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Impact Evaluation of a Community Engagement Intervention for Improving Childhood Immunization Coverage in Rural Assam, India: A Cluster Randomized Controlled Trial

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ABSTRACT

Background: For childhood immunization, community engagement interventions can potentially address demand-side barriers to achieving immunization coverage targets, while also mobilizing the community to advocate for better service delivery. However, high-quality evidence that can causally relate such interventions to increased immunization coverage is scarce. We evaluated the impact of a community engagement intervention on childhood immunization coverage in rural India.

Methods and findings: The community engagement intervention, referred to by the acronym SALT (Stimulate, Appreciate, Learn, Transfer), is a complex intervention involving an iterative process of multiple steps and continued engagement with the community. To evaluate the SALT intervention, we conducted a cluster randomized controlled trial in 196 villages spread across 3 districts in rural Assam, a state in the northeast region of India. The villages in the intervention group (n=97) received the SALT intervention for about one year along with routine immunization services and the villages in the control group (n=99) received only routine immunization services. The primary evaluation outcomes were full immunization, defined as one dose of Bacillus Calmette–Guérin vaccine, three doses of oral polio vaccine, three doses of diphtheria-pertussis-tetanus (DPT) vaccine or Pentavalent vaccine and one dose of measles vaccine, in children 12-23 months old, and three doses of DPT or Pentavalent vaccine in 6-23 months old children. To gather information on evaluation outcomes, we conducted cross-sectional household surveys at baseline and after 22 months at endline, in the 196 villages. We interviewed mothers with a 6-23 months old child in a random sample of households in each village. In our analyses, we followed the intention-to-treat principle and used mixed-effects models to account for clustering. At endline, a total of 2,907 mothers were interviewed resulting in a median number of 15 (interquartile range (IQR)= 0) 6-23 months old children and 10 (IQR=2) 12-23 months old children from each village in both the intervention and the control groups. There was no difference between the two groups in the proportion of 12-23 months old children receiving full immunization (OR=0.98, 95% CI: 0.71 – 1.36) or in the proportion of children receiving three or more doses of DPT or Pentavalent among 6-23 months old children (OR=1.01, 95% CI: 0.76 – 1.35).

Conclusions: The intervention was not found to be effective in increasing childhood immunization coverage in our study. After baseline survey, we noted that the vaccination coverage in the three districts was substantially higher than previously reported in national surveys which were used in designing the trial. The higher coverage rates were most likely due to widespread implementation of a supplementary immunization programme led by the Government of India prior to this study. We do not know whether selecting study sites with a lower vaccination coverage rate at baseline or having a more targeted approach in implementing the intervention would have resulted in a positive impact.

Trial registration: The trial was registered on 7th February, 2017 under the Clinical Trials Registry- India (CTRI), hosted at the Indian Council of Medical Research's National Institute of Medical Statistics, with registration number CTRI/2017/02/007792

Introduction

Vaccination is a globally accepted public health intervention that helps avert vaccine-preventable diseases. Incomplete vaccination and non-vaccination increase the risk of illness and death among children. The Global Vaccine Action Plan (GVAP 2011-2020) sets the goal of 90% coverage at the national level and 80% in every district or equivalent administrative unit with all vaccines in national programs by 2020 [1]. India is one of the 194 Member States of the World Health Assembly which endorsed the GVAP framework in 2012. Despite a long standing national program for immunization in India since 1985, only 62% of 12-23 months old children are fully immunized, as estimated in the fourth round of National Family Health Survey (NFHS-4) conducted in 2015-16 [2]. Full immunization is defined as children receiving one dose of Bacillus Calmette–Guérin (BCG) vaccine to prevent tuberculosis, three doses of oral polio (OPV) vaccine, three doses of diphtheria-pertussis-tetanus (DPT) vaccine or the more recently introduced Pentavalent (DPT-Hepatitis B- Haemophilus Influenzae type B) vaccine, and one dose of measles vaccine. Completion of schedule of vaccines that require multiple doses (for example, OPV and DPT or Pentavalent) remains a major challenge towards achieving higher full immunization coverage. Both demand- and supply-side bottlenecks contribute to sub-optimal vaccination coverage rates in India [3-8].

In the context of universal immunization program (UIP) in India, most of the existing interventions are geared towards addressing supply-side challenges such as ensuring better immunization services and more focused implementation by deploying more health workers across health facilities, introducing alternate vaccine delivery system, including new vaccines in the immunization schedule, organizing sessions in hard-to-reach areas, and initiating supplementary immunization activities for children who are missed out in the routine immunization program [5,9,10]. But there is a growing body of literature showing that demand-side interventions lead to significant improvement in childhood vaccination coverage in low- and middle-income countries [11,12]. Community engagement approaches can address demand-side barriers while also mobilizing the community to advocate for better service delivery [13,14]. With the growing realization that community-level factors influence vaccination uptake, more recent strategies to increase vaccination coverage have attempted to focus on community-based interventions [15-18].

Most of the existing community engagement programs, however, focus on communication activities that do not actively involve communities in the planning, monitoring and surveillance activities [15]. Participatory engagement of communities can help identify barriers to vaccination at the local level and thus might lead to sustainable solutions in a manner that a top-down approach cannot achieve. The SALT (Stimulate, Appreciate, Learn, Transfer) intervention is a community-based intervention which aims to develop and strengthen a sense of community 'ownership'. This community-based intervention has been shown to be effective in generating behaviour change in combating HIV/AIDS in Papua New Guinea [19] and cost-effective when comparing incremental cost-effectiveness ratio with other HIV prevention programs in Thailand [20]. A retrospective study of SALT versus non-SALT districts in Togo showed significant increase in impregnated bednet use and decrease in malaria prevalence among children under five [21]. A recent study (unpublished) in Democratic Republic of the Congo found that SALT intervention can reduce vaccine hesitancy and increase vaccination rates for oral polio vaccine [22]. However, the research design of the study lacks the methodological rigor needed to measure attributable impact. Studies using experimental designs to evaluate the effectiveness of community engagement approaches to increasing immunization coverage are few [15,18,23-25].

In order to identify the impact of the SALT approach in increasing immunization coverage, we conducted a cluster randomized trial in 196 villages across 3 districts in Assam, a state in the northeast region of India. Our study assessed the intervention's impact on two primary outcomes– full immunization and three doses of DPT or Pentavalent in children. We also explored whether the intervention has an impact on a few secondary outcomes – dropout between doses 1 and 3 for DPT or Pentavalent vaccine, availability of vaccination card, mother's exposure to immunization messages, household's engagement with village communities and mother's belief in community's role in and ability to have impact on her child's health.

Methods

We adopted a cluster randomized controlled trial design with two groups to evaluate the impact of the intervention, where the villages are the clusters and 6-23 months old children are the study participants. Villages in the intervention group received the SALT intervention for about a year (March 2017-March 2018) along with routine immunization services. Villages in the control group received routine immunization services alone. The evaluation used a repeated cross-sectional design where we tracked the same sampled villages but drew independent random samples of eligible children to measure immunization outcomes at baseline and after 22 months at endline.

The full study protocol has been published [26]. The IRB approval (TRC-IEC- 285/16) for the study was received from the Institutional Ethics Committee of the grant holding institute in April 2016. Written informed consent was obtained from the participants. However, informed consent to randomize was not sought as the unit of randomization (village) and the unit of observation (child) are different [27]. A letter of support was obtained from the Directorate of Health Services, Assam, to facilitate the implementation of the study.

Sampling design: recruitment of clusters and participants

We considered 3 districts from Assam – Bongaigaon, Kamrup Rural, and Udalguri, selected using stratified purposeful sampling so that they represent varied sociodemographic characteristics of Assam. Within each district, we used a two-stage stratified cluster sampling design. In the *first stage*, we selected 80 villages from each of the three districts using a stratified sampling

technique. We stratified eligible villages, defined as having 50-500 households, within a district into four strata and then randomly selected 20 villages from each stratum. The study protocol provides details on how the stratified sampling was carried out [26]. In the *second stage*, from each of the 240 sampled villages (80 in each district), after identifying the eligible households having a child 6-23 months old, a random sample of 15 households was selected for the baseline survey. In a selected household, all mothers having children in the age group 6-23 months were eligible to participate in the survey. From mothers, we collected information pertaining to her youngest 6-23 months old child.

In the endline survey, the sampled villages remained the same. A fresh round of house-listing exercise was carried out in these villages at endline to identify the eligible households with a 6-23 months old child. Given the restrictive age range of 6-23 months, eligible households at endline were for the large majority, different from the ones at baseline. A random sample of 15 households was drawn from each village to be interviewed during the endline survey and mothers and children were selected for interview following the same procedure as in baseline. The baseline survey was conducted during June-August 2016. The endline survey was conducted after the conclusion of the intervention, during July-September 2018.

Intervention

The intervention is described in detail in the study protocol paper [26]. The key steps and underlying principles are described here. A pictorial illustration is presented in the appendix (Figure S2.1). The foundation of the intervention is that '*Communities change themselves. We do not change communities*'. The intervention uses the Community Life Competence Process (CLCP), a form of learning cycle where a community identifies a problem and solutions thereof, takes action and learns from the process. The underlying principle of the intervention is that when a community takes ownership of the challenge it faces, it is on the road to sustainable change. CLCP is facilitated in communities by trained facilitators who use an attitudinal approach referred to by the acronym SALT – Simulate, Appreciate, Learn and Transfer. The intervention is a combination of CLCP and SALT, but for simplicity we have used just one acronym, SALT, to refer to the intervention.

The intervention starts with *home visits* by trained facilitators to build rapport with the community and to identify the strengths of the community. The next step is collective *dream building* which starts from individuals and small groups and then involves the wider community. The idea is to identify and prioritize a set of achievable 'dreams' for the community.

Once the community agrees on a dream, a *self-assessment* exercise starts under the guidance of the facilitator. Using a scale of 1 to 5 they assess where the community stands with respect to practices linked to their shared dream. The facilitators stimulate conversations so that actionable points emerge. With respect to the dream of healthy children, immunization related practices were discussed during self-assessment. The underlying principle being that members of the community assess themselves, rather than the facilitator (an outsider) assessing them.

The community then lists practices, relevant to their shared dream, where it feels that it can make progress within a stated timeframe (say, 2-3 months). The discussion during the community meetings evolves around what actions need to be taken (*action plan*) in order to reach a next desired level from the current level agreed to by the community during self-assessment. This is followed by an *action phase* and a review process to further assess their level of achievement. Subsequently (end of a year) the facilitators bring the communities together to share with and learn from each other in a *knowledge fair* when transfer of knowledge and experience takes place between communities. Learning, self-assessment, planning and action ideally repeats itself in a continuous but evolving cycle. Each time the same or new dreams and priorities may be identified and actions thereof.

The intervention was implemented in the three districts of Assam by two local non-governmental organizations (NGOs), namely Voluntary Health Association of Assam (VHAA) and the Centre for North East Studies and Policy Research (CNES) under the supervision of the lead NGO, the Constellation. VHAA was responsible for two districts (Kamrup Rural and Udalguri) and CNES was in charge of Bongaigaon district. For each district, the local NGOs hired three SALT facilitators leading to a total of nine facilitators who were the key implementers of the intervention. Each district had a district coordinator who was responsible for overall monitoring and supervision of facilitator's work and intervention activities. Regular training and support were provided and site visits made by the national and international coaches of the Constellation.

Randomization

The village was our unit of randomization. All 240 villages sampled in the baseline survey were randomized to the intervention and control groups after the baseline survey using a 1:1 ratio. Randomization of villages was stratified – villages within a district were stratified into four strata based on a composite score constructed using village-level data from baseline survey. Details of the composite score are provided in the appendix (S5). After stratification within a district, each stratum contained 20 villages. Within each stratum, we randomly allocated 10 villages to receive the intervention and the remaining 10 villages continued to receive immunization services from the routine immunization program in place (control group). This led to 40 villages in each group in each district.

Sample size

The sample size calculation at the design stage was based on estimates from relatively old national surveys available at the time and was subsequently revised using baseline survey data. The initial sample size calculation suggested a requirement of 120 intervention and 120 control villages to detect a difference of at least 10 percentage points in immunization coverage between the two groups with 80% statistical power using a two-sided test at 5% level of significance, after accounting for an intracluster correlation coefficient (ICC) of 0.21 and 0.25 for three doses of DPT or Pentavalent and full

immunization, respectively. The expected coverage was 55.3% for full immunization and 65.9% for three doses of DPT or Pentavalent in the control group. We revisited the calculation after completion of baseline survey. The revised sample size calculations, based on updated estimates of coverage and ICC derived from the baseline survey, required 90 intervention and 90 control villages to detect an increase of at least 8 percentage points from an expected coverage of 84% and 79% for three doses of DPT or Pentavalent and full immunization, respectively, in the control group, with 80% statistical power based on a two-sided test having 5% level of significance, after accounting for an ICC of 0.17 for three doses of DPT or Pentavalent and 0.18 for full immunization. Details of the initial sample size calculation and subsequent revisions are provided in the appendix (S6).

We therefore needed 30 intervention and 30 control villages in each district. Instead of randomly excluding villages, we dropped villages that would help ensure a geographical buffer of at least 3 kilometres between the intervention and control villages, to reduce the chance of contamination. The procedure followed for identifying villages to be dropped is described in detail in the study protocol in the subsection *Minimizing Intervention-Control Contamination* [26].

Study outcomes

We considered two primary immunization outcomes, three secondary immunization outcomes and two secondary outcomes related to community processes. The two primary outcomes are full immunization in 12-23 months old children and receipt of three doses of DPT or Pentavalent in 6-23 months old children. Full immunization is defined as the 12-23 months old child receiving one dose of BCG vaccine, three doses of OPV, three doses of DPT or Pentavalent vaccine, and one dose of measles vaccine. We defined the 6-23 months old child as having received all three doses of DPT, if the child received three or more doses of either DPT or Pentavalent vaccine. We will hereafter use *DPT* to indicate vaccination with either DPT or Pentavalent. We combined information from the vaccination card and mother's recall to define the vaccination status for each vaccine, following the procedure outlined in the appendix (S3).

The three secondary immunization outcomes were – dropout between doses 1 and 3 for DPT vaccine, availability of vaccination card, and mother's exposure to immunization messages. Dropouts between doses 1 and 3 were defined as children who had failed to receive all three doses but had received at least one dose. The vaccination card was defined as available for the child if it was seen by the interviewer. The card could be in possession of the mother or another member of the household, as in most cases, or in some villages with the community health worker of that village for safekeeping. In the latter case, the interviewer requested to see the card from the community health worker. If the mother had heard, seen or read any immunization messages in the last 6 months then she was considered as being exposed to immunization messages.

We considered two secondary outcome variables indicating community processes – household's engagement with village communities and mother's perception about role of community in improving children's health. If the household reported that their community met occasionally or regularly and that they attended these meetings and they engaged in community actions to collectively tackle issues, then the household was considered as engaging with the village communities. The mother was asked if she believed that community had a role to play in improving the health of her child and if the community was capable of taking actions to prevent her child from getting sick. If the mother replied 'yes' to both these questions, then we considered her to believe in community's role in and ability to have impact on her child's health. We describe these secondary outcomes in detail in the appendix (S4).

Process evaluation

In order to measure the extent of community's exposure to the intervention we collected process indicators throughout the intervention phase. Specifically, the aim was to gain understanding about the intervention fidelity around the following aspects: 1) whether the intervention was implemented as intended, 2) whether the intervention incorporated the primary objective of the study (that is, increasing immunization coverage), 3) consistency of intervention delivery across communities in terms of the process of administering the intervention, 4) the reach and coverage of the intervention across villages and districts, and 5) whether contextual factors influenced the implementation of intervention.

The components of the process evaluation were developed based on the framework of Grant et al [28]. Data on the indicators relevant for each step of the intervention were collected through a combination of methods, including monthly reporting format developed by the evaluation team and duly filled in by the SALT facilitators, direct observation of different steps of the intervention by the evaluation team, and in-depth interviews of SALT facilitators and district coordinators by the evaluation team. The team also interacted informally with community members during the dream building, self-assessment, and action planning sessions in the community.

Monthly reporting format

The purpose of developing the monthly reporting format was to collect routine data on the intervention implementation at the community (village) level. We kept the format simple to enable the facilitators to fill it quickly and easily on a monthly basis. The indicators were identified so as to cover the entire intervention process and also to gain understanding of the intervention fidelity. Based on the monthly data, the following village-level indicators were consolidated by the evaluation team for the entire duration of the intervention: total number of visits made to the village by the SALT facilitator, total number of households in the village where home visits were conducted, total number of community meetings, total number of meetings involving specific groups (e.g. community block officers, self-help groups, health workers, religious leaders), timing (number of months after the start of intervention) of the first community dream building in the village, whether immunization emerged as a topic during dream building, timing of the first self-assessment exercise and whether it was repeated, whether practices

around immunization were discussed during self-assessment, timing of the action phase, and number of visits made to the village specifically for follow up of action plan. All nine SALT facilitators used to fill in the monthly reporting format and share with the evaluation team after the end of each month.

Direct observation and in-depth interviews

The evaluation team developed checklists for on-site process monitoring of home visits, dream building, self-assessment and action plan. The checklists included indicators to understand whether the facilitators followed the concept and the steps discussed during the training, and more generally, to gain understanding about the consistency of intervention delivery. Furthermore, to understand the implementation of the intervention through the lens of the implementing agencies, in-depth interviews (IDIs) were conducted with SALT facilitators and district coordinators. Key objectives of the IDIs were to cross verify some of the indicators of the monthly reporting format and to know about the challenges faced during the implementation of the intervention.

Process evaluation data collection

The intervention started in March 2017 with training of facilitators. The evaluation team began process evaluation data collection from June. The initial months were used to gain understanding of the intervention and to develop reporting formats, various checklists, and IDI guides. Each of the nine SALT facilitators and three district coordinators were interviewed twice in person during the intervention phase. In addition, one-to-one follow up was done over phone and WhatsApp in order to resolve discrepancies around monthly process indicators. The interviews were conducted in Assamese language and were audio recorded. The audio-recordings were transcribed into English and further analyzed.

Statistical Analysis

All analyses were based on intention-to-treat principle, that is, by analysing all villages according to the group they were randomised to. We conducted individual-level analyses using logistic regression with a random effect for the village to account for correlation between observations from the same village. The effect of the intervention at endline on the primary and secondary outcomes, all binary in nature, was estimated using odds ratios. The model included fixed effects for strata to account for the stratified randomization and adjusted for the baseline level of the outcome variable (as log-odds-cluster-level proportion of the outcome) in order to improve the precision of the intervention effect estimates [29,30]. Further analyses were conducted after adding the following covariates: gender and birth order of the child, mother's age, education, spouse's education, household head's religion and caste, household wealth quintile (constructed based on housing characteristics, sanitation facility of the household, and asset possession), and village-level variables –proportion of households in the poorest wealth quintile, proportion of mothers who cannot read and/or write, and average travel time to vaccination site.

We used district, gender and birth order of child to explore heterogeneity in intervention effect, as part of predefined subgroup analyses. In addition, as post-hoc analysis, we explored if there is heterogeneity in the effect of the intervention by village-level baseline immunization coverage. For each subgroup, we repeated the main analysis with the addition of the subgroup variable along with its interaction with the intervention group indicator. Heterogeneity was assessed based on the statistical significance of the interaction term.

We conducted a sensitivity analysis by combining the dropped villages (no intervention) with the control villages and comparing them to the intervention villages. Data from this repeated cross-sectional cluster randomized trial can also be analysed to assess whether the change from baseline to endline in the outcome differs between the two groups [29,30]. We conducted a sensitivity analysis to examine the effect of the intervention on the change in outcome from baseline by including an interaction term between the survey round and intervention group.

Study statisticians were blinded to group allocation until all results were finalized. All analyses were performed in R (R Core Team 2019).

Results

Figure 1 describes the key features of the trial design and how we derived the final analytical dataset. Post sample size re-estimation, we dropped 44 villages – 23 and 21 villages from the intervention and control groups respectively. The intervention group had 97 villages and the control group 99 villages with 32-33 intervention villages and 32-34 control villages in each district. The intervention was implemented in 90 villages – 89 villages out of the 97 in the intervention group and 1 village out of the 99 in the control group. The endline survey was conducted in the 97 intervention and 99 control villages, as well as in 43 of the 44 villages that were dropped. The primary, intention-to-treat analysis, uses data from the 97 intervention and 99 control villages, unless specified otherwise. In the 97 intervention and 99 control villages, we administered the survey in 1,424 and 1,465 households, respectively. We had information on 1,429 and 1,478 children aged 6-23 months and 985 and 966 children aged 12-23 months from the intervention and the control groups, respectively.

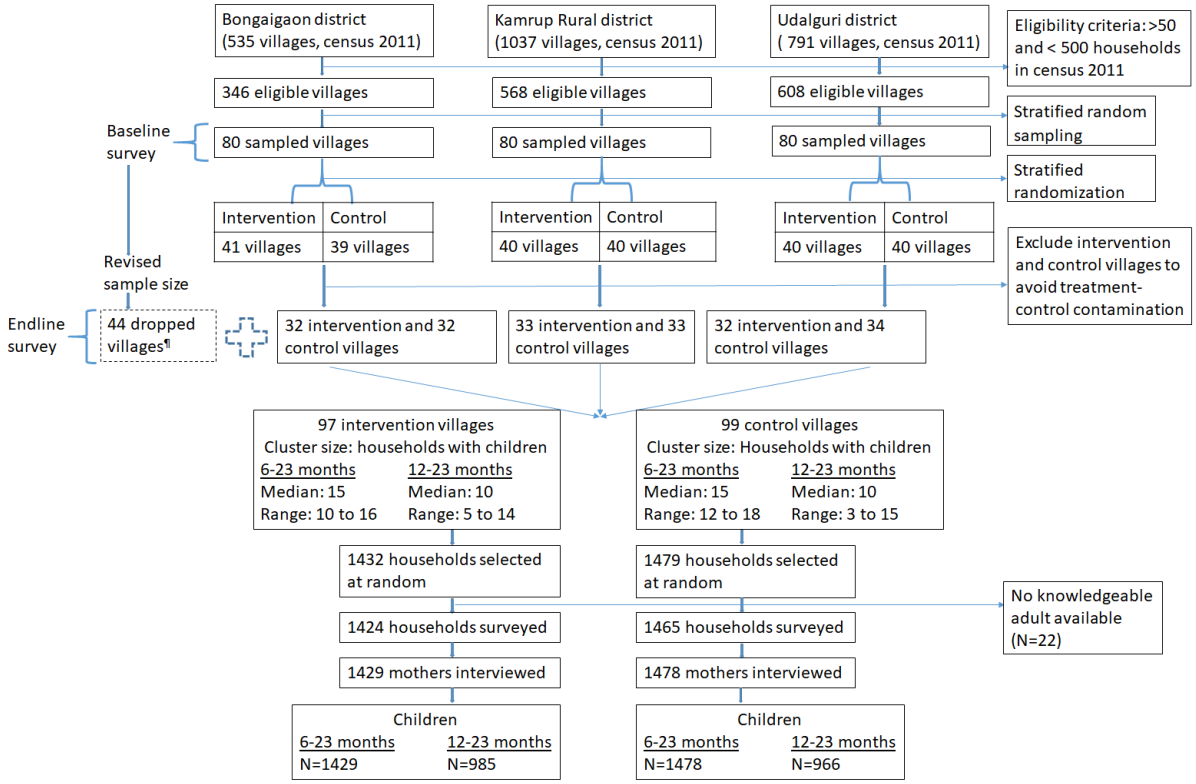

Figure 1. Trial profile. Of the 44 villages dropped from the study after baseline survey, 43 were included in the endline survey.

The 6-23 months old children and their mothers interviewed in the baseline survey in the two groups were very similar with respect to background characteristics (Table 1). Households also had similar characteristics across the two groups. There were small differences between the two groups, for example, a higher proportion of household heads belonged to the 'other backward class' caste category in the control group than in the intervention group (31% vs. 21%). Villages in the control group, on average, had a higher proportion of households in the poorest wealth quintile as compared to the villages in the intervention group (Table 1) (median = 20%, interquartile range (IQR)=27% in control villages vs. median = 9%, IQR = 27% in intervention villages). The control villages also had on average a higher proportion of households where the head of household belonged to a scheduled tribe as compared to the control villages (median = 7%, IQR=47% in control villages vs. median = 0%, IQR=53% in intervention villages).

Table 1. Background characteristics of participants in the baseline survey by arm. Background characteristics of participants in the endline survey can be found in Supplementary Table S1.1.

Characteristics	Intervention (*N*=1447)	Control (*N*=1482)	Total (*N*=2929)
Child			
Sex			
Boy	731 (51%)	763 (51%)	1494 (51%)
Girl	716 (49%)	719 (49%)	1435 (49%)
Age in months			
6-11	568 (39%)	586 (40%)	1154 (39%)
12-23	879 (61%)	896 (60%)	1775 (61%)
Birth order			
First	766 (53%)	769 (52%)	1535 (52%)
Second	492 (34%)	475 (32%)	967 (33%)
Third or more	186 (13%)	235 (16%)	421 (14%)
Missing	3 (0%)	3 (0%)	6 (0%)
Born in a health facility			
No	164 (11%)	220 (15%)	384 (13%)
Yes	1280 (88%)	1259 (85%)	2539 (87%)
Missing	3 (0%)	3 (0%)	6 (0%)
Has vaccination card			
No	31 (2%)	24 (2%)	55 (2%)
Yes	1416 (98%)	1458 (98%)	2874 (98%)
Mother			
Age in years			
Less than 20	80 (6%)	69 (5%)	149 (5%)
20-24	502 (35%)	511 (34%)	1013 (35%)
25-34	773 (53%)	792 (53%)	1565 (53%)

Characteristics	Intervention (*N*=1447)	Control (*N*=1482)	Total (*N*=2929)
35-plus	92 (6%)	110 (7%)	202 (7%)
Age at marriage			
Less than 18	298 (21%)	283 (19%)	581 (20%)
18-24	962 (66%)	1026 (69%)	1988 (68%)
25 or more	187 (13%)	173 (12%)	360 (12%)
Education			
No schooling	175 (12%)	201 (14%)	376 (13%)
Some primary¶	303 (21%)	369 (25%)	672 (23%)
Some secondary¥	773 (53%)	724 (49%)	1497 (51%)
More than secondary£	196 (14%)	188 (13%)	384 (13%)
Spouse's education			
No schooling	157 (11%)	164 (11%)	321 (11%)
Some primary¶	298 (21%)	317 (21%)	615 (21%)
Some secondary¥	753 (52%)	734 (50%)	1487 (51%)
More than secondary£	239 (17%)	267 (18%)	506 (17%)
Received full antenatal care during pregnancy			
No	827 (57%)	850 (57%)	1677 (57%)
Yes	617 (43%)	629 (42%)	1246 (43%)
Missing	3 (0%)	3 (0%)	6 (0%)
Household			
Household head's caste			
Scheduled caste	106 (7%)	96 (6%)	202 (7%)
Scheduled tribe	398 (28%)	378 (26%)	776 (26%)
Other backward class	311 (21%)	454 (31%)	765 (26%)
General/Don't know	632 (44%)	554 (37%)	1186 (40%)
Household head's religion			
Hindu	958 (66%)	1019 (69%)	1977 (67%)
Muslim	431 (30%)	393 (27%)	824 (28%)
Other	58 (4%)	70 (5%)	128 (4%)
Household wealth quintile			
Poorest	259 (18%)	321 (22%)	580 (20%)
Poorer	284 (20%)	304 (21%)	588 (20%)
Middle	290 (20%)	285 (19%)	575 (20%)
Richer	328 (23%)	271 (18%)	599 (20%)
Richest	286 (20%)	301 (20%)	587 (20%)
Village (cluster)			
N[a]	97	99	196
Percentage of households in poorest wealth quintile[a], Median (IQR)	9% (27%)	20% (27%)	13% (27%)
Percentage of mothers who cannot read and/or write[a], Median (IQR)	13% (20%)	13% (20%)	13% (20%)
Percentage of households with Muslim head of household[a], Median (IQR)	0% (67%)	0% (50%)	0% (67%)
Percentage of households with the head of household belonging to a scheduled tribe[a], Median (IQR)	0% (53%)	7% (47%)	6% (47%)
Average time to vaccination site (in minutes)[a], Median (IQR)	20 (11)	18 (10)	19 (11)

Data are *N (%)* unless specified otherwise. *N* indicates number of children expect for variables measured at the village level (indicated by [a]).
¶Standard/Class I to V.
¥ Standard/Class VI to X.
£Standard XI or above.

We present the background characteristics of the participants in the endline survey in the appendix (Table S1.1). Of the 2907 children aged 6 to 23 months at endline, around half were boys, 67% were one year or older and 13% were of third or higher birth order. The mothers of the children were, on average, 25 years old (standard deviation = 6 years), more than a quarter reported getting married before 18 years of age and more than half the women had not received full antenatal care during pregnancy. 29% of the household heads identified themselves as Muslims and 58% belonged to a socially and economically backward class, including 24% who reported belonging to a tribe. Median percentage of households in the poorest wealth quintile across the villages was 13% (IQR=20%). In half the villages 7% (IQR=20%) or more mothers could not read or write. 58% villages had no Muslim households and a quarter of the villages had 64% or more Muslim households. Half the villages had no households belonging to a tribe and a quarter of the villages had 44% or more households belonging to a tribe.

Table 2 compares the distribution of the primary immunization outcomes – full immunization and three doses of DPT, in the two groups. At endline, 76% of the 12-23 months old children in the intervention group were fully immunized as compared to 77% in the control group. In the unadjusted analysis, where we only adjusted for

the strata variable and the log odds of the village-level proportion of children fully immunized at baseline, we did not find any difference in full immunization rates between the intervention and control groups (OR=0.99, 95% CI: 0.72 – 1.36). The adjusted model, where we include a wide range of individual- and village-level covariates, yielded a similar result (OR=0.98, 95% CI: 0.71 – 1.36). For the other outcome – receipt of all three doses of DPT vaccine, the immunization rate among 6-23 months old children in both the intervention and control groups at endline was 82%. In both the adjusted and unadjusted analyses, the odds of receiving all three doses of DPT among 6-23 months old children are similar in the intervention and control groups (OR=0.99, 95% CI: 0.74 – 1.33 in unadjusted analysis and OR=1.01, 95% CI: 0.76 – 1.35 in adjusted analysis).

Figure 2 presents the findings of the subgroup analyses for the two primary immunization outcomes. There is no evidence of heterogeneity of the intervention effect across the four subgroups (all interaction p-values > 0.4).

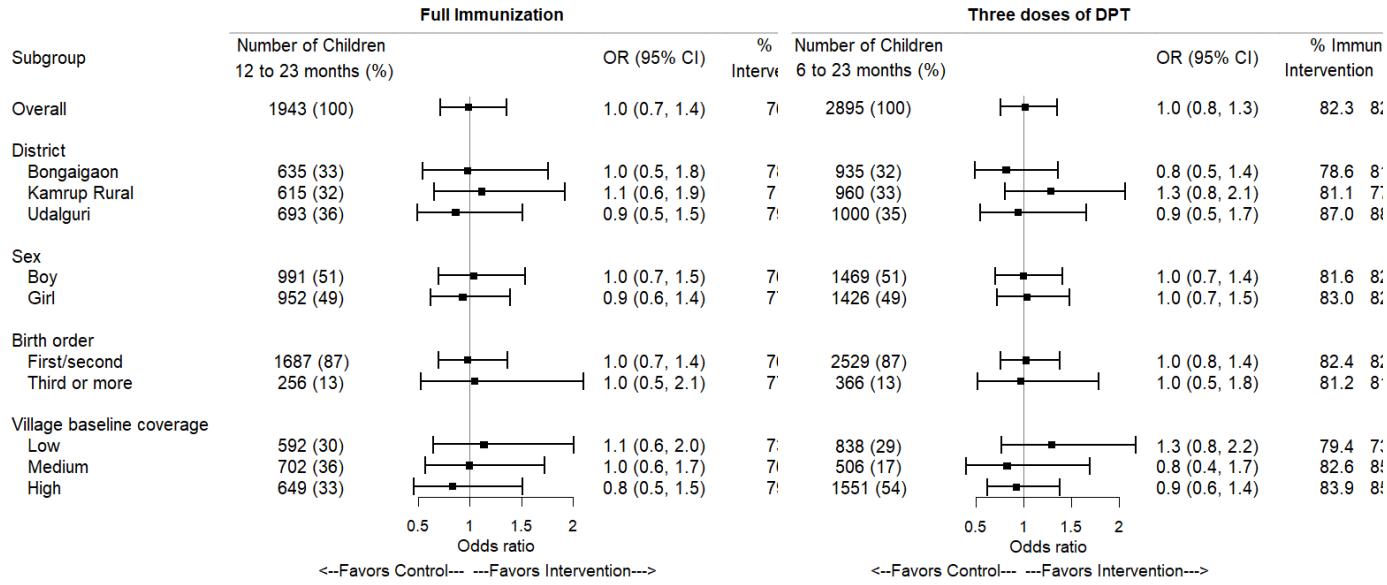

Figure 2. Subgroup analyses of primary outcomes. Village baseline coverage for the outcome – full immunization, is the log odds of baseline village-level full immunization coverage among 12–23 month old children and for the outcome – receipt of three doses of DPT, is the log odds of baseline village-level coverage for three doses of DPT among 6-23 month old children.

Table 2. Analysis of primary immunization outcomes.

Outcome	Intervention N (%)	Control N (%)	Total N (%)	Unadjusted[α]				Adjusted[β]			
				N	Odds ratio (95% CI)	P value	ICC	N[γ]	Odds ratio (95% CI)	P value	ICC
Full immunization (12-23 month old child)											
Baseline											
No	211 (24%)	214 (24%)	425 (24%)								
Yes	660 (75%)	679 (76%)	1339 (75%)								
Missing	8 (1%)	3 (0%)	11 (1%)								
Endline											
No	230 (23%)	223 (23%)	453 (23%)	1948	0.99 (0.72, 1.36)	0.94	0.14	1943	0.98 (0.71, 1.36)	0.92	0.14
Yes	753 (76%)	742 (77%)	1495 (77%)								
Missing	2 (0%)	1 (0%)	3 (0%)								
Three doses of DPT (6-23 month old child)											
Baseline											
No	267 (18%)	265 (18%)	532 (18%)								
Yes	1174(81%)	1210 (82%)	2384 (81%)								
Missing	6 (0%)	7 (0%)	13 (0%)								
Endline											
No	253 (18%)	258 (17%)	511 (18%)	2902	0.99 (0.74, 1.33)	0.97	0.12	2895	1.01 (0.76, 1.35)	0.95	0.11
Yes	1173 (82%)	1218 (82%)	2391 (82%)								
Missing	3 (0%)	2 (0%)	5 (0%)								

[α] Explanatory variables in the unadjusted model include the group assignment indicator, the strata variable used for stratified randomization, and the baseline village-level log-odds of the outcome.

[β] Explanatory variables in the adjusted model include, in addition to the variables in the unadjusted analysis, gender and birth order of the child, mother's age, education, spouse's education, household head's religion and caste, household wealth quintile, and village-level variables –proportion of households in the poorest wealth quintile, proportion of mothers who cannot read and/or write, and average travel time to vaccination site.

[γ] Because of missing adjustment variables data, the observations used in adjusted analysis are fewer than those used in unadjusted analysis.

Table 3 presents the findings for effect of the intervention on the secondary outcomes. The 6-23 months old children in both the intervention and control groups had very similar immunization-related secondary outcomes at endline – 16% and 17% of the ones who received the first DPT dose did not receive all three DPT doses; 84% and 87% of the children had a vaccination card that was seen by the interviewer; and 64% and 68% of the mothers had seen, heard or read immunization-related messages in the last 6 months, in the intervention and control groups, respectively. The unadjusted and adjusted analyses suggest that these immunization-related secondary outcomes are similarly distributed across the two groups at endline, after adjusting for baseline levels.

We had considered two more secondary outcomes – these were related to household's engagement with village communities and mother's perception of role of community in children's health. The proportion of mothers who believed that community had a role to play in improving the health of her child was higher in the control group than in the intervention group (84% vs 79%) at endline. The household's participation in community meetings and engagement in community-led actions again was higher in the control group than in the intervention group (71% vs. 68%), although the difference was not found to be statistically significant in the unadjusted or adjusted analyses.

Table 3. Analysis of secondary outcomes.

				Unadjusted[α]				Adjusted[β]			
Outcome	**Intervention N (%)**	**Control N (%)**	**Total N (%)**	**N**	**Odds ratio (95% CI)**	**P value**	**ICC**	**N[γ]**	**Odds ratio (95% CI)**	**P value**	**ICC**
Dropout between DPT doses 1 and 3											
Baseline											
No	1174 (81%)	1210 (82%)	2384 (81%)								
Yes	247 (17%)	241 (16%)	488 (17%)								
Missing	26 (2%)	31 (2%)	57 (2%)								
Endline											
No	1173 (82%)	1218 (82%)	2391 (82%)		0.98				0.97		0.10
Yes	230 (16%)	248 (17%)	478 (16%)	2869	(0.73, 1.31)	0.89		2863	(0.73, 1.30)	0.84	
Missing	26 (2%)	12 (1%)	38 (1%)				0.12				
Vaccination card available to be seen by enumerator											
Baseline											
No	117 (8%)	125 (8%)	242 (8%)								
Yes	1330 (92%)	1357 (92%)	2687 (92%)								
Endline											
No	225 (16%)	198 (13%)	423 (15%)		0.84		0.09		0.77		0.08
Yes	1204 (84%)	1280 (87%)	2484 (85%)	2907	(0.64, 1.10)	0.20		2900	(0.59, 1.01)	0.06	
Mother has seen/heard/read any immunization messages in the last 6 months											
Baseline											
No	727 (50%)	690 (47%)	1417 (48%)								
Yes	720 (50%)	792 (53%)	1512 (52%)								
Endline											
No	517 (36%)	468 (32%)	985 (34%)		0.77		0.28		0.79		0.31
Yes	912 (64%)	1010 (68%)	1922 (66%)	2907	(0.53, 1.12)	0.17		2900	(0.52, 1.18)	0.24	
Mother believes that community has a role to play in improving the health of her child and that community is capable of taking actions to prevent her child from getting sick											
Baseline											
No	528 (36%)	449 (30%)	977 (33%)								
Yes	919 (64%)	1033 (70%)	1952 (67%)								
Endline											
No	299 (21%)	232(16%)	531 (18%)		0.69		0.24		0.69		0.20
Yes	1130 (79%)	1246 (84%)	2376 (82%)	2907	(0.47, 1.00)	0.05		2900	(0.48, 0.98)	0.04	
Household attends village meetings and engages in community actions to tackle village issues											
Baseline											

				Unadjusted[α]				Adjusted[β]			
Outcome	**Intervention N (%)**	**Control N (%)**	**Total N (%)**	**N**	**Odds ratio (95% CI)**	**P value**	**ICC**	**N[γ]**	**Odds ratio (95% CI)**	**P value**	**ICC**
No	723 (50%)	606 (41%)	1329 (45%)								
Yes	724 (50%)	876 (59%)	1600 (55%)								
Endline											
No	459 (32%)	423 (29%)	882 (30%)		0.79		0.13		0.78		0.13
Yes	970 (68%)	1055 (71%)	2025 (70%)	2907	(0.60, 1.03)	0.08		2900	(0.59, 1.04)	0.09	

[α] Explanatory variables in the unadjusted model include the group assignment indicator, the strata variable used for stratified randomization, and the baseline village-level log-odds of the outcome.

[β] Explanatory variables in the adjusted model include, in addition to the variables in the unadjusted analysis, gender and birth order of the child, mother's age, education, spouse's education, household head's religion and caste, household wealth quintile, and village-level variables –proportion of households in the poorest wealth quintile, proportion of mothers who cannot read and/or write, and average travel time to vaccination site.

[γ] Because of missing adjustment variables data, the observations used in adjusted analysis are fewer than those used in unadjusted analysis.

We present the effect of the intervention on the change in outcome from baseline in the appendix (Table S1.2). The intervention did not have any effect on the change from baseline in the primary immunization outcomes. No evidence of intervention effect was found for any of the secondary outcomes as well, except for the proportion of households attending village meetings and engaging in community actions to tackle village issues – odds ratio comparing baseline to endline was higher in the intervention group than in the control group (ratio of odds ratios = 1.31, 95% CI: 1.03 – 1.64).

The sensitivity analyses comparing the dropped villages with the ones that were retained in the trial did not show any substantial difference in baseline characteristics (S1 Appendix, Table S1.3). The analyses comparing the primary immunization outcomes in the intervention group versus the control group combined with the dropped villages show similar results as the main analyses (S1 Appendix, Table S1.4), that is, no evidence of an effect of the intervention on the primary immunization outcomes. We also conducted a "per-protocol" analysis, where we used all the 239 villages surveyed at endline and compared the primary immunization outcome between the 90 villages that received the SALT intervention and the remaining 149 villages. The finding was similar to the main analysis – the intervention was not found to have any effect on the primary immunization outcomes (S1 Appendix, Table S1.5).

District-wise summary of village-level process indicators are presented in the appendix (Table S1.6). During the 13-month intervention period (March 2017- March 2018), all steps of the intervention were completed in 88 of the 90 villages where implementation happened. The median number of visits to a village made by SALT facilitators during the intervention period varied from 14 in Kamrup Rural to 20 in Udalguri. The protocol suggested that the facilitators visit each village twice a month implying a requirement of a total of about 25 visits per village. During home visits, the facilitators were able to reach out to 19% (median, IQR = 16% to 25%) of households in the village. The intervention resulted in an average of 8 (median, IQR = 6 to 12) community meetings (including meetings with specific groups). During the intervention period, the dream-building activity took place at 7 months, leaving 6 months for the remaining activities – self-assessment, action planning and action phase. These activities are meant to be iterative – the number of villages in which self-assessment was repeated at least once varied between 23 (more than two-thirds) in Bongaigaon to 14 (less than half) in Udalguri.

Discussion

Community engagement intervention like SALT, in theory, has the potential to improve immunization coverage as it can help identify barriers to vaccination at the local level and thus might lead to customized and sustainable solutions. The findings from this evaluation study based on a cluster randomized controlled trial, however, showed no effect of the SALT intervention on children's immunization coverage in our study population after one year of implementation.

A meta-analysis of the effectiveness of community engagement in public health interventions suggests that there is solid evidence that community engagement approaches have a positive impact on a range of health outcomes including health behaviours (for example, diet, physical activity, smoking habits), health consequences (for example, change in body mass index, reduction in cholesterol) and participant self-efficacy pertaining to the health behaviours [31]. However, studies evaluating the impact of community engagement interventions in improving immunization coverage are sparse [18,23-25,32]. Our study addresses this gap in the literature.

Randomized controlled trials of complex interventions like SALT are often criticised as being a 'black box' as it can be difficult to know why and how the intervention worked (or not) [28]. The absence of evidence of an impact in our study could be simply because SALT was ineffective in this particular context or it could potentially be because of less than optimal implementation of the intervention. We attempted to collect relevant process indicators to explain the findings from the evaluation study. The potential reasons behind the observed lack of evidence of an impact are elaborated below.

The process evaluation data suggest less than optimal coverage of the intervention – the proportion of households in the village reached out to by SALT facilitators was less than 19% for half the villages. In addition, we do not know whether the households selected for endline evaluation were exposed to the intervention or not. We did not include questions on participation in SALT activities in endline survey to prevent the possibility of data collectors being able to identity the intervention villages from the responses. Unblinding of outcome assessors in a randomized controlled trial can lead to substantial bias in the assessment of the outcome variable [33-36]. Moreover, for a multi-step complex intervention like SALT, it was not straightforward to define exposure to the intervention.

The intervention could potentially have been more targeted in order to reach the last mile. In our baseline assessment (June-August 2016), we found that all three study districts had significantly higher immunization coverage compared to estimates from previous surveys. This most likely is due to implementation of Mission Indradhanush, a supplementary immunization programme of the Government of India, in the study districts prior to this study. Given the high level of vaccination coverage at baseline in the three districts, to achieve further improvement through SALT intervention, it would have been better if the intervention was adapted to engage with the marginalized and hard to reach population in a targeted manner. While within village transfer and sharing of learning among households was one of the assumptions of SALT intervention, this may not have happened per expectation during the implementation.

Any behavioral change takes time and requires sustained effort until a critical mass is reached, more so if it requires identifying and reaching out to the population who are usually left behind by the health system. The limited time frame for the SALT intervention was perhaps inadequate for sustained interactions with the community, and for

development of a sense of ownership at the community level regarding the issue of children's immunization. Also, the concept of SALT is difficult to grasp for both the facilitators and the communities. Allowing more time for training and implementation of the intervention could have helped improve uptake and achieve the desired level of community ownership. To address vaccine hesitancy in US, a relatively longer term intervention that was implemented for three years showed the promise of using parent advocates as part of a community-based approach to reduce vaccine hesitancy [32].

The SALT intervention being grounded in a democratic, sensitive and ethical approach, ideally it is the community who decides their priorities. It is therefore natural that some communities may not prioritize immunization, especially if there are other pressing issues. Our experience during process evaluation suggests that many communities initially did not perceive immunization as a major problem. However, child health was accepted by all villages as a shared dream, and it was through this dream that the facilitators stimulated the discussion around immunization. The objective of the study was to evaluate the impact of SALT in increasing immunization coverage. Hence the facilitators had to stimulate the discussion so that immunization related issues 'emerged' as a topic during dream building and practices around immunization are taken up for developing action plans. In one sense, this is a conflict between the idea of community ownership and decision-making and some level of external influence or 'coercion' by the facilitators during the implementation of the intervention.

In the context of evaluating a community engagement intervention, our study grappled with some dilemmas. Firstly, we debated whether to involve the entire community or include only households of eligible women in the intervention. Had we only recruited households having pregnant women in villages before the start of the intervention and implemented SALT with them, we may have observed better immunization outcomes at endline, because the implementation would have been more targeted and would have utilized the resources in an efficient manner. We, however, believe it would not have led to sustainable improvement in immunization outcomes. Also, it would not have aligned well with the objective of development of community ownership of the issue of immunization, as majority of the community members would have remained unexposed to the intervention.

Secondly, we deliberated on what would be a more appropriate design choice for evaluating a community engagement intervention. The cohort design is commonly used, that is, recruit participants at baseline, implement the intervention with the recruited participants from the community, and use the same set of participants for evaluating outcomes at endline. If the extent of reach of the intervention is an important metric for evaluation, this design choice may not be the ideal. We argue that a repeated cross-sectional design, where the communities remain the same at baseline and endline but a new random sample of eligible participants are recruited at endline for evaluation of outcomes, is perhaps more appropriate to ensure reach of intervention is incorporated in evaluation.

Strengths of our study include the use of a theoretically grounded community engagement intervention and the use of robust methods to assess the intervention. The SALT community engagement intervention is participatory, interactive, involves multiple inter-related steps and requires continued engagement. Based on the level of participation and involvement of the community, community engagement interventions can be classified into five graded categories ranging from inform, consult, involve, to collaborate and empower; the last being the highest form of engagement [37]. Most common intervention strategies in public health include providing education and advice which can be considered as low-level of community engagement [31]. The next common intervention strategies provide social support and skill development training through involvement with the community and can be classified as mid-level of community engagement. The SALT intervention belongs in the fifth category of empowering the community. In the context of evaluation design, the internal validity of our study is justified through identification of a comparable control group, selection of clusters and participants using probability sampling design, consideration of a sample size adequate to detect programmatically significant effect size with recommended statistical power, random allocation of clusters to the intervention and control groups ensuring treatment allocation being independent of outcome, measurement of relevant covariates at the participant and cluster level [26].

Our impact evaluation study includes two primary outcomes – full immunization in 12-23 months old children and three doses of DPT in 6-23 months old children. Having two primary outcomes may require adjustment for multiplicity of testing. However, the two age-groups overlap, and the two outcomes are strongly correlated. It would be difficult to control the error rate without being overly conservative. We, therefore, made no adjustments for multiplicity of testing. Moreover, the vaccination outcomes are constructed using information recorded from vaccination cards and that elicited from mothers. Depending on the age of the child and complexity of vaccination schedule, accuracy of mother's recall data is questionable. On the other hand, vaccination card may be unavailable, or all vaccinations may not be recorded accurately in the card [38]. Sensitivity analysis suggest that coverage rates are different depending on the data source used for defining child's vaccination status – vaccination card only, mother's recall only and combination of the two.

Conclusion

The null results from our study suggest that a more targeted implementation strategy may be the way forward if SALT community engagement intervention has to be effective across various contexts. Behavior change in villages could take time and require sustained effort. We believe that the SALT approach may be better suited in situations that target a smaller group of individuals or where the issue is perceived as a priority by the community and emerges organically through discussions, for instance, in villages with high prevalence of vaccine hesitancy.

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Supporting information

Supporting information
Appendix S1. Supplementary results
Table S1.1 Background characteristics of participants in the endline survey.

Characteristics	Intervention (*N*=1429)	Control (*N*=1478)	Total (*N*=2907)
Child			
Sex			
Boy	730 (51%)	744 (50%)	1474 (51%)
Girl	699 (49%)	734 (50%)	1433 (49%)
Age in months			
6-11	444 (31%)	512 (35%)	956 (33%)
12-23	985 (69%)	966 (65%)	1951 (67%)
Birth order			
First	778 (55%)	823 (56%)	1601 (55%)
Second	460 (32%)	473 (32%)	933 (32%)
Third or more	186 (13%)	180 (12%)	366 (13%)
Missing	5 (0%)	2 (0%)	7 (0%)
Born in a health facility			
No	134 (9%)	126 (9%)	260 (9%)
Yes	1290 (91%)	1350 (91%)	2640 (91%)
Missing	5 (0%)	2 (0%)	7 (0%)
Mother			
Age in years			
Less than 20	97 (7%)	76 (5%)	173 (6%)
20-24	563 (39%)	605 (41%)	1168 (40%)
25-34	693 (48%)	732 (50%)	1425 (49%)
35-plus	76 (5%)	65 (4%)	141 (5%)
Age at marriage			
Less than 18	410 (29%)	377 (26%)	787 (27%)
18-24	870 (61%)	964 (65%)	1834 (63%)
25 or more	149 (10%)	137 (9%)	286 (10%)
Education			
No schooling	146 (10%)	121 (8%)	267 (9%)
Some primary¶	324 (23%)	279 (19%)	603 (21%)
Some secondary¥	742 (52%)	821 (56%)	1563 (54%)
More than secondary£	217 (15%)	257 (17%)	474 (16%)
Spouse's education			
No schooling	160 (11%)	118 (8%)	278 (10%)
Some primary¶	342 (24%)	352 (24%)	694 (24%)
Some secondary¥	677 (47%)	730 (49%)	1407 (48%)
More than secondary£	250 (17%)	278 (19%)	528 (18%)
Received full antenatal care during pregnancy			
No	780 (55%)	838 (57%)	1618 (56%)
Yes	644 (45%)	638 (43%)	1282 (44%)
Missing	5 (0%)	2 (0%)	7 (0%)
Household			
Household head's caste			
Scheduled caste	109 (8%)	82 (6%)	191 (7%)
Scheduled tribe	309 (22%)	385 (26%)	694 (24%)
Other backward class	369 (26%)	422 (29%)	791 (27%)
General/Don't know	642 (45%)	589 (40%)	1231 (42%)
Household head's religion			
Hindu	931 (65%)	981 (66%)	1912 (66%)
Muslim	425 (30%)	417 (28%)	842 (29%)
Other	73 (5%)	80 (5%)	153 (5%)
Household wealth quintile			
Poorest	296 (21%)	280 (19%)	576 (20%)
Poorer	279 (20%)	301 (20%)	580 (20%)
Middle	289 (20%)	291 (20%)	580 (20%)
Richer	288 (20%)	294 (20%)	582 (20%)
Richest	277 (19%)	312 (21%)	589 (20%)

Village (cluster)			
N[a]	97	99	196
Percentage of households in poorest wealth quintile[a], Median (IQR)	20% (27%)	13% (20%)	13% (20%)
Percentage of mothers who cannot read and/or write[a], Median (IQR)	12% (25%)	7% (20%)	7% (20%)
Percentage of households with Muslim head of household[a], Median (IQR)	0% (60%)	0% (70%)	0% (64%)
Percentage of households with the head of household belonging to a scheduled tribe[a], Median (IQR)	6% (33%)	0% (54%)	3% (44%)
Average time to vaccination site (in minutes)[a], Median (IQR)	18 (9)	19 (9)	18 (9)

Data are *N (%)* unless specified otherwise. *N* indicates number of children expect for variables measured at the village level (indicated by [a]).
¶Standard/Class I to V.
¥ Standard/Class VI to X.
£Standard XI or above.

Table S1.2 Effect of intervention on change in primary and secondary outcomes from baseline: difference-in-difference analysis.

Outcome	Unadjusted[α]			Adjusted[β]		
	N	Odds ratio	P value	N[γ]	Odds ratio	P value
Full immunization (12-23 month old child)	3712	1.04 (0.76, 1.44)	0.79	3703	1.11 (0.80, 1.55)	0.53
Three doses of DPT (6-23 month old child)	5818	1.02 (0.77, 1.35)	0.89	5805	1.09 (0.82, 1.45)	0.56
Dropout between DPT doses 1 and 3	5741	0.92 (0.69, 1.23)	0.58	5729	0.87 (0.64, 1.20)	0.34
Vaccination card available to be seen by enumerator	5836	0.79 (0.56, 1.11)	0.17	5823	0.75 (0.53, 1.07)	0.11
Mother has seen/heard/read any immunization messages in the last 6 months	5836	0.93 (0.74, 1.16)	0.51	5823	0.97 (0.77, 1.21)	0.76
Mother believes that community has a role to play in improving the health of her child and that community is capable of taking actions to prevent her child from getting sick	5836	0.94 (0.73, 1.22)	0.65	5823	0.98 (0.75, 1.29)	0.90
Household attends village meetings and engages in community actions to tackle village issues	5836	1.25 (1.00, 1.56)	0.05	5823	1.31 (1.03, 1.64)	0.03

[α] Explanatory variables in the unadjusted model include the group assignment indicator, the survey (baseline or endline), their interaction, and the strata variable used for stratified randomization.

[β] Explanatory variables in the adjusted model include, in addition to the variables in the unadjusted analysis, gender and birth order of the child, mother's age, education, spouse's education, household head's religion and caste, household wealth quintile, and village-level variables – proportion of households in the poorest wealth quintile, proportion of mothers who cannot read and/or write, and average travel time to vaccination site.

[γ] Because of missing adjustment variables data, the observations used in adjusted analysis are fewer than those used in unadjusted analysis.

Table S1.3 Characteristics of participants in villages excluded from the intervention and control arms compared to villages that were included, at baseline and endline.

Characteristics	Baseline		Endline	
	Dropped villages	Intervention and control villages	Dropped villages	Control villages
Child				
Sex				
Boy	236 (37%)	946 (32%)	240 (38%)	475 (32%)
Girl	196 (31%)	990 (34%)	190 (30%)	485 (33%)
Age in months	210 (33%)	993 (34%)	210 (33%)	518 (35%)
6-11				
12-23	327 (51%)	1494 (51%)	317 (50%)	744 (50%)
Birth order	315 (49%)	1435 (49%)	323 (50%)	734 (50%)
First				
Second	237 (37%)	1154 (39%)	211 (33%)	512 (35%)
Third or more	405 (63%)	1775 (61%)	429 (67%)	966 (65%)
Missing				
Born in a health facility	325 (51%)	1535 (52%)	332 (52%)	823 (56%)
No	212 (33%)	967 (33%)	223 (35%)	473 (32%)
Yes	104 (16%)	421 (14%)	85 (13%)	180 (12%)
Missing	1 (0%)	6 (0%)	0 (0%)	2 (0%)
Has vaccination card				
No	105 (16%)	384 (13%)	79 (12%)	126 (9%)
Yes	536 (83%)	2539 (87%)	561 (88%)	1350 (91%)
Mother				
Age in years				
Less than 20	28 (4%)	149 (5%)	30 (5%)	76 (5%)
20-24	239 (37%)	1013 (35%)	265 (41%)	605 (41%)
25-34	338 (53%)	1565 (53%)	303 (47%)	732 (50%)
35-plus	37 (6%)	202 (7%)	42 (7%)	65 (4%)
Age at marriage				
Less than 18	130 (20%)	581 (20%)	198 (31%)	377 (26%)
18-24	452 (70%)	1988 (68%)	374 (58%)	964 (65%)
25 or more	60 (9%)	360 (12%)	68 (11%)	137 (9%)
Education				
No schooling	93 (14%)	376 (13%)	61 (10%)	121 (8%)
Some primary¶	144 (22%)	672 (23%)	122 (19%)	279 (19%)
Some secondary¥	337 (52%)	1497 (51%)	361 (56%)	821 (56%)
More than secondary£	68 (11%)	384 (13%)	96 (15%)	257 (17%)
Spouse's education				
No schooling	91 (14%)	321 (11%)	69 (11%)	118 (8%)
Some primary¶	132 (21%)	615 (21%)	164 (26%)	352 (24%)
Some secondary¥	338 (53%)	1487 (51%)	310 (48%)	730 (49%)
More than secondary£	81 (13%)	506 (17%)	97 (15%)	278 (19%)
Received full antenatal care during pregnancy				
No	399 (62%)	1677 (57%)	339 (53%)	838 (57%)
Yes	242 (38%)	1246 (43%)	301 (47%)	638 (43%)
Missing	1 (0%)	6 (0%)	0 (0%)	2 (0%)
Household				
Household head's caste	35 (5%)	202 (7%)	66 (10%)	82 (6%)
Scheduled caste	164 (26%)	776 (26%)	144 (22%)	385 (26%)
Scheduled tribe	166 (26%)	765 (26%)	160 (25%)	422 (29%)
Other backward class	277 (43%)	1186 (40%)	270 (42%)	589 (40%)
General/Don't know				
Household head's religion	392 (61%)	1977 (67%)	424 (66%)	981 (66%)
Hindu	226 (35%)	824 (28%)	201 (31%)	417 (28%)
Muslim	24 (4%)	128 (4%)	15 (2%)	80 (5%)
Other				
Household wealth quintile	148 (23%)	563 (19%)	128 (20%)	277 (19%)
Poorest	137 (21%)	575 (20%)	130 (20%)	304 (21%)
Poorer	128 (20%)	584 (20%)	146 (23%)	282 (19%)
Middle	125 (19%)	595 (20%)	120 (19%)	296 (20%)

Richer	104 (16%)	612 (21%)	116 (18%)	319 (22%)
Richest	35 (5%)	202 (7%)	66 (10%)	82 (6%)
Village (cluster)				
N[a]	43	196	43	99
Percentage of households in poorest wealth quintile[a], Median (IQR)	20 (28%)	13 (27%)	20 (20%)	13 (20%)
Percentage of mothers who cannot read and/or write[a], Median (IQR)	20 (20%)	13 (20%)	13 (17%)	7 (20%)
Percentage of households with Muslim head of household[a], Median (IQR)	6 (90%)	0 (67%)	0 (90%)	0 (70%)
Percentage of households with the head of household belonging to a scheduled tribe[a], Median (IQR)	7 (40%)	6 (47%)	7 (35%)	0 (54%)
Average time to vaccination site (in minutes)[a], Median (IQR)	19 (10)	19 (11)	20 (12)	19 (9)

Data are *N (%)* unless specified otherwise. *N* indicates number of children expect for variables measured at the village level (indicated by [a]).
¶Standard/Class I to V.
[¥] Standard/Class VI to X.
[£]Standard XI or above.

Table S1.4 Analysis of primary immunization outcomes after including the villages that were excluded from the intervention and control groups.

Outcome	Intervention villages N (%)	Control villages & dropped villages N (%)	Total N (%)	Adjusted[α]		
				N	Odds ratio (95% CI)	P value
Full immunization (12-23 month old child)						
Baseline						
No	211 (24%)	304 (23%)	515 (24%)			
Yes	660 (75%)	992 (76%)	1652 (76%)			
Missing	8 (1%)	5 (0%)	13 (1%)			
Endline						
No	230 (23%)	306 (22%)	536(23%)	2372	0.88 (0.65, 1.18)	0.38
Yes	753 (76%)	1088 (78%)	1841 (77%)			
Missing	2 (0%)	1 (0%)	3 (0%)			
Three doses of DPT (6-23 month old child)						
Baseline						
No	267 (18%)	371 (17%)	638 (18%)			
Yes	1174(81%)	1744 (82%)	2918 (82%)			
Missing	6 (0%)	9 (0%)	15 (0%)			
Endline						
No	253 (18%)	341 (16%)	594 (17%)	3534	0.89 (0.66, 1.19)	0.41
Yes	1173 (82%)	1774 (84%)	2947 (83%)			
Missing	3 (0%)	3 (0%)	6 (0%)			

[α] Explanatory variables in the adjusted model include the group assignment indicator, the strata variable used for stratified randomization, the baseline village-level log-odds of the outcome and covariates – gender and birth order of the child, mother's age, education, spouse's education, household head's religion and caste, household wealth quintile, and village-level variables – proportion of households in the poorest wealth quintile, proportion of mothers who cannot read and/or write, and average travel time to vaccination site.

Table S1.5 Per-protocol analysis of primary immunization outcomes.

Outcome	90[£] villages that received SALT intervention N (%)	149[¶] villages that did not receive SALT intervention N (%)	Total N (%)	Adjusted[α]		
				N	Odds ratio (95% CI)	P value
Full immunization (12-23 month old child)						
Baseline						
No	198 (24%)	317 (23%)	515 (24%)			
Yes	602 (74%)	1050 (77%)	1652 (76%)			
Missing	9 (1%)	4 (0%)	13 (1%)			
Endline						
No	214 (23%)	322 (22%)	536 (23%)	2372	0.87 (0.65, 1.18)	0.37
Yes	707 (77%)	1134 (78%)	1841 (77%)			
Missing	2 (0%)	1 (0%)	3 (0%)			
Three doses of DPT (6-23 month old child)						
Baseline						
No	248 (18%)	390 (18%)	638 (18%)			
Yes	1088 (81%)	1830 (82%)	2918 (82%)			
Missing	7 (1%)	8 (0%)	15 (0%)			
Endline						
No	234 (18%)	360 (16%)	594 (17%)	3534	0.89 (0.65, 1.24)	0.43
Yes	1087 (82%)	1860 (84%)	2947 (83%)			
Missing	3 (0%)	3 (0%)	6 (0%)			

[£] Intervention was implemented in 89 out of 97 villages in the intervention group and in 1 village out of the 99 in the control group.

[¶] These include 8 villages out of the 97 in the intervention group, 98 villages out of the 99 in the control group and 43 dropped villages (1 dropped village was not surveyed in endline).

Table S1.6 Summary of process indicators over 13 months of intervention (March 2017- March 2018), overall and for the three districts.

Process indicators	Kamrup Rural (n=30 villages)	Bongaigaon (n=30 villages)	Udalguri (n=30 villages)	Total (n=90 villages)
Median (IQR) number of visits to village made by SALT facilitator	14 (12 – 15)	19 (16 – 20)	20 (18 – 22)	18 (14 – 20)
Median (IQR) percentage of households in village where home visits were conducted	19% (12% – 25%)	20% (16% – 25%)	19% (17% – 25%)	19% (16% – 25%)
Median (IQR) number of community meetings in village (including meetings involving specific groups¶)	8 (6 – 13)	10 (7 – 12)	7 (4 – 8)	8 (6 – 12)
Median (IQR) number of months after start of intervention when first community dream building exercise happened in village§	7 months (6 – 9) ¥	7 months (5 – 8)	8 months (6 – 9)	7 months (5 – 9) ¥
Number of villages in which self-assessment was repeated£	20¥	23	14	57¥
Median (IQR) number of visits made to village for follow up of action plan	1 (1 – 2) ¥	3 (2 – 4)	2 (1 – 2)	2 (1 -3) ¥

¶ community block officers, self-help groups, health workers, religious leaders, and so on.
¥ In 2 villages in Kamrup Rural, the steps – dream building, self-assessment and development of action plan, did not happen.
§ In all villages where community dream building took place, immunization emerged as a topic during dream building.
£ In all villages where self-assessment took place, practices around immunization were discussed during self-assessment.

Appendix S2. Pictorial illustration of SALT intervention

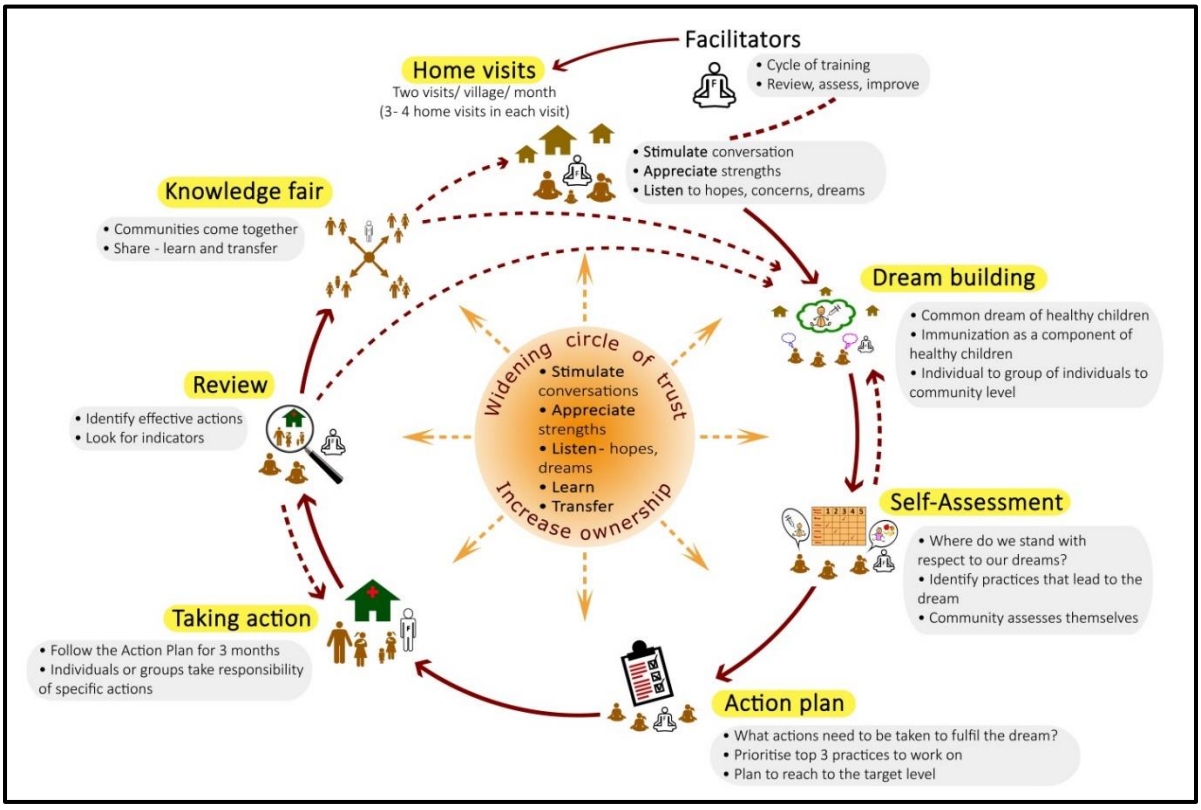

Figure S2.1. Pictorial illustration of different steps of SALT intervention.

Appendix S3. Vaccination outcomes

For each vaccine, mothers were asked whether the child had received the vaccination and the number of doses received, for vaccines requiring more than one dose. During the interview, mothers were asked to recall this information before the interviewer asked to see the child's vaccination card. The interviewer then noted down the dates for various vaccinations as recorded in the vaccination card. If the card indicated that a vaccine was administered but no date was recorded or was partially recorded, then the interviewer also noted it down.

Depending on the age of the child and complexity of vaccination schedule, accuracy of mother's recall data is questionable. On the other hand, vaccination card of a child may also be incomplete. All instances of vaccination may not be recorded in the card for several reasons – caregiver may forget to bring the card to the vaccination site on the day of vaccination, the health worker may not have time to record the date on the card because of her workload, the child may receive some vaccinations from the public health facilities and some from private practitioners, which may not be recorded in the card. Sensitivity analysis of vaccination coverage rate for children having vaccination card indicates significant differences in coverage rates depending on the source of information used to define child's vaccination status – vaccination card only, mother's recall only and combination of both the sources [1]. Moreover, the extent of differences in coverage rate by source of information vary by vaccines. We combined information from vaccination card, wherever available, and mother's recall. In the absence of vaccination card, we relied solely on mother's recall.

For different vaccines, to define whether the child received that vaccination or not, we followed the procedure described below.

For BCG and measles vaccine, we considered the child to be vaccinated if either the mother reported or the vaccination card indicated this. If the vaccination card was not seen by the interviewer and the mother reported that the child did not receive the vaccination, we considered the child to be not vaccinated. If the vaccination card was not seen by the interviewer and the mother reported 'don't know', we set the value to missing.

For polio and DPT or Pentavalent, we first calculated the number of doses received from mother's recall. In cases where enumerator had seen the vaccination card of child, we calculated number of doses of the vaccine from the vaccination card. We then combined the two counts as presented in Table S3.1 to derive the number of doses.

Table S3.1. Number of doses reported by mother and recorded in the vaccination card. The number in the cell denotes the number of doses constructed combining the two sources.

Number of doses from vaccination card	Number of doses reported by mother				
	0	1	2	3	Don't know
0	0	1	1	1	0
1	1	1	1	1	1
2	2	2	2	2	2
3	3	3	3	3	3
No vaccination card	0	1	2	3	Missing

Appendix S4. Secondary outcomes – community processes

We considered two secondary outcome variables indicating community processes - household's engagement with village communities and mother's perception of role of community in children's health. The respondent for the household questionnaire was asked the following questions

How frequently does the community meet to discuss local affairs?

- Never
- Occasionally
- Regularly (at least once per month, in most months)

How often in the last 12 months have you (or any HH member) attended any meeting in which there was discussion of local affairs?

- Never
- Occasionally
- Regularly (at least once per month, in most months)

Have you (or any HH member) been engaged in community actions to tackling community issues?

- Yes
- No

We defined the binary secondary outcome variable 'household attends village meetings and engages in community actions to tackle village issues' as a 'yes' if the respondent answered 'occasionally' or 'regularly (at least once per month, in most months)' to both the first and second questions and 'yes' to the third question; and as a 'no' otherwise.

The mother was asked the following questions to capture her perception about community's role in child's health

Do you believe that community has a role to play in improving the health of your child?

- Yes
- No

Do you believe that your community is capable of taking actions to prevent your child from getting sick?

- Yes
- No

We defined the secondary outcome '*mother believes that community has a role to play in improving the health of her child and that community is capable of taking actions to prevent her child from getting sick*' as a '*yes*' if the mother responded with a yes to both the questions and as a 'no' otherwise.

Appendix S5. Composite score for stratified randomization

Sampled villages from baseline survey, within a district, were stratified into four strata based on a composite score constructed using the following village-level indicators: average number of (under 5 years) children, percentage of households living more than 50 years in the village, percentage of households with heads belonging to a Scheduled Caste (SC), percentage of households with heads belonging to a Scheduled Tribe (ST), percentage of Muslim households, percentage of households belonging to the poorest wealth quintile, percentage of households belonging to the richest wealth quintile, percentage of mothers having no formal schooling, percentage of mothers with 12 or more years of schooling, percentage of mothers receiving full antenatal care[1] during pregnancy, village had flood last year or not. All indicators were not used for stratification within a district, the choice of variables depended on the district-specific context. For example, in Kamrup rural, all three indicators— percentage of SC households, percentage of ST households, and percentage of Muslim households, were considered whereas for Bongaigaon only percentage of Muslim households and for Udalguri only percentage of ST households were relevant. For each district, the selected village-level indicators were combined using principal component analysis. The first principal component provided a score for each village. The villages were then categorized into four strata based on quartiles of the score.

Appendix S6. Sample size

To calculate the sample size, we considered the two primary outcomes: three doses of DPT (DPT3) coverage among 6-23 month old children and full immunization coverage (FIC) among 12-23 months old children. Per our initial (pre-baseline) sample size calculation, we needed 120 villages per group, intervention and control, leading to a total of 240 villages, to detect a difference of at least 10 percentage points in coverage between the two groups, with 80% statistical power using a two-sided test at 5% level of significance, after accounting for the correlation in immunization status among children from the same village. We considered an equal allocation of 240 villages across 3 districts, resulting in 40 intervention and 40 control villages in each of the selected districts. Estimates of the coverage rate for DPT3 and FIC in the control group were obtained from the most recent data available at the time (RSOC, 2013-14) [2]. In Assam, the estimates were 65.9% and 55.3% for DPT3 and FIC, respectively. If the coverage rates for DPT3 and FIC in the intervention group are at least 10 percentage points higher, i.e., 75.9% and 65.3%, respectively, our sample size would allow us to detect the difference in coverage rates between the two groups. To calculate the intracluster correlation (ICC) for these outcomes, we extracted DLHS-3 (2007-08) [3] unit level data for Assam and obtained the estimates as 0.21 and 0.25 for DPT3 and FIC, respectively. We further assumed that a village will have a minimum of 15 children 6-23

[1] Full antenatal care: Consumed Iron/Folic Acid tablet/syrup for 100 days or more, received 3 or more antenatal check-up visits, received at least one tetanus toxoid injection

month old and 10 children 12-23 month old. If there were more than 15 eligible children in a village, we randomly selected 15 children. Baseline survey was conducted in all 240 villages, as per the requirement of pre-baseline sample size calculation.

Up-to-date ICC and Re-estimation of Sample Size

Sample size is sensitive to the estimate of ICC used in the calculation. ICC, often interpreted as the degree of homogeneity of units within cluster with respect to the outcome variable, is defined as the ratio of between-cluster variability to total variability in the outcome. ICC estimates used in the pre-baseline sample size calculation were based on DLHS-3 (2007-08) data. We expected the recent ICC estimates for DPT3 and FIC to be different, most likely smaller in magnitude because of the improved reach of maternal and child health services, including immunization, under the National Rural Health Mission (NRHM, 2005-2012) [4]. Immunization service delivery, supply chain system, vaccine logistics and the process of linking health system and communities through ASHA- all these have been standardized to a large extent in all rural areas. Moreover, the estimates for coverage rate for DPT3 and FIC may have also changed. These changes would affect the sample size needed to detect a difference in coverage rates between the control and intervention groups.

On another note, our intervention is complex in nature, involves sustained interaction over several months with the community. Owing to this intense nature of our intervention, there were concerns that implementation of the intervention may not happen optimally within the timeframe and budget if the sample size was unnecessarily large. The international panel of reviewers of this study also recommended that the sample size and ICC be recalibrated based on new data that would become available to us from the baseline survey. These considerations led us to recalculate the sample size based on estimates derived from baseline data.

Table S6.1. Revised sample size for two primary outcome variables based on SALT baseline survey data.

Outcome of interest	Updated coverage rate (%)	Updated ICC	Updated sample size (villages in each group)
DPT3	84	0.17	57
FIC	79	0.18	90

Table S6.1 presents the revised estimates based on data from baseline survey and the revised sample size. Note that the ICC estimates based on baseline data have decreased relative to earlier estimates from DLHS-3, as anticipated. On the other hand, vaccination coverage rates have increased substantially relative to RSOC data (2013-14). This sudden increase in vaccination coverage can perhaps be attributed to Mission Indradhanush (MI), a flagship program of the Ministry of Health and Family Welfare (MoHFW) and was also observed in other historically poor-performing states such as Bihar, Rajasthan and Madhya Pradesh [1]. Two phases of MI happened before our baseline survey (phase 1: April-July 2015 and phase 2: Nov 2015-Feb 2016) and all three study districts (Bongaigaon, Kamrup rural, and Udalguri) received at least one round of MI intervention. However, it was possible that this high level of immunization coverage would not be sustained in future after the supplementary immunization activities under MI are discontinued. In view of these high coverage rates, we reduced the minimum detectable difference from 10 to 8 percentage points in the revised calculation of sample size.

Per our revised sample size calculation, we needed 90 villages per group to detect a difference of at least 8 percentage points in coverage between the control and intervention groups with 80% statistical power based on a two-sided test having 5% level of significance, after accounting for the correlation in immunization status among children from the same village. Total number of villages required for the study is 180 (90×2). We considered an equal allocation of 180 villages across the 3 districts, resulting in 30 intervention and 30 control villages in each of the three selected districts. The intervention was implemented in 90 villages across 3 districts. However, endline data were collected from all 240 villages (120 intervention and 120 control) where the baseline survey happened before the launch of the intervention.

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2. UNICEF, *Rapid Survey on Children (2013-14): India fact Sheet*. 2015, Minsitry of Women and Child Development, Government of India.
3. International Institute for Population Sciences, *District Level Household and Facility Survey (DLHS-3), 2007-08: India report, IIPS: Mumbai*. 2010: p. Accessed on Oct 10, 2013 at http://www.rchiips.org/pdf/INDIA_REPORT_DLHS-3.pdf.
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