

Intermediate Assessment of the Khushi Baby cRCT:

*Implementation of a novel mHealth solution for vaccination record keeping
in rural Udaipur, Rajasthan, India.*

by

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Abstract

Background: Khushi Baby (KB) is a mobile health platform that tracks child immunizations using a mobile application and a Near Field Communication (NFC) necklace worn by the child. Quantitatively assessing intermediate indicators of the KB program's progress is important, especially when considering the program's scalability.

Objectives: This study seeks to quantitatively examine three key intermediate outcomes of the KB cluster Randomized Controlled Trial (cRCT), using group comparisons of mothers' survey responses, that are indicative of whether the necklace is discussed, visible, and liked by users. Two data collection tools were compared in this study: the NFC sticker and the NFC necklace worn by the child. The dependent variables (number of people data collection tool was discussed with, positivity rating of data collection tool, and visibility of data collection tool to grandmothers/fathers) were assessed in relation to the independent variable of group membership.

Methods: Mothers were enrolled in the cRCT from August to December 2015, and the study period is to last 7 months. 208 mothers had been enrolled and 128 children had completed the DTP1-DTP3 vaccination series by the midline assessment (end of January 2016). Clustering was done on the village level, with 96 immunization camps randomly assigned to 3 arms: mothers given an NFC sticker placed on the immunization card (control group), mothers given an NFC necklace (group P), and mothers given an NFC necklace with voice calls reminding them to come to camp (group P+V). A Kruskal-Wallis H test was used to assess discussion level around the system. User satisfaction was analyzed using a chi-squared test, and visibility of the data collection tool to key relatives was modeled using logistic regression.

Results: Findings suggest that the necklace generates discussion and is well liked; however, the voice calls do not significantly amplify discussion or improve mothers' perceptions of the necklace. Mothers discussed the data collection tool with significantly more people in P compared to control, and in P+V compared to control. In the follow-up surveys, 35.3% of mothers rated the necklace "very good" in P and 36.4% rated the necklace "very good" in P+V; these were both significantly greater than the 11.1% of control group mothers who rated the sticker "very good" ($p = 0.005$ and $p = 0.008$, respectively). P and P+V were significant predictors of the grandmother having seen the necklace, as per the mother ($p < 0.001$ for both). P was a significant predictor of the father having seen the data collection tool ($p = 0.008$).

Conclusion: Mothers reportedly like the necklace more than the sticker. The use of a culturally appropriate wearable as the data collection tool is amplifying discussion around the KB system, but little impact of the voice calls is evident as call deployment was inconsistent. Missing data limits the validity of the regression models used to assess visibility. There may be potential for the engaging quality of the KB necklace to improve health outcomes, if the necklaces are strategically used to encourage more mothers to bring their children to immunization camps.

Introduction

1.5 million children worldwide continue to die from vaccine-preventable diseases each year (UNICEF), and about 500,000 of these children are in India alone (EndPolioNow, 2015). A major factor contributing to this is the lack of efficiency and granular data needed to track each child's immunization; as a result, many children fall through the cracks and do not complete their essential vaccination series in the first year of life, leaving them vulnerable to diseases. Khushi Baby (KB) was developed as a potential solution to this problem, as it streamlines the vaccination data collection process in low-resource settings. Khushi Baby is a novel mHealth platform that tracks child immunization history using a mobile application and a Near Field Communication (NFC)-powered necklace worn by the child. Health workers are equipped with NFC-enabled smartphones, which contain the Khushi Baby mobile application. When a child with the NFC necklace is brought to a given immunization camp, the health worker scans his or her necklace to automatically bring up the child's immunization history on the KB mobile application. The application indicates which vaccines are due that day, based on the child's birth date, and can be updated by scanning the necklace once more. The child's vaccination data is then synced to a cloud-based database when cellular connectivity is available (see Figure 1). The necklace is not only used as a data storage device, but is also a culturally tailored piece of jewelry, as the black thread on which the pendant is strung is commonly believed to ward off evil spirits in the Udaipur community and in many tribal regions of India (Bhasin, 2007; Jain and Agrawal, 2005). The Khushi Baby team proposes that this necklace could also serve as a social symbol and a potential talking point for caregivers (typically mothers), and may be usable as a "campaign tool" for increasing immunization camp attendance rates and vaccination completion rates in the future.

While many new technologies are being developed to address problems like this in resource-limited settings, such innovations need to be rigorously tested and supported by data-driven evidence; in the case of Khushi Baby, this testing was done through a cluster Randomized Controlled Trial (cRCT). The current study seeks to systematically evaluate intermediate outcomes of the Khushi Baby cRCT being implemented in rural Udaipur, Rajasthan, India.

Qualitative measures are much needed for obtaining more nuanced feedback from intervention participants, but such responses can be hard to analyze in a way that is consistent and definitive, making them difficult to appraise concretely (Dixon-Woods *et al.*, 2004). Another issue is that many public health program evaluations tend to take the “lessons learned” approach; that is, they focus on what was done in the past and use these insights to determine what can be improved in the future for further expansion and scale-up of the intervention (WHO, 2000). For example, a process evaluation of the “Stop My Smoking USA” mHealth program conducted by Ybarra and colleagues (2014) used qualitative post-program survey questions to gauge efficacy and identify areas of improvement for the program. However, as opposed to retrospectively assessing the efficacy of a given program, analyzing intermediate outcomes during the program itself may provide greater insight as to whether the intervention is having the desired impact on specific, defined quantitative measures. This method of quantitatively assessing indicators that are relevant to the main study outcomes at the midline of an intervention can be useful in concretely demonstrating program progress, which is particularly important when considering program scalability to other regions or under various contexts.

With regard to immunization record-keeping programs in particular, there is limited research analyzing intermediate outcomes (e.g. user impression of the record-keeping system) that are related to the main program outcomes (e.g. increasing immunization adherence, or

increasing vaccination clinic attendance rates). To date, a few studies have explored mHealth innovations for vaccination record keeping, including the usage of mobile phone image capture for secondary immunization data collection (Jandee *et al.*, 2015) and the use of NFC technology for global public health in general (Marcus, 2009). However, studies that are focused specifically on a midline evaluation of a vaccination record-keeping mHealth RCT are very sparse. It is useful to have quantitative methods in place to evaluate progress of such programs at the midline, before spending valuable time and resources on expansion.

While the overarching aim of the Khushi Baby RCT is to assess whether the KB system increases on-time vaccination and draws more mothers to immunization camps to vaccinate their children, the goal of this assessment is to quantitatively examine three key intermediate outcomes that are indicative of whether the necklace generates discussion, is visible, and is well liked by users. The control group being used for this RCT uses a transparent NFC sticker in place of the necklace, which is adhered to the child's immunization card. This way, the data of children in the control group is still digitized while remaining as close to the status quo (manual, written data entry on the immunization card) as possible. The first intervention group (P) consists of children who are given a necklace with an NFC pendant to digitize their vaccination data, and the second intervention group (P+V) consists of children who are given the necklace with NFC pendant as well as local dialect-specific voice call reminders, sent to the mother's cell phone 1 day prior to when their child's next vaccination is due. At each camp, in addition to having their children vaccinated and the data digitized, mothers were asked to answer an oral survey that included relationship-type questions gauging their social ties to other community members, user satisfaction measures, and questions about their experience at the immunization camp. For a full list of the survey questions asked, see Table 3.

The first outcome assessed will be the level of discussion around the data collection tool (NFC necklace versus NFC sticker) between mothers and other community members. Other outcomes assessed include mothers' general impression of the data collection tool, and visibility of the data collection tool to key family members (fathers and grandmothers of the household). There is evidence to support the notion that fathers and grandmothers are key influencers who impact maternal and child health (Thuita, 2015), and that there is a general need to involve influential household members like grandmothers and men in community health interventions (USAID, 2011).

Our team speculated that the NFC necklace could be a potential talking point for mothers, attracting more mothers to bring their children to immunization camps and subsequently increasing immunization rates. We also thought that the dialect-specific voice call reminders might make mothers more cognizant of their child's immunization status and of the NFC necklace, which could generally increase discussion around the necklace. Thus, the hypotheses for this study are as follows:

- The discussion level around the data collection tool (NFC necklace or NFC sticker) in P+V > P > control
- User impression of the data collection tool would be significantly more positive in P and P+V (both NFC necklace arms) relative to the sticker arm (control).
- Fathers and grandmothers of children in P and P+V would be more likely to have seen the data collection tool compared to fathers and grandmothers of children randomized to the control group.

Discussion level was indicated by a survey question gauging how many other community members the mother showed or discussed the data collection tool with. User impression of the

data collection tool was indicated by a survey question gauging mothers' general reaction to the pendant or sticker on a 5-point Likert scale consisting of "very good", "good", "no reaction", "bad" or "very bad" (Likert, 1932). Lastly, "visibility" was assessed by survey questions that asked whether grandmothers and fathers of the household had seen the data collection tool.

Methods

Study Design and Justification

The analyses for this thesis were conducted using responses from a survey, implemented during the Khushi Baby cRCT. A cluster randomized study design was chosen for the cRCT to avoid contamination among study arms (Hayes and Moulton, 2009). This becomes important if, for example, Mother A was randomized to group P and lived next to Mother B, who was randomized to the control arm. Mother B may see or hear about Mother A's necklace and unintentionally be more influenced to bring her child to the next vaccination camp. Clustering on the village level minimizes this potential for contamination. 96 immunization camps were randomly assigned to the aforementioned 3 arms: NFC sticker (control), NFC necklace (P), and NFC necklace with vocal reminder call to household mobile phone (P+V) (see Figure 2). Voice reminders were delivered automatically to mothers' household phones in the P+V group, 1 day prior to the scheduled camp. For details on enrollment duration calculations for the overarching Khushi Baby cRCT, see Table 2.

The study procedures were as follows: at the first immunization camp (the camp at which the child was first enrolled), infants randomly assigned to the sticker camp (control) received an NFC sticker placed on the existing immunization card. Infants assigned to either group P (NFC necklace) or P+V (necklace + voice call) received the NFC necklace, applied by the health worker using a safe tying technique. After obtaining consent, administering the due vaccines and

inputting the information into the mobile app, the mother is asked to answer a series of survey questions (Table 3). Surveys are conducted at baseline, and at each of the two follow-up camps.

The major questions of interest for this study are:

- How many people have you shown the necklace (or sticker) to? [numeric; count data]
- What is your general reaction to the necklace (or sticker)? [5-point Likert scale]
- Has the child's grandmother (*dadi*) seen the necklace (or sticker)? [binary]
- Has the child's father seen the necklace (or sticker)? [binary]

Study Population

The target population for this cRCT includes those living in rural regions of Udaipur, Rajasthan, India. This population is composed mostly of agricultural laborers and some migrant workers, and falls into the lowest socioeconomic status (SES) category of the country. The vast majority of people live on less than two US dollars per day, and most have literacy and education at or below the fifth grade level (Banerjee and Duflo, 2007). Access to basic amenities, such as electricity, clean water and cellular connectivity, is limited in this region. Mothers across the study arms were roughly of the same education level, marital status and marital age, average household size and SES. A detailed breakdown of baseline descriptive characteristics of the study population can be found in Table 1. This table consists of a subset of mothers surveyed who completed the full DTP1-3 series and thus answered the survey questions of interest, at exit. Villagers in the study's catchment area receive their immunizations at vaccination camps held by Seva Mandir, a local NGO that is well established in the Udaipur community.

Participants were enrolled in the study over a 4-month period, from mid-August to mid-December 2015, and the study period is to last a total of 7 months. A total of 208 mothers were enrolled in the study, with 128 children having completed the DTP1-DTP3 vaccination series by

the end of January 2016 (midline assessment). Children were enrolled based on the following inclusion and exclusion criteria:

Inclusion Criteria	Exclusion Criteria
1. Mother has an infant less than 6 months old	1. Infant has already received one or more doses of the DTP vaccine
2. Mother is a self-identified resident within one of the villages associated with the immunization camp	2. Mother and infant intend to move from the area in the next 6 months
3. Mother is willing to give informed consent. The study description was read to the participant orally and consent was given via thumbprint.	3. Mothers without mobile phone access were excluded from P+V study arm.

Because on-time vaccination is not a measure of interest for this study, all mothers who finished the DTP1-3 series and took the exit survey were included in the analyses regardless of timeliness of vaccination (camps are held once monthly and the DTP series is meant to be completed in 3 months).

Method of Analysis and Justification of Statistical Tests

To analyze discussion level around the KB intervention, a Kruskal-Wallis H test was used. The survey question analyzed for this outcome asked the mother to indicate the number of people she had shown the child’s necklace or sticker to. This question was asked at exit (follow-up camp at which DTP3 was administered). A Kruskal-Wallis H test was deemed an appropriate non-parametric alternative to a one-way analysis of variance (ANOVA), as the count data for this outcome did not meet the assumptions of normality (right-skewed distribution) and visually appear to have similar distributions across treatment arms (see Figure 3). Multiple comparisons were conducted to examine between which study arms a significant difference was found, using the “kruskalmc” function in the “pgirmess” R statistical software package (Giraudoux, 2016).

User satisfaction with the KB system was analyzed using a chi-squared test. The survey question of interest asked mothers across the 3 study arms to rank their general impression of the data collection tool (NFC necklace or sticker) on a 5-point Likert scale; possible responses included “very good”, “good”, “no reaction”, “bad” or “very bad”. No respondents answered “bad” or “very bad” in any of the study arms, so these categories were excluded from the analysis. This question was asked at exit (follow-up camp at which DTP3 was administered) (See Figure 5). A chi-squared test was deemed appropriate, as the sample size is adequately large (no contingency cells having expected counts < 5) and the data is independent. Pairwise t-tests of proportions were conducted to determine between which study arms the proportion of “good” and “very good” responses were significantly different.

To assess “visibility” of the data collection tool (NFC necklace or sticker) to key family members (namely, grandmothers and fathers of enrolled children), mothers across the 3 study arms were asked 2 separate questions pertaining to whether the grandmother or father of the household, respectively, had seen the necklace or sticker (“yes” or “no”). These questions were asked at exit (follow-up camp at which DTP3 was administered) (See Figures 6 and 7). A logistic regression model was deemed appropriate for assessing visibility to grandmothers and fathers, as the dependent variable is binary and each observation is independent. It should be noted that the survey did not gauge the frequency at which grandmothers or fathers saw the data collection tool for each child. If the father or grandmother was deceased, the response to the visibility question was marked as “no”.

Results

Presentation and Analysis of Findings

All analyses were conducted at an alpha level of 0.05, unless otherwise stated. In the assessment of discussion level, mothers in the P+V arm showed the necklace to an average of 2.82 other people, and mothers in the NFC necklace arm (P) showed the necklace to 3.77 other people; this is in comparison to the sticker arm (control), in which mothers only showed the sticker to an average of 1 other person (See Figure 4). According to the Kruskal-Wallis H test, there was a statistically significant difference in the number of people the data collection tool was shown to/discussed with, by study arm ($H = 9.505$, $df = 2$, $p = 0.008$). The H statistic, or Kruskal-Wallis test statistic, approximately follows a chi-square distribution with $k-1$ degrees of freedom where k = the number of comparison groups (Boston University School of Public Health, 2016). Pairwise comparisons between study groups revealed that mothers showed and discussed the data collection tool with significantly more people in the necklace camps (P) compared to the sticker camps (control), and in the necklace with voice call camps (P+V) compared to control, but no significant difference was found between P and P+V groups. It is important to note that only 44.7% of the mothers assigned to the P+V arm expressed that they received a voice call reminder at the first follow-up camp, and only 56.4% of the mothers assigned to the P+V arm said they received a call at the second follow-up camp (at exit). Thus, the inconsistent delivery of the voice call reminders is a study limitation that must be addressed in the future before gauging the success of the voice calls in increasing discussion, likeability or visibility of the KB necklace.

A chi-squared test of independence was performed to examine “user satisfaction”, and identified a significant relationship between mothers’ general reaction to the data collection tool and study arm ($\chi^2 = 21.05$, $p < 0.001$ with $df = 4$). Pairwise t-tests of proportions revealed where this difference lies. No significant differences were found between arms in the proportion of

mothers who rated the necklace or sticker as “good”. However, 35.3% of mothers rated the necklace as “very good” in P and 36.4% of mothers rated the necklace as “very good” in P+V; these were both significantly greater than the 11.1% of mothers in the control group who rated the sticker “very good” ($p = 0.005$ and $p = 0.008$, respectively). No significant differences in mothers’ reactions to the necklace were found between P and P+V arms.

To assess the visibility of the data collection tool to grandmothers of the household, a logistic regression analysis was conducted. The model was used to determine whether group membership (control group, P or P+V) is predictive of the grandmother of the household seeing the data collection tool, controlling for other covariates in the model. Covariates were conceptually chosen (i.e. variables that were of substantive interest and were conceptually related to the outcome were included in the full model, and sequentially removed (backwards selection) until only those with statistical significance at the $\alpha = 0.05$ level remained in the reduced model). Covariates in the full model included study arm, child’s gender, block in which the mother was located, number of children the mother had, number of child deaths the mother had, number of institutional births the mother had, mother’s education level, mother’s access to a mobile phone, mother’s age, and whether or not the father of the household was a migrant worker (an indicator of how much time the father spends at home with family). Of these, P and P+V study arms were found to be statistically significant predictors of visibility to grandmothers. This finding remained true, even after controlling for random effects of clustering on the block level ($p < 0.001$ for both P and P+V). A test of the full model against the null model was statistically significant, indicating that study arm reliably distinguished between grandmothers who had seen the data collection tool and those who had not ($X^2 = 35.00$, $p < 0.001$ with $df = 6$). Grandmothers of children who were randomized to P had 10.94 times the odds of having seen

the data collection tool compared to those in the control group (95% CI: [3.39, 35.37]).

Grandmothers of children randomized to P+V had 8.62 times the odds of having seen the data collection tool compared to those in the control group (95% CI: [1.05, 70.98]).

To assess the visibility of the data collection tool to fathers of the household, a logistic regression analysis was also conducted. The model was used to determine whether group membership (control group, P or P+V) is predictive of the father of the household seeing the data collection tool, controlling for other covariates in the model. The same covariates were used in this model as were used in the model of visibility to grandmothers. After removing variables that were not statistically significant or were otherwise unfit for inclusion (e.g. very large standard deviation and confidence interval), belonging to study arm P was found to be a statistically significant predictor of the father having seen the data collection tool ($p = 0.008$). After accounting for random effects of clustering on the block level, belonging to study arm P was still a significant predictor ($p = 0.006$), as was having a male child ($p = 0.029$). Using a Likelihood Ratio Test, this model was compared to a model that included the interaction between child's gender and study arm. This test revealed a significant difference between models ($X^2 = 56.80, p < 0.001$ with $df = 1$), indicating that child's gender is an effect modifier of the relationship between study arm and visibility of the data collection tool to fathers. A test of the full model against the null model was statistically significant, indicating that study arm reliably distinguished between fathers who had seen the data collection tool and those who had not ($X^2 = 25.86, p = 0.004$ with $df = 10$). Fathers of children who were randomized to group P (NFC necklace arm) had 38.15 times the odds of having seen the data collection tool compared to those in the control group (95% CI: [2.80, 519.20]).

Significance and Applicability of Findings

Based on this preliminary evidence, it appears that the NFC necklace generates discussion and is well liked by mothers in the study's catchment area. No mothers refused the necklace in this study, and a significantly greater proportion of mothers rated their general reaction toward the NFC necklace as "very good" in both P and P+V, compared to the proportion of mothers who rated their general reaction toward the NFC sticker as "very good" in the control group. Likeability and cultural fit are central to the Khushi Baby approach; when considering acceptance of the NFC necklace in this region, this data is promising. This suggests that mothers may embrace and utilize the Khushi Baby system as a new method of vaccination data collection and storage for their children. In addition, there is evidence to suggest that the NFC necklace is already being used as a talking point for mothers, as mothers have shown and talked to approximately 3 other people about the necklace on average, in both P and P+V, compared to an average of only 1 other person in the control group. However, as no statistically significant differences were found between P and P+V, there is not enough evidence to suggest that the voice call reminders enhance the effect of the pendant as a talking point for mothers.

With regard to visibility, there is evidence to suggest that key community members (namely, grandmothers and fathers of children enrolled in the study) are significantly more likely to have seen the data collection tool if the child was enrolled in P. Grandmothers were also more likely to have seen the data collection tool if the child was enrolled in a P+V camp. This suggests that the NFC necklace has the potential to be a visible symbol, although data limitations weaken the validity of this result, as will be discussed further as a study limitation. In the future, with more robust data, this may be applicable in the context of the necklace acting as an immunization camp recruitment tool. As there is no strong evidence for any independent effects of the voice call reminders on drawing attention to the KB system, more research is needed to determine

whether the voice calls are useful in increasing awareness among mothers and other key family members (as, for example, fathers are sometimes the ones who pick up the phone calls or own the household mobile phone). As mentioned previously, any positive impacts of the reminder calls may also be masked, as call deployment was inconsistent. This will be discussed further as a study limitation as well.

There are a myriad of mHealth solutions in existence that, from a data collection standpoint, serve the same function as the Khushi Baby system. Any mobile application can be used to simply collect and store data with the help of a data collection chip. The factor that distinguishes the Khushi Baby system from these solutions is that the data is actionable; it can be used to inform targeting strategies for future interventions, with the intention of bringing more mothers to immunization camps.

Conclusion & Discussion

Summary of Findings

As hypothesized, being randomly assigned to a study arm that included the NFC necklace (P or P+V) was associated with a greater level of satisfaction with the data collection tool, compared to those assigned to the control group. Mothers randomized to P and P+V showed and discussed the data collection tool with more people than those randomized to the control group; however, there is not enough evidence to conclude any significant difference in the number of people the data collection tool was shown to/discussed with, between P and P+V. This suggests that the voice reminders may not be functioning as anticipated, and therefore are not bringing additional attention to the KB system or increasing discussion around the necklace in a meaningful way. Logistic regression demonstrated that being assigned to P was predictive of fathers of the household having seen the data collection tool, and that being assigned to P or P+V

was predictive of grandmothers of the household having seen the data collection tool. These findings remained true, even after controlling for random clustering effects at the block level.

Limitations

There were several limitations to this study. Firstly, as this is an intermediate assessment, much of the data is incomplete and there is potential for the outcomes to change further over the study period. In addition, not all of the baseline descriptive characteristics of the sample population (subset of participants from the greater study population who completed the DTP1-3 series) were balanced between the 3 study arms; specifically, the number of institutional births and type of electricity were determined to be unequal between the 3 groups ($p < 0.05$; see Table 1). Nevertheless, this subset of participants proved to be more balanced in baseline characteristics than the greater study population (which includes those who did not finish the DTP series and did not participate in the exit survey by the midline assessment). Including the baseline characteristics for this subset is more appropriate for this study anyhow, since only mothers who completed the survey at exit were included in the analyses. Because mothers in the P+V arm had to be able to receive voice call reminders, a greater proportion of these mothers may have also had access to electricity, leading to the observed imbalance in the electricity type variable. Another potential reason for this imbalance could be that mothers in P+V had some difference in an SES-related variable that was not accounted for in the randomization, compared to the other 2 arms.

Secondly, the p -values obtained from post-hoc comparisons for the user satisfaction outcome were compared to an alpha level of 0.05; however, this does not account for the problem of multiple comparisons or otherwise account for the false discovery rate (Bland and Altman, 1995). Adjustments such as the Bonferroni correction yield highly conservative alpha

levels that can mask significance and can also increase the likelihood of type II errors, which may treat important differences as non-significant (Perneger, 1998). There are also inherent limitations to using the logistic regression analysis, as the regression model will only include mothers who have a recorded response for every variable included in the model; thus, the sample size included in the regression analysis is decreased. Because over 50 observations were deleted due to missing values in both logistic regression models, the sample size is small, resulting odds ratios are large, and the confidence intervals are quite wide. While the model suggests that there is a positive effect of being in a necklace study arm on visibility, this is still inconclusive given the limitations in the data.

As is common in the Indian family system, the grandmothers of children enrolled in the cRCT typically resided in the same household as the mother and child (Chadda and Deb, 2013); however, no data was formally collected on any deviations from this pattern. In addition, the response to the question of whether the grandmother has seen the data collection tool was marked “no” if the grandmother was deceased. Significantly more grandmothers reportedly had seen the necklace compared to the sticker, despite this inflated number of “no” responses; however, this is still an inaccuracy in the data that must be addressed in future studies. Self-report bias is also a limitation to be considered, as mothers may have lied, exaggerated, or withheld information in the survey due to embarrassment or social desirability. Future research may address this using multiple self-report questions on the same topic, to ensure convergent validity (Westen and Rosenthal, 2003). The covariates included in the logistic regression models may be missing important factors and also may be expanded in the future, to include social network indicators (e.g. what is the mother’s network centrality? Does network centrality impact discussion level, or visibility of the necklace to key family members?).

Finally, inconsistent delivery of the voice call reminders is a large limitation that may have masked any significant impacts of the reminder calls on discussion level, satisfaction or visibility/awareness of the KB intervention. As mentioned in the study results, only 44.7% of the mothers assigned to the P+V arm expressed that they received a voice call reminder at the first follow-up camp, and only 56.4% of the mothers assigned to the P+V arm said they received a call at the second follow-up camp (at exit). No significant impacts of the voice calls were found on discussion level or on user satisfaction between P and P+V, even after stratifying the data to include only those who had reported receiving a call at the first or second follow-up camp. It is also important to note that this stratification limits sample size, impacting the ability to achieve sufficient power and determine statistical significance. As there is promising evidence showing that voice call reminders can positively influence health-seeking behaviors and provide engaging, trusted health information in low and middle income countries (Mobile Alliance for Maternal Action (MAMA)), there is reason to believe that the same positive impacts can be achieved through the KB voice call system. Much improvement is needed to increase the reliability of the KB voice call reminder system; only then will it be possible to measure any significant impacts of the voice reminders.

Implications for Future Research

The preliminary evidence from this study indicates that the NFC necklace is likeable and promotes discussion, which has implications for its future use as an immunization camp recruitment tool. However, it is still unclear as to what extent the KB system has affected health outcomes by increasing on-time vaccination rates, and what role the wearable NFC symbol has played in this. In addition, a larger sample size and more reliable voice call deployment system are needed to assess the true impact of the voice call reminders in future studies.

More nuanced information is needed in order to gauge the true impact of the KB system; for example, future studies should explore what exactly mothers are saying to other community members with whom they discuss the data collection tool, and what the nature of these community members' responses is. More information can be collected on grandmothers and fathers who have seen the data collection tool, including their perceptions of the necklace or sticker, and the frequency at which they have seen either the necklace or sticker for each child. As mentioned previously, child's gender was found to be an effect modifier of the relationship between study group and visibility of the data collection tool to fathers. Future research might explore this relationship further to see if it remains consistent, and to explore potential explanations (e.g. perhaps fathers tend to spend more time with male children and therefore are more likely to see the necklace if the child is male as opposed to female).

The significant levels of discussion and likeability of the necklace exhibited in this study, relative to the control group, warrant further research to assess what kinds of targeting strategies would be most effective in influencing health-seeking behaviors using the necklace. Mothers who discussed the necklace with the greatest number of people, for example, can be employed as "recruitment champions" to bring other mothers to camp. This could increase discussion about the necklace and increase the number of high positivity ratings of the necklace above the 30% range. This question will be examined further in an expansion of the RCT of which the study reported here is a component. This second RCT will test new targeting strategies and extend the reach of the KB system to include both antenatal care for pregnant mothers and vaccination tracking for their newborn children. With more robust evidence that the KB system is at once well liked, visible, and can increase on-time vaccination adherence and health camp attendance,

the system can be integrated at the local government level to improve maternal and child health on a much larger scale.

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Tables & Figures

Figure 1: Visual overview of Khushi Baby system (Khushi Baby, Inc.)

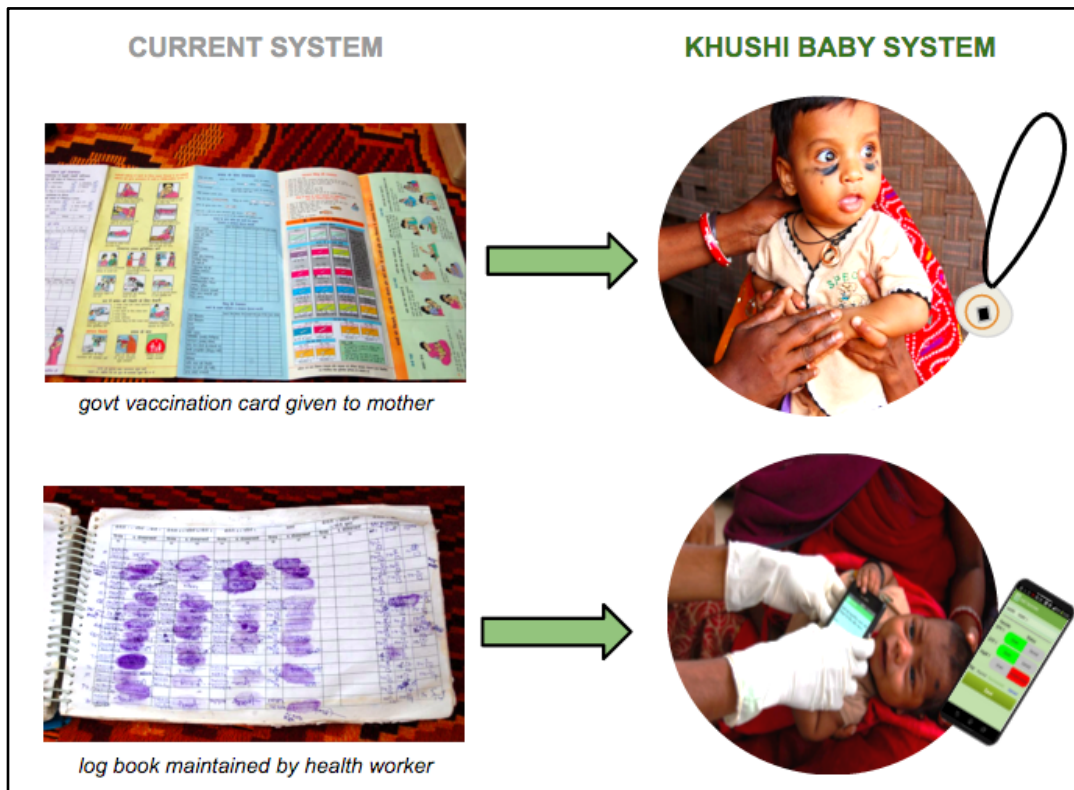


Figure 2: Randomization of immunization camps into three study arms

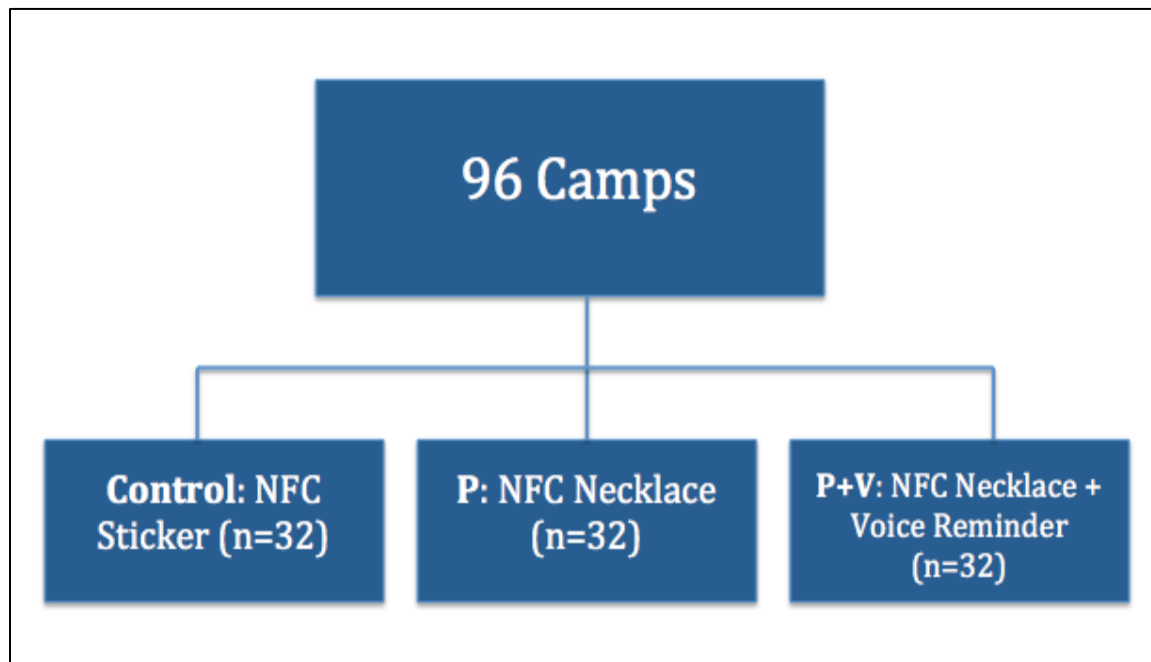
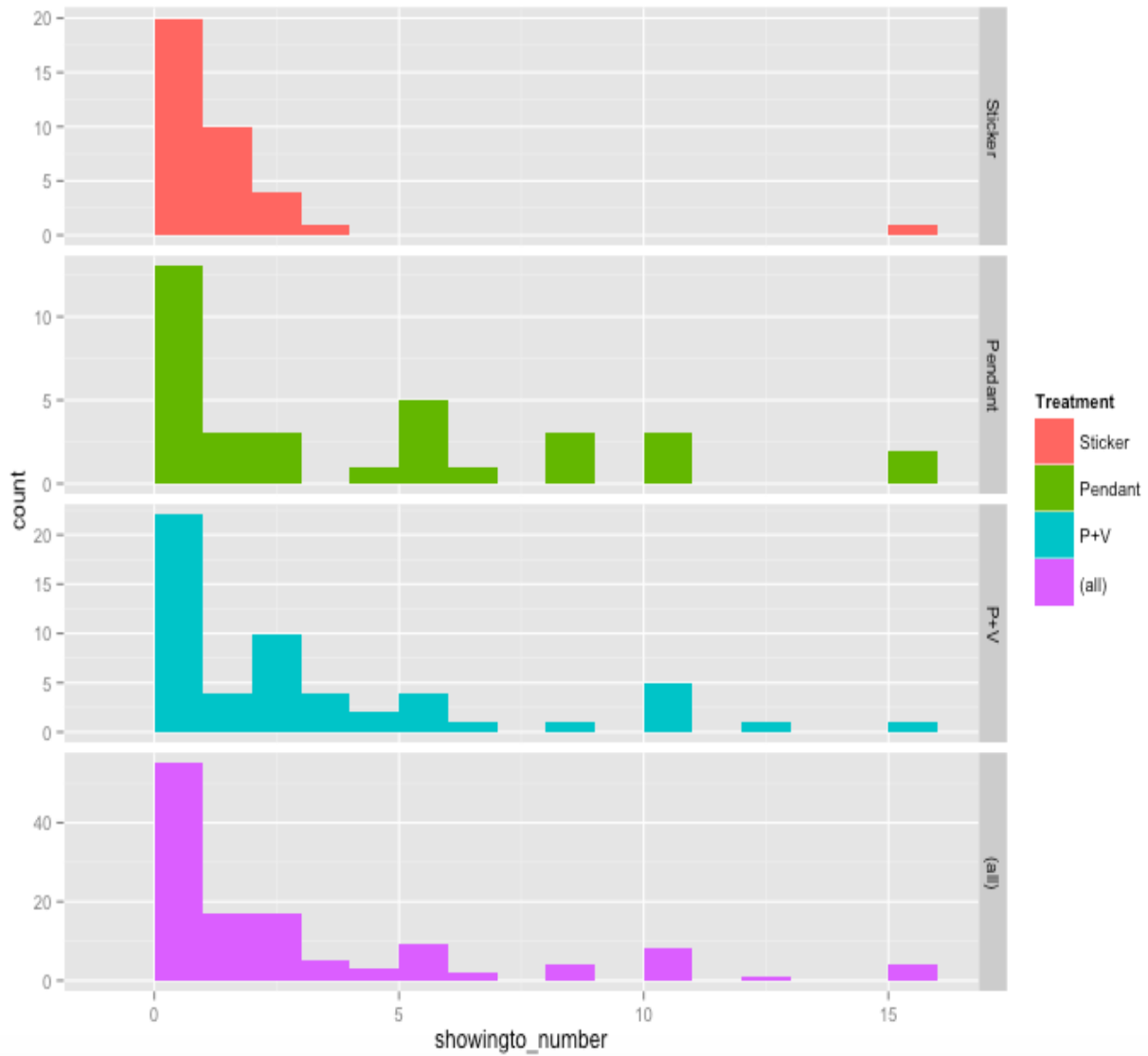
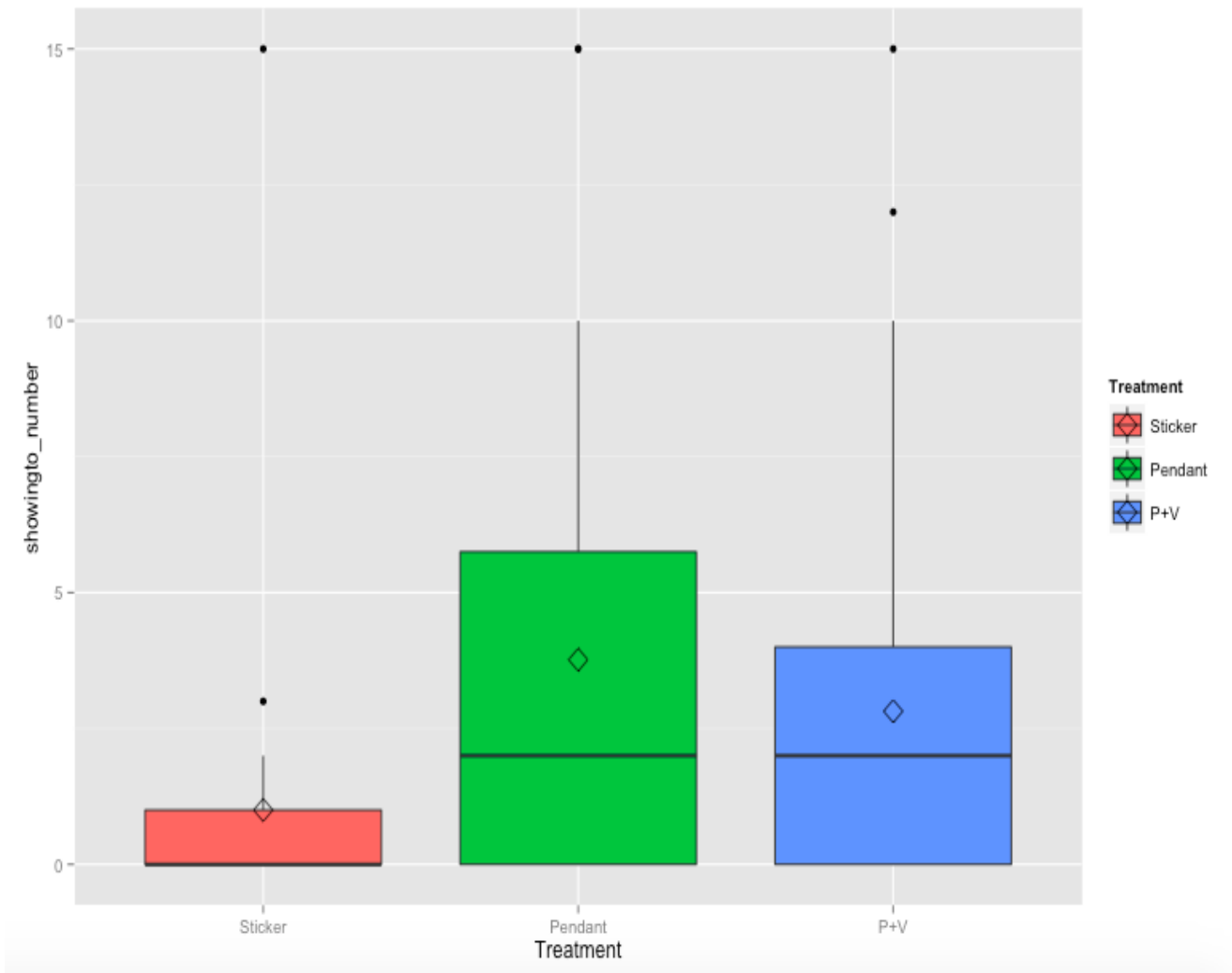


Figure 3: Distribution* of number of persons the data collection tool was shown to/discussed with, by study arm



*Distribution of responses was non-normal (right-skewed). Distribution is similar across each of the study arms. This justified the use of a non-parametric test (Kruskal-Wallis) to analyze the number of people that the data collection tool was shown to/discussed with.

Figure 4: Boxplot of number of persons data collection tool was shown to, by study arm



Averages indicated by diamond icon. Mothers in P+V showed the necklace to an average of 2.82 other people. Mothers in P showed the necklace to 3.77 other people on average. This is in comparison to the sticker arm (control), in which mothers only showed the sticker to an average of 1 other person.

Figure 5: Mothers' reactions to data collection tool, by study arm

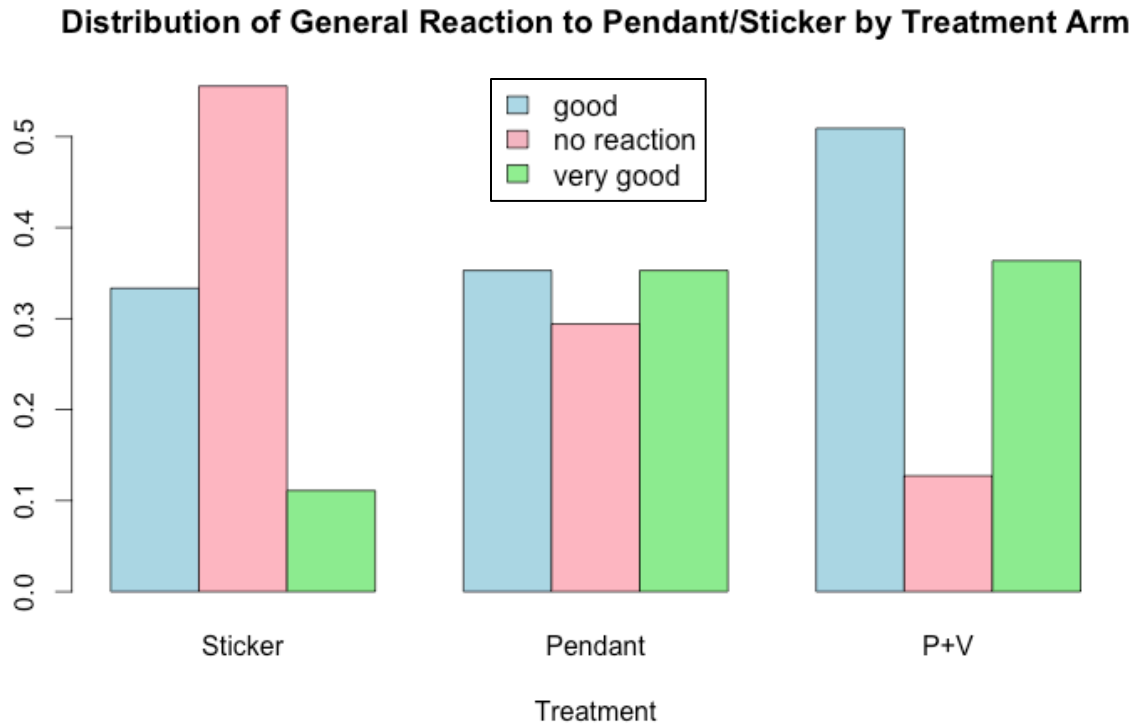


Figure 6: Proportion of grandmothers (*Dadis*) who have seen data collection tool, by study arm

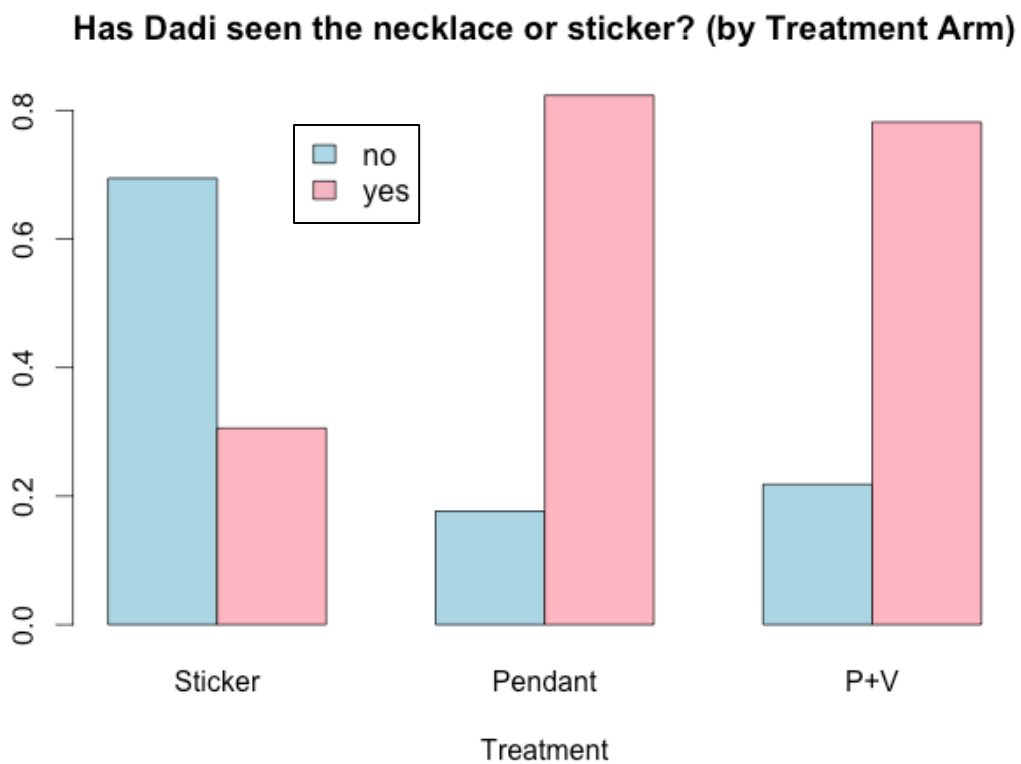


Figure 7: Proportion of fathers who have seen the data collection tool, by study arm

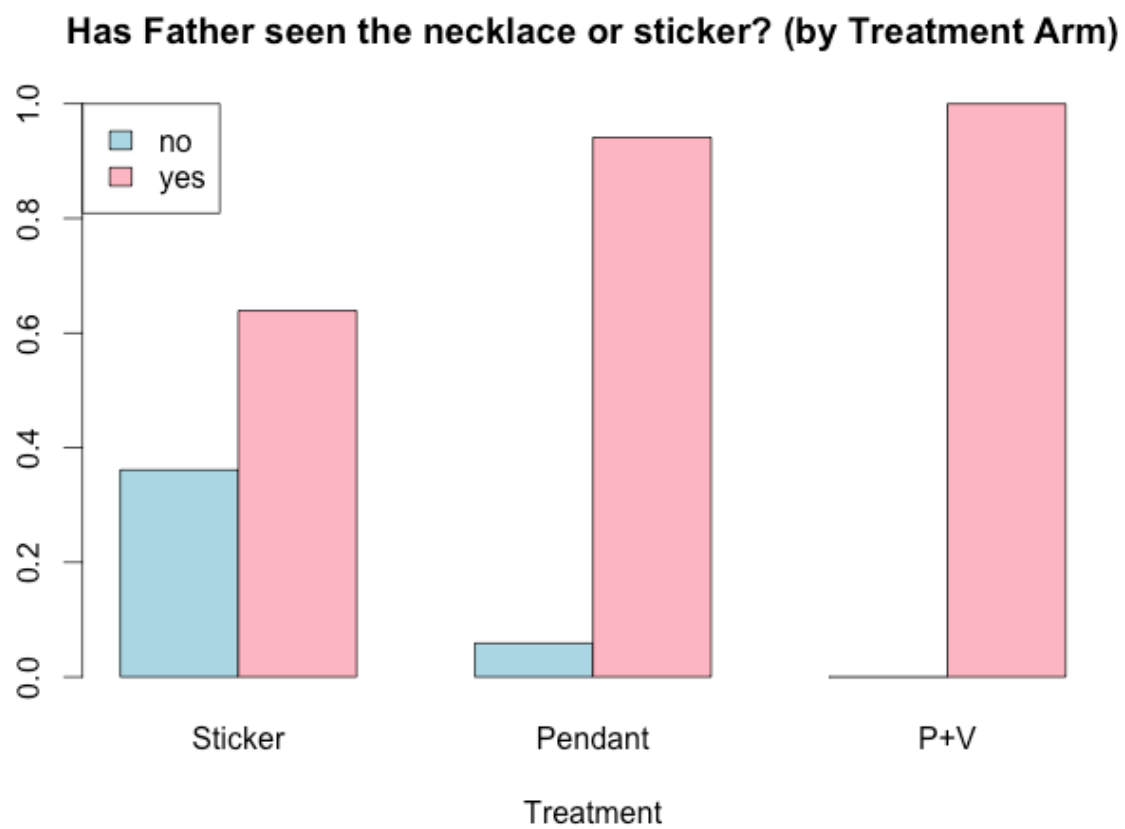


Table 1: Baseline characteristics of participants who completed the DTP1-3 series (n=128)

	Sticker	Pendant	P+V	p-value
N	39	36	53	
Gender of child = m (%)	25 (64.1)	24 (66.7)	26 (49.1)	0.179
Caregiver's marital status = Married (%)	39 (100.0)	35 (97.2)	48 (90.6)	0.087
Caregiver's marital age (mean (sd))	19.05 (1.09)	18.69 (1.04)	19.29 (1.61)	0.12
Caregiver's education level (mean (sd))	2.36 (3.53)	2.56 (3.43)	2.23 (3.47)	0.908
Number of child deaths (mean (sd))	0.38 (0.71)	0.31 (0.58)	0.26 (0.84)	0.737
Number of children (mean (sd))	2.49 (1.14)	2.75 (1.38)	2.32 (1.21)	0.28
Number of institutional births (mean (sd))	1.64 (1.18)	1.31 (0.86)	1.06 (1.01)	0.029
Do you have a MAMTA card (%)				0.106
No, never received	2 (5.1)	3 (8.3)	9 (17.0)	
No, lost the card	1 (2.6)	2 (5.6)	2 (3.8)	
Yes	30 (76.9)	22 (61.1)	24 (45.3)	
Yes, but at home	6 (15.4)	9 (25.0)	18 (34.0)	
Baseline number of people that caregiver talked to about the camp (mean (sd))	1.72 (2.52)	1.78 (1.97)	1.55 (1.58)	0.852
Minutes it takes for caregiver to get to camp (mean (sd))	30.95 (20.82)	42.42 (35.16)	32.36 (29.03)	0.17
Caregiver's baseline camp satisfaction (%)				0.095
Not satisfied	0 (0.0)	2 (5.6)	0 (0.0)	
Satisfied	24 (61.5)	24 (66.7)	28 (52.8)	
Very satisfied	15 (38.5)	10 (27.8)	25 (47.2)	
Bathroom type (%)				0.203
Covered	0 (0.0)	0 (0.0)	2 (3.8)	
Open	39 (100.0)	34 (94.4)	47 (88.7)	
Ventilated	0 (0.0)	2 (5.6)	4 (7.5)	
Electricity type (%)				0.009
No/neither	12 (30.8)	20 (55.6)	16 (30.2)	
Yes, line	25 (64.1)	10 (27.8)	33 (62.3)	
Yes, solar	2 (5.1)	6 (16.7)	4 (7.5)	
Mobile phone ownership/access (%)				0.296
No/neither	8 (20.5)	6 (16.7)	4 (7.5)	
Yes,access	27 (69.2)	26 (72.2)	46 (86.8)	
Yes,own	4 (10.3)	4 (11.1)	3 (5.7)	

Unbalanced characteristics (significant difference in number of institutional births across study arms and in type of electricity across study arms) indicated by yellow highlighted *p*-values

Table 2: Assumptions* for determining appropriate enrollment duration in Khushi Baby cRCT

Number of Fixed Camps	96
Number of Camps Per Cluster	32
Power	0.80
Alpha	0.05
Attrition	0.10
Intraclass Correlation Coefficient (ICC)	0.15
Coefficient of Variation for Cluster Size	0.89
Number of Infants Enrolled Per Camp Each Month	1
DTP3 Rate in Control Arm Infants	70% (conservative)

*These assumptions were made with the intention of seeing a 20% (clinically significant) absolute difference in DTP3 immunization coverage between control and intervention arms in the Khushi Baby cRCT. Based on the calculations, enrollment was to last for 3 months minimum, with at least 3 DTP-naïve children enrolled per camp in total. To account for camp cancellations, enrollment was extended to 4 months.

Table 3: Full list of survey questions asked of mothers at vaccination camps during KB cRCT

Question (English)	Answer 1 English	Answer 2 English	Answer 3 English	Answer 4 English	Answer 5 English	Answer 6 English	Answer 7 English	Answer 8 English	Answer 9 English	Answer 10 English
Do you have your MAMITA card?	Yes	Yes but at home	No lost	No never received						
How many children do you have? [NUMERIC]										
How many of your children have died? [NUMERIC]										
How many children have had hospital births? [NUMERIC]										
At what age were you married? [NUMERIC]										
With which caste do you associate? [FREE TEXT]										
Till what grade in school have you studied? [NUMERIC]										
What line of work do you do?	wage earner	self employed	housewife	farmer	other					
What line of work does your spouse do?	wage earner	migrant worker	self employed	farmer	govt job					
Do you own or have access to a mobile phone?	yes, own	yes, access	neither							
What type of electricity source do you have?	yes, solar	yes, line	none	pipe water						
From where do you retrieve water?	handpump	well	bore well	waterfall						
Where do you go to the bathroom?	open	covered	ventilated							
What fuel do you use for cooking?	wood	dung	grass or crop	charcoal	coal					LPG
What material is used for your roof?	grass thatch clay	plastic/polythene	tiles	burnt brick	stone slate					cement
How many shots does your child need in first year of life? [NUMERIC]										
Who provides you vaccine service?	SM camp	govt hospital	ANM clinic	Private clinic						
Why does your child need vaccines?	prevents disease	prevents specific disease	improves health	because others do it	Don't know					
Who reminded you of the camp? [LIST PERSON - social relationship question]										
Who did you come with to the camp? [LIST PERSON - social relationship question]										
How many mothers did you speak to about the camp? [LIST PERSON - social relationship question]										
Who, if anyone, told you not to come to the camp? [LIST PERSON - social relationship question]										
How long (in minutes) does it take to reach the camp? [NUMERIC]										
How satisfied are you with the camp?	not satisfied	satisfied	very satisfied							
Who did you come with to the camp? [LIST PERSON - social relationship question]										
In addition to the <i>dai ma</i> , who else publicizes the camp? [LIST PERSON - social relationship question]										
Did you receive a phone call reminder?	Yes	No								
How many times did you receive a phone call reminder? [NUMERIC]										
Who did you tell about the phone call reminders? [LIST PERSON - social relationship question]										
Do you know any mothers not attending camps regularly? If so, who? [LIST PERSON - social relationship question]										
Did you show your necklace to anyone? If so, who? [LIST PERSON - social relationship question]										
Did you experience any problems with the necklace?	yes	no	Not relevant for sticker							
Why have you missed a camp?	camp is too far	cant go alone	due to poor health	had work at home	forgot about camp					Da ma (TBA) did not inform
Have you had any issues after the camp?										camp is hard to reach
What treatment arm is this camp? [FILLED BY SURVEYOR]	Sticker (control)	Pendant (P)	P+V							
Have you shown your sticker/pendant to anyone? If so, who? [LIST PERSON - social relationship question]										
How many people did you show or discuss the sticker/necklace with? [NUMERIC]										
What is your general reaction to the necklace/sticker?	Very good	Good	Bad	Very Bad	No reaction					
Has the father of the family seen the necklace?	yes	no (or relative deceased)								
Is the father aware of the voice call reminders?	yes	no								
How has the father's attitude towards vaccines changed?	Negative	no reaction	positive							
Has the grandmother of the family seen the necklace?	yes	no (or relative deceased)								
How has the grandmother's attitude toward vaccines changed?	Negative	no reaction	positive	grandmother is no more						
What factors were important in influencing camp turn up?	TBA	Phone call	Pendant	GMM	Other mothers					Husband
Do you have the ability to recruit nonattenders?	Yes	No	Don't know							Mother in Law
Do you have friends who have the ability to recruit nonattenders? If so, who? [LIST PERSON - social relationship question]										
How do you expect nonattenders to react to the necklace?	Negative	no reaction	positive							
What is the best way to convince non-attenders mother to attend?	Need for good health	Lentils as incentive	Pendant	better care for children	Follow up call reminders					
At what age should your child get vaccinated with measles?	9 months	12 months	15 months	Don't know						

Questions highlighted in green were those used in the main analyses of this study.

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