-wed women in existing and new policies.

CONCLUSION AND IMPLICATIONS

Being a controlled evaluation, Swabhimaan will measure impact of community-led interventions over standard practice of public health and nutrition services for adolescent girls, pregnant women and lactating mothers. A third party evaluator, International Institute for Population Sciences, India, with no role in implementation, further bolsters the evaluation design. Swabhimaan operates in complete alignment with DAY-NRLM's mandate under the joint convergent action plan for Poshan Abhiyaan. In coordination with departments of Woman and Child Development and Health, DAY-NRLM shares responsibility for (1) SHG members mobilizing communities for utilizing entitled services through Department of Health, (2) SHG members participating in Behaviour Change and Communication activities, promoting recommended health, nutrition and WASH behaviours, (3) common use of infrastructure by the three departments such as use of Panchayat halls for SHG and VO meetings and (4) promoting nutri-based livelihoods for women's collectives. These activities are integrated in VO's poshan microplans and system strengthening activities under Swabhimaan.

Swabhimaan operates as three different models in Bihar, Chhattisgarh and Odisha. Bihar is the demonstration and learning site, with financial support for human resources and activities through UNICEF India. In Chhattisgarh and Odisha, the initiative is almost completely led by the respective SRLMs with UNICEF to SRLM cost ratio at 1:5. UNICEF India supports some human resource at state and block levels, but none at the VO level in these two states. By 2020, it is planned to advocate for increased number of positions at SRLMs to support implementation of the convergent action plan

and create a system of CRPs graduating to block level positions in the three states. UNICEF India's support on human resource will gradually lessen. DAY-NRLM has recognized the Chhattisgarh model of Swabhimaan as a best practice for integrating health, nutrition and WASH on the SHG platform and has planned to take elements from the initiative for horizontal expansion to poorest resource blocks in other states. Findings from the Swabhimaan midline survey will inform scale-up plans in other states.

DECLARATIONS

Abbreviations

AIIMS All India Institute of Medical Sciences, ANM Auxiliary Nurse Midwife , ASHA Accredited Social Health Activist, AWW Anganwadi Worker, BMI Body Mass Index, BPMU Block Project Management Unit, CLF Cluster Level Federation, CRP Community Resource Person, DAY-NRLM Deendayal Antyodaya Yojana- National Rural Livelihoods Mission, DPMU District Project Management Unit, ICDS Integrated Child Development Services, IFA Iron Folic Acid, MIS Management Information System, MUAC Mid-upper Arm Circumference, PLA Participatory Learning Action, PDS Public Distribution System, RIDIE Registry for International Development Impact Evaluation , SHG Self-help group, SPMU State Project Management Unit, SRLM State Rural Livelihoods Mission, VHSND Village Health Sanitation and Nutrition Day, VRP Village Resource Person, VO Village Organization, WASH Water Sanitation and Hygiene

Ethics approval and consent to participate

The baseline survey was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving human subjects were approved by the Institutional Ethics Committee of the All India Institute of Medical Sciences (AIIMS), Bihar, Chhattisgarh and AIIMS, Odisha in July 2016. Written informed consent was obtained from all subjects. The impact evaluation has been registered with the Registry for International Development Impact Evaluations (RIDIE-STUDY-ID-58261b2f46876) and Indian Council of Medical Research National Clinical Trials Registry of India (CTRI/2016/11/007482).

Data sharing

Funding

This research received no specific grant from any funding agency in public, commercial or not-for-profit sectors.

Competing interests

None of the authors have any competing interests.

Authors' contributions

VS and ADW provide technical oversight and VS is the national focal point of the initiative. NK is key contact in NRLM and advises on effective utilization of NRLM platforms. VS, AB, SB, NN, AD,RNP, SS, AL and NK were involved in designing Swabhimaan initiative at national and state level. RG, VN and NN contributed to the Participatory Learning Action component of the initiative. DS and US contributed to the agriculture component. SB, RNP, SS (Sonali Sinha), AL, NA (Naushad Ali), FS, MP, PM are involved in the implementation of the initiative in Bihar, Chhattisgarh and Odisha. BM, SS and AP (Apollo Purty) are government counterparts; BM provides management support in Odisha and SS (Somya S) and AP (Apollo Purty) in Bihar. AP (Audrey Prost), HPS and SU advise on evaluation of the initiative and AP (Audrey Prost) drafted the registered protocol. NA (Neeraj Agarwal), VB, MR, BS, RRS, SP, LKD were part of evaluation team; NA (Neeraj Agarwal), VB and MR led baseline evaluation in Bihar, Odisha and Chhattisgarh, respectively. VS, AB and AP (Audrey Prost) drafted the manuscript. All authors reviewed the manuscript.

Acknowledgements

Shivani Dar (UNICEF Bihar) and Anoop Jha (Independent consultant) supported stakeholder coordination in Bihar. Anoop Jha was part of implementation team in Bihar. Shibanand Rath (Ekjut) participated in the designing workshop and made significant contribution to the participatory learning action component of the initiative. CM Singh (AIIMS, Patna, Bihar) managed evaluation teams in Bihar. Aparajita Chattopadhyay, Preeti Dhillon, Prakash H. Fulpagare and Konsam Dinachandra Singh (IIPS) supported quality control in baseline survey and are part of the evaluation team. Sarita

Anand (Roshni, Lady Irwin College, New Delhi) leads process documentation of the initiative. Rachna Sharma (UNICEF India) and Dhruv Sengupta (DAY-NRLM) offer technical advice on specific components related to communication and government coordination, respectively.

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Figure 1 Evaluation design

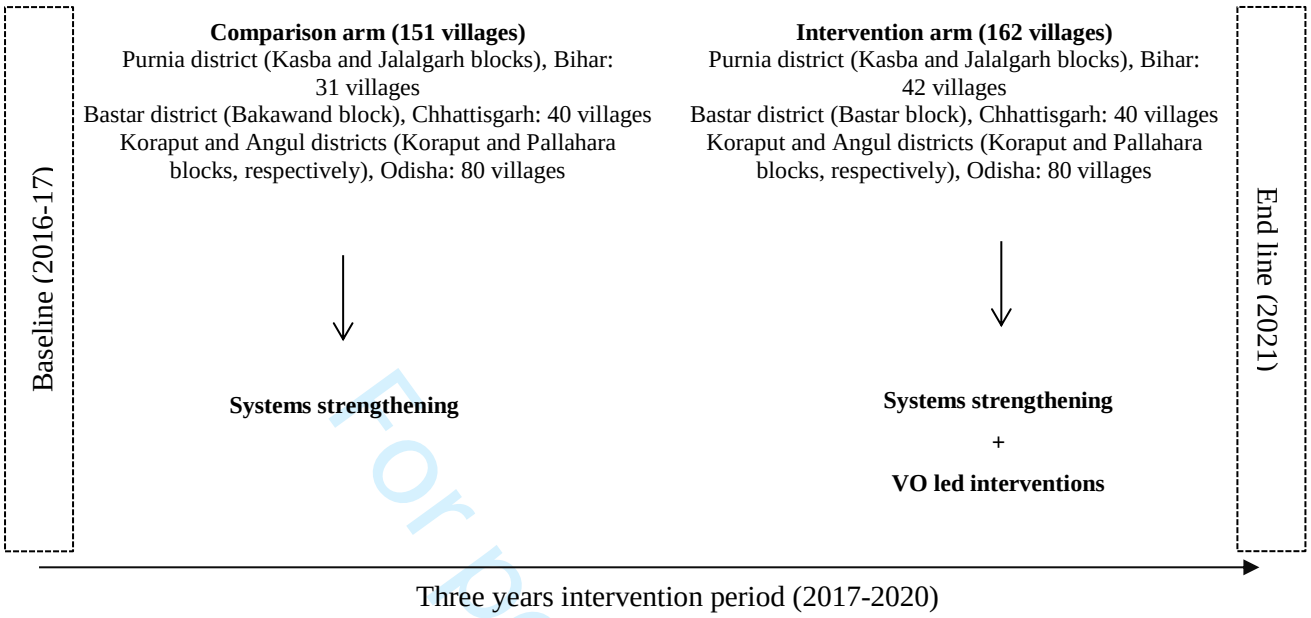
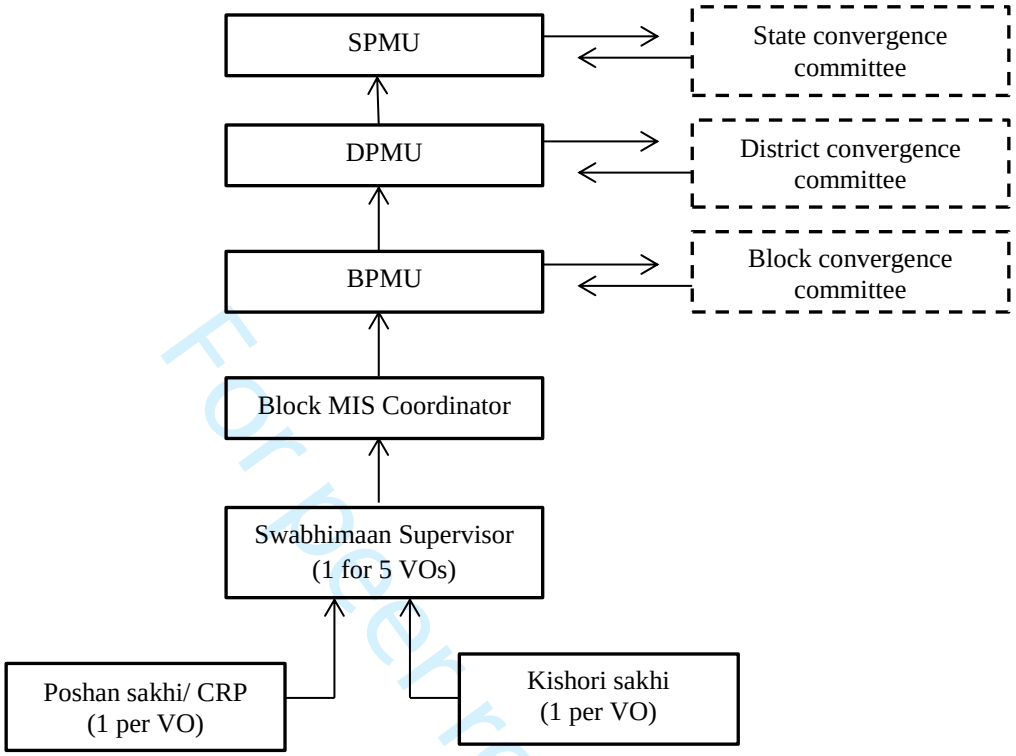
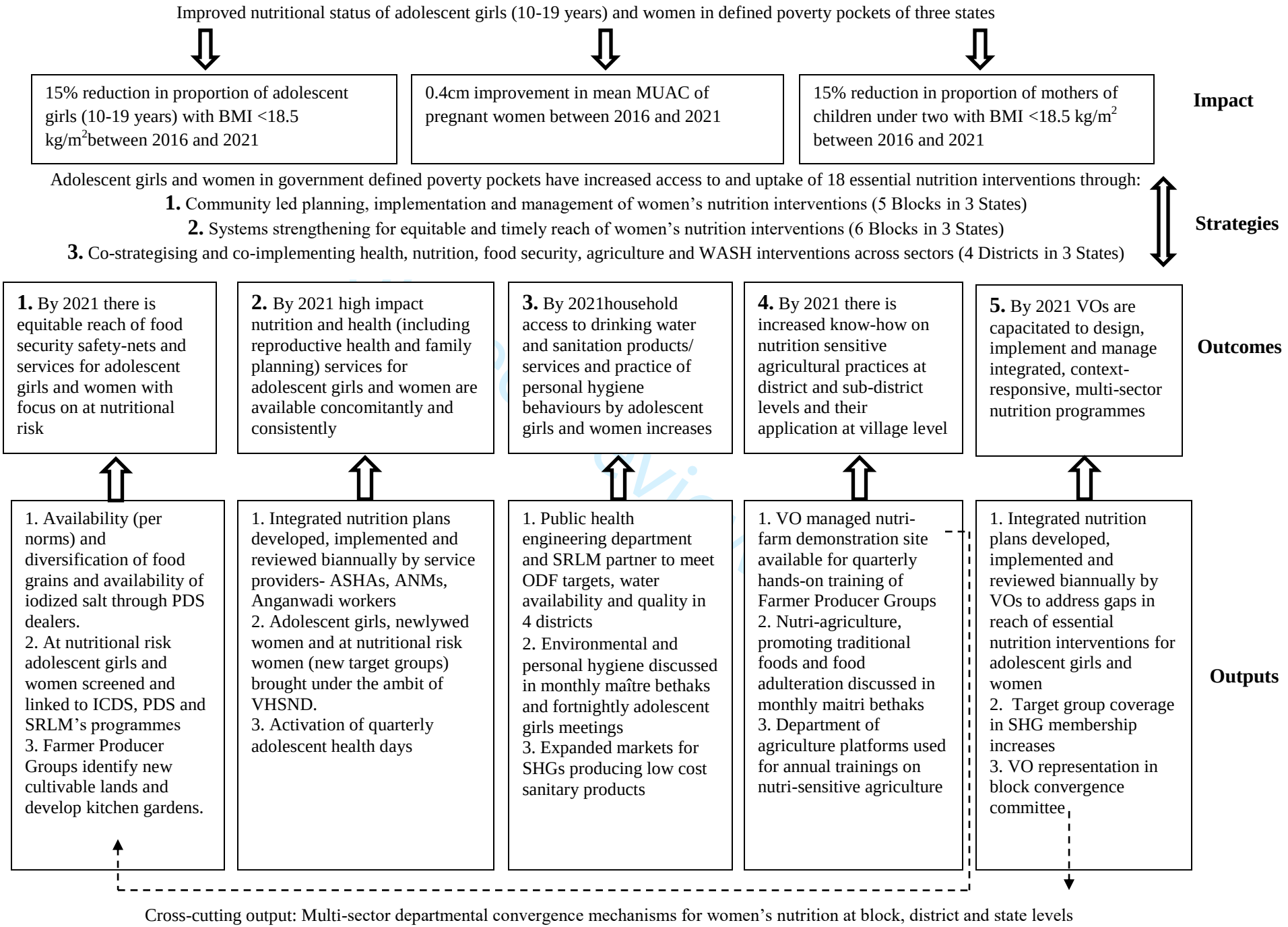
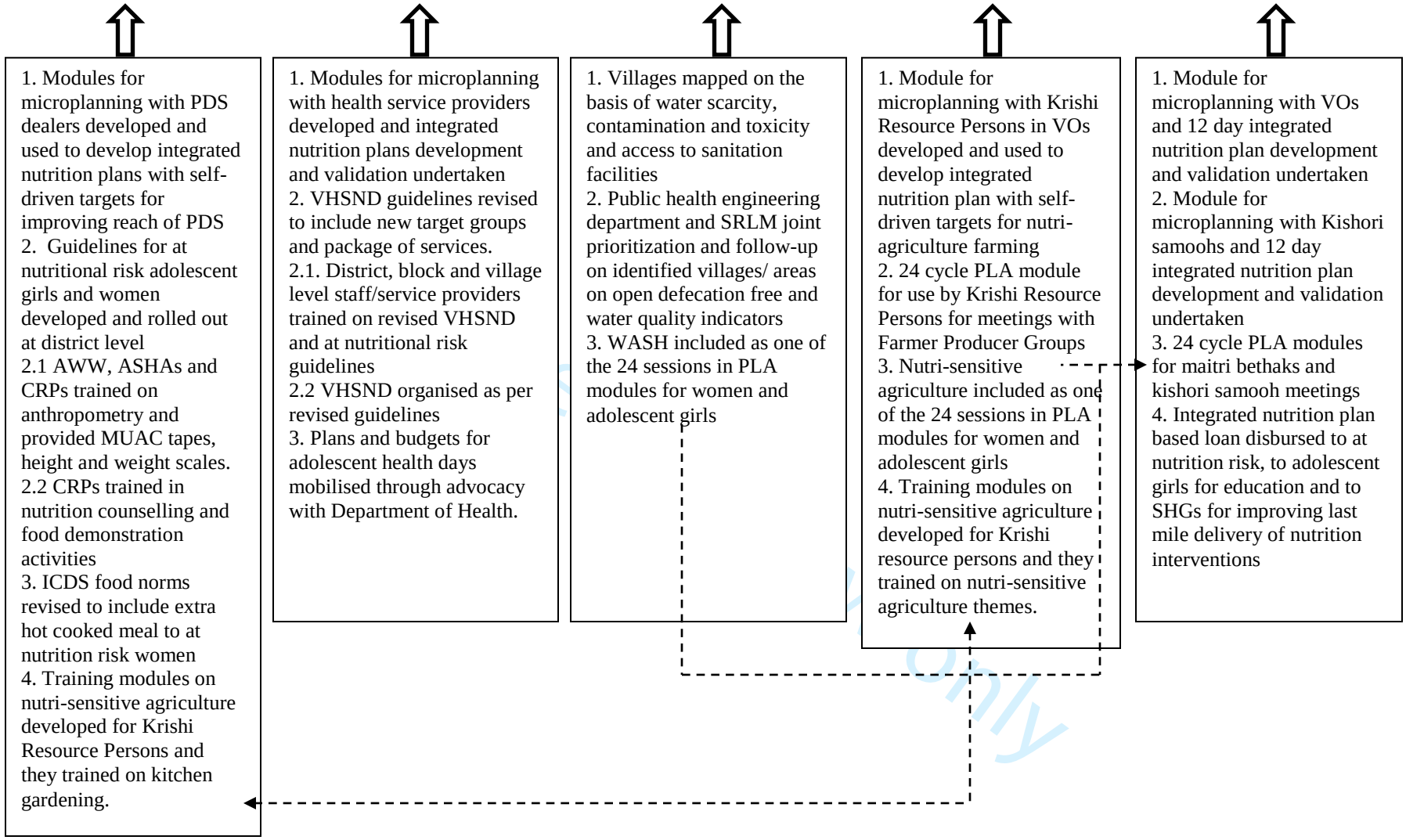


Figure 2 SRLM organization structure and its adaptation in Swabhimaan, Bihar



Theory of change for Swabhimaan: Bihar, Chhattisgarh and Odisha (2016 -2021)





Cross-cutting input: Annual planning and review of selected nutrition indicators by a multi-sector nutrition committee at block, district and state levels

All India Institute of Medical Sciences, Patna

Ethics committee approval letter

Date: 23/01/2016

Dr. Neeraj Agarwal
Prof.& Head
Department of Community & Family Medicine
AIIMS, Patna

Dear Dr. Neeraj Agarwal

Ref: IEC/AIIMS/PAT/52/2016

The Institutional Ethics Committee, All India Institute of Medical Sciences, Patna reviewed & discussed your study documents entitled **"Prospective, controlled, non-randomized evaluation of a programme to improve the nutritional status of women before conception, during pregnancy and after birth in Bihar". (The Swabhimaan Programme)** dated: 19.01.2016 study code: IEC/AIIMS/PAT/52/2016 on 19.01.2016.

The following members of ethics committee were present at the meeting held on 19.01.2016 at 2:00 P.M. at Department of Community and Family Medicine, All India Institute of Medical Sciences, Patna.

S. No.	Name and address of the EC members	Designation
1.	Dr. R.N. Singh, Consultant Orthopaedic Surgeon	Chairman
2.	Dr. P.P. Gupta, HOD, Pharmacology, AIIMS, Patna	Member: Pharmacologist
3.	Dr. Sadhana Sharma, Professor, Biochemistry, AIIMS, Patna	Member: Basic Sciences
4.	Dr. Ramji Singh, Addl. Prof. & Head, Physiology, AIIMS, Patna	Member: Pre-Clinical
5.	Dr. Ravi Kirti, Asst. Prof., General Medicine, AIIMS, Patna	Member: Physician
6.	Dr. Subhash Kumar, Assit. Prof., Radio Diagnosis, AIIMS, Patna	Member: Clinician
7.	Mr. Binay Kumar Pandey, Advocate, Patna High Court	Member: Legal Expert
8.	Mr. Ajit Kumar Chaudhary, Social Worker	Member: Social Worker
9.	Ms. Shahina Khan, Director of Raza International Group of Schools	Member: Philosopher
10.	Dr. C.M. Singh, Addl. Prof., Dept. of C&FM, AIIMS, Patna	Member Secretary

Address: All India Institute of Medical Sciences, District - Patna, State - Bihar, Pin Code – 801507,
E-mail – iecaiimspatna@gmail.com

The IEC approves the study to be conducted in its presented form.

Principal Investigator is responsible for fulfilling the following requirements:

- All Co-investigator must be kept informed of the status of the project.
- Any, amendment(s) to the protocol or the consent form(s), must be informed and submitted to the IEC for review and approval prior to the activation of the same. The IEC number assigned to the project should be cited in any correspondence.
- Serious Adverse Events (SAE), if any, should be reported to the IEC immediately. New information that becomes available which could change the risk-benefit ratio must be submitted promptly for IEC review.
- Records of documents related to signed consent (by subjects/witnesses) should be maintained properly for the audit by IEC.
- Approved study needs to be reviewed by IEC AIIMS Patna periodically at least once in a year as appropriate.
- After completion of the permitted tenure of the study, submission of the study report to the IEC AIIMS Patna is mandatory.
- A continuing review application must be submitted to the IEC in order to continue the study beyond the approved period. Failure to submit the same will result in the termination of the study.
- IEC AIIMS Patna will maintain the confidentiality of all the approved studies and will share the information with authentic bodies only on justification of the request.

Yours sincerely

Member Secretary
IEC, AIIMS, Patna

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
AIIMS, PATNA

Address: All India Institute of Medical Sciences, District - Patna, State - Bihar, Pin Code – 801507,
E-mail – iecaiimspatna@gmail.com

आरोग्यम् सुख सम्पदा

Institute Ethics Committee
अखिल भारतीय आयुर्विज्ञान संस्थान ,रायपुर (छत्तीसगढ़)
All India Institute of Medical Sciences, Raipur(Chhattisgarh)
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Raipur-492 099 (CG)
www.aiimsraipur.edu.in
Ethics Committee Registration No.: ECR/714/Inst/CT/2015

Letter No.: 114/IEC-AIIMSRPR/2016 Date: 02.09.2016

CERTIFICATE OF APPROVAL

To : Dr. Manisha Ruikar (Principal Investigator)
Professor & Head, Department of Community & Family Medicine,
AIIMS Raipur (CG)

Review Date : 06.08.2016

Reference : IEC Proposal No: **AIIMSRPR/IEC/2016/042**

Title : Baseline Survey for Swabhimaan Project, Bastar Block and Bakavand Block, Bastar District (Developed in consultation with UNICEF)

The Institute Ethics Committee, All India Institute of Medical Sciences, Raipur (Chhattisgarh) reviewed and discussed your above referenced research proposal in the meeting held on 06.08.2016.

The following documents were reviewed.

1. Covering Letter
2. Research Project Proposal (Version 2.0)
3. Case Record Form (Version 1.0)
4. Participant information sheet for participants more than 18 years of age (English & Hindi) (Version 1.0)
5. Participant information sheet for participants less than 18 years of age - English & Hindi (Version 1.0)
6. Consent Form for participant more than 18 year of age (English & Hindi) (Version 1.0)
7. Assent Form - English & Hindi (Version 1.0)
8. Undertaking regarding GCP guidelines and reporting of SAE
9. Other documents

Certificate of Approval: Proposal No. AIIMSRPR/IEC/2016/042
Ref: 114/IEC-AIIMSRPR/2016 dated 02.09.2016

a. Duly signed compliance sheet submitted to IEC by PI alongwith following documents :
   i. E-comunication by Dr Abner Daniel, Nurition Specialist, Child Development and Nutrition, UNICEF to the Principal Investigator
   ii. Letter by Director, National Rural Livelihood Promotion Society to Mision Director, Chhatttisgarh Gramin Ajjevika Samvardaan Samiti
   iii. Letter by Mission Director, SRLM, Chhattisgarh to the Chief, Field Office , UNICEF

The following members of Institute Ethics Committee were present at the meeting held on 06.08.2016 at 11:00 AM at Department of Pharmacology, AIIMS Raipur.

Sr. No.	Name of IEC Member	Designation
1	**Dr. Arun T. Dabke** Ex. Vice-chancellor Ayush and Health Science University Raipur (CG)	Chairman
2	**Dr. S. R. Gupta** M.D. (Med.), M.D. Pharmacology Retired Professor & Head Department of Medicine Pt. J. N. M. Medical College, Raipur	Basic Medical Scientist
3	**Dr. P. K. Neema** Professor and Head Department of Anaesthesiology AIIMS Raipur	Clinician
4	**Dr. Sarita Agrawal** Professor and Head Department of Obstetrics and Gynaecology AIIMS Raipur	Clinician
5	**Mrs. Kamla Janswami** Ex-president Lion's Club, Raipur	Lay Person from Community
6	**Ms. Pushpy Michael** Principal Bharatmata Higher Secondary School GE Road, Tatibandh, Raipur Chhattisgarh	Social Scientist
7	**Dr. Nitin Gaikwad** Associate Professor Department of Pharmacology AIIMS Raipur	Member Secretary
Outside Legal Expert		
8	**Advocate Shekhar Amin**	Legal Expert

Certificate of Approval: Proposal No. AIIMSRPR/IEC/2016/042
Ref: 114/IEC-AIIMSRPR/2016 dated 02.09.2016

Clear statement of decision reached:

At Institute Ethics Committee meeting held on 06.08.2016, the committee reviewed the research project and study related documents and discussed the ethical issues involved.

A letter to this effect was sent to you seeking certain clarifications / modifications vide letter no. 104/IEC-AIIMSRPR/2016, dated 19.08.2016. In response to this, you have submitted required clarifications / modifications vide letter no. CFM/MR/Project/348/2016 dated 24.08.2016 (IEC inward letter no. 2016/84 dated 25.08.2016). Therefore, the research project and study related documents are approved with respect to ethical issues.

Hence, at the convened meeting of IEC-AIIMS Raipur on 02.09.2016, IEC decided to **approve** the above referenced research project.

As Principal Investigator, you are responsible for fulfilling the following requirements of approval:

1. This is approval is valid for entire duration of the study (i.e. Six months). The review application must be submitted to the IEC-AIIMS Raipur in order to continue the study beyond the approved period.
2. All the co-investigators must be kept informed of the status of the project.
3. Changes, amendments, and addendum to the protocol or the consent form, must be submitted to the IEC-AIIMS Raipur for re-review and approval prior to the activation of the changes.
4. Any change of study site, change of investigator/s, termination of study (with reason to do so) should also be informed to IEC-AIIMS Raipur.
5. The IEC proposal number assigned to the project should be cited in any correspondence.
6. Any Serious Adverse Event (SAE) occurring during the course of the study should be reported to the IEC-AIIMS Raipur.
7. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for IEC review.
8. Only approved consent forms are to be used in the enrolment of participants. All consent forms signed by subjects and/or witnesses should be retained on file. The

Certificate of Approval: Proposal No. AIIMSRPR/IEC/2016/042
Ref: 114/IEC-AIIMSRPR/2016 dated 02.09.2016

IEC may conduct audits of all study records, and consent documentation may be part of such audits.

9. The study progress report should be made available for the IEC review on every 6 month.
10. The final report of the study must be submitted to IEC-AIIMS Raipur after the completion of the study.

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

Sincerely,

Dr. Arun T. Dabke
Chairman
Institute Ethics Committee
All India Institute of Medical Sciences
Raipur 492 099 (C.G.)

02/09/2016

Dr. Nitin Gaikwad
Member Secretary
Institute Ethics Committee
All India Institute of Medical Sciences
Raipur 492 099 (C.G.)

INSTITUTIONAL ETHICS COMMITTEE
(ECR/534/Inst/OD/2014)

All India Institute of Medical Sciences Bhubaneswar,
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751019, Odisha
Email: iec.aiimsbbsr@gmail.com
Phone:

54 (1)

To: Dr. Vikas Bhatia (Principal Investigator)

Date: 10.05.16

Re: IEC Proposal: T/EM -F/CMFM/16/02

Title: **Swabhiman- a nutritional intervention program in Odisha. Pre-implementation status assessment.**

I am pleased to inform you that at the convened meeting of 07.05.2016, the IEC voted to approve an amendment and to re-approve (renewal approval of the protocol and the consent form(s) is for 12 months) the above referenced protocol. As Principal Investigator, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators must be kept informed of the status of the project.
2. Changes, amendments, and addenda to the protocol or the consent form must be submitted to the IEC for re-review and approval prior to the activation of the changes. The IEC number assigned to the project should be cited in any correspondence.
3. Adverse events should be reported to the IRB. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for IEC review. The IEC and outside agencies must review the information to determine if the protocol should be modified, discontinued, or continued as originally approved.
4. Only approved consent forms are to be used in the enrolment of participants. All consent forms signed by subjects and/or witnesses should be retained on file. The IEC may conduct audits of all study records, and consent documentation may be part of such audits.
5. IEC AIIMS needs review of an approved study not less than once per 12-month period. **Therefore, a continuing review application must be submitted to the IEC in order to continue the study beyond the approved period.** Failure to submit a continuing review application in a timely fashion will result in termination of the study, at which point new participants may not be enrolled and currently enrolled participants must be taken off the study.
6. Principal investigator should initiate the project only after obtaining administrative permission from Director/Dean, AIIMS, Bhubaneswar.

Sincerely,

Chairman, IEC

(Chairman)
Institutional Ethics Committee
AIIMS, Bhubaneswar

Members of the IEC who voted in Favour of the Proposal
Dr. Debasish Hota, Dr. Manaswini Mangaraj, Dr Amit Ghosh, Dr. Swagata Tripathy, Dr. K C Mishra, Dr. Somnath Mukherjee.

56 (2)

अखिल भारतीय आयुर्विज्ञान संस्थान, भुबनेश्वर – ७५१ ०१९
RESEARCH CELL
All India Institute of Medical Sciences, Bhubaneswar-751 019

AIIMS-BBSR/RC/EM-F/02/2016/05 Dt: 13/05/2016

Dr. Vikas Bhatia

Professor & Head

Department of Community Medicine & Family Medicine

Subject: Regarding initiation of extramural research project.

Dear Prof. Bhatia,

The research cell is pleased to inform you that your extramural funded project entitled **"Swabhiman- a nutritional intervention program in Odisha, Pre-implementation status assessment"** (bearing provisional project code T/EM-F/CMFM/16/02 and IEC approval letter No T/EM-F/CMFM/16/02 dated 10.05.2016) has been examined and approved by the competent authority.

Kindly note that following the approval, you have been assigned permanent project code: P/EM-F/CMFM/16/02 and the study may be initiated in the institute.

You are requested to provide 6 monthly progress reports (in case study duration is longer than 6 months) and a consolidated summary report within 1 month of end of study to the research cell.

Dept. of CMFM
AIIMS, BBSR
Date of Receipt 14/05/16
Date of Despatched

Thanking You

Yours sincerely

Project file

13/05/16

Dr. Dillip Kumar Parida,
Faculty-in-Charge, Research Cell

13/5/16