Randomized Cluster Trial

Conducted By: ARMMAN

Supported By: UKAID (DFID)
Aims of the study: To determine is

i) improved access to preventive information during pregnancy and first year of a child’s life through a mobile phone voice call (mMitra) as well as animation film service and

ii) improved access to after work-hours home based diagnostic investigation and referral service during the antenatal period and infancy through trained ArogyaSakhis (community health workers)

leads to improved health outcomes among rural underprivileged pregnant women and infants.

Methodology

3 arm randomized cluster trial

Group A: Control group: 84 villages

Group B: Improved access to preventive information: mMitra group (voice messages and animations): 83 villages

Group C: Improved access to both preventive information (through mMitra) and after work hours home based investigation and care (through the Arogya Sakhis): mMitra and Arogya Sakhi intervention group: 83 villages

mMitra and Arogya Sakhi

DFID Study Location

250 Villages in 3 Districts: Solapur, Osmanabad and Washim Of Rural Maharashtra

250 Villages in 3 Districts: Solapur, Osmanabad and Washim Of Rural Maharashtra
Purposive Sampling to handpick the following:
Solapur (100 villages), Osmanabad (100 villages), Washim (50 villages)

Select villages where implementing partner had undertaken several community health, food security, women's empowerment projects in the past and villages folk trusted the organization.

Baseline Survey 2013
Conducted with 500 pregnant women (2 from each village)

Randomization of 250 villages in 3 arms:
A bio-statistician unrelated to project applied computer software to randomize 250 villages

Group A
(Control Group)
84 villages
Total enrolled - 558

Group B
Antenatal and infancy mMitra Voice and Animation
83 villages
Total enrolled - 593

Group C
Antenatal and infancy mMitra Voice and Animation and home based care
83 villages
Total enrolled - 630

Midline Survey 2014: Post-pregnancy

Group A
(Control Group)
209

Group B
ANTENATAL mMitra Voice and Animation
202

Group C
Antenatal and infancy mMitra and home based care
213

Endline Survey 2015: Post pregnancy and infancy

Group A
(Control Group)
410

Group B
Antenatal and infancy mMitra
475

Group C
Antenatal and infancy mMitra and home based care
474
Study Population Groups

**Midline Study: Pregnancy**

- Women who ONLY heard pregnancy messages/animation
  - Group A: Control
  - Group B: Messages+ Animations
  - Group C: Message + Animation+ Home-based Care

**Endline Study: Pregnancy & Infancy**

- Women who heard pregnancy & infancy messages/animation
  - Group A: Control
  - Group B: Messages+ Animations
  - Group C: Message + Animation+ Home-based Care
FLOW CHART 1: ENROLMENT AND DROP OUT INFORMATION OF RCT PARTICIPANTS IN SOLAPUR, OSMANANBAD, WASHIM

**GROUP A**
- Total number of women enrolled = 558
- Total number of drop out = 148

<table>
<thead>
<tr>
<th>Abortion</th>
<th>Still birth</th>
<th>Neo natal death</th>
<th>Child death</th>
<th>Mother accidental death</th>
<th>Out migration</th>
</tr>
</thead>
<tbody>
<tr>
<td>53</td>
<td>13</td>
<td>5</td>
<td>6</td>
<td>0</td>
<td>71</td>
</tr>
</tbody>
</table>

**GROUP B**

<table>
<thead>
<tr>
<th>Abortion</th>
<th>Still birth</th>
<th>Neo natal Death</th>
<th>Child Death</th>
<th>Mother accidental death</th>
<th>Out migration</th>
</tr>
</thead>
<tbody>
<tr>
<td>44</td>
<td>18</td>
<td>12</td>
<td>2</td>
<td>1</td>
<td>41</td>
</tr>
</tbody>
</table>

**GROUP C**
- Total number of women enrolled = 630
- Total number of drop out = 156

<table>
<thead>
<tr>
<th>Abortion</th>
<th>Still birth</th>
<th>Neo natal Death</th>
<th>Child Death</th>
<th>Mother accidental death</th>
<th>Out migration</th>
</tr>
</thead>
<tbody>
<tr>
<td>48</td>
<td>17</td>
<td>12</td>
<td>7</td>
<td>1</td>
<td>71</td>
</tr>
</tbody>
</table>

**Total Grp A women remaining after drop out = 410**
**Total Grp B women remaining after drop out = 475**
**Total Grp C women remaining after drop out = 474**
Study Population Groups

Women who ONLY got pregnancy messages/animation

Group A: Control

Group B: Messages+ Animations

Group C: Messages + Animations+ Home-based Care during pregnancy

Midline Study: Post-Pregnancy
### Socioeconomic Data

#### Midline Study: Post-Pregnancy

<table>
<thead>
<tr>
<th>Family Income in Rs*</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>22</td>
<td>6</td>
<td>9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age*</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td>22</td>
<td>22</td>
<td>22</td>
<td>22</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Household Size*</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>6</td>
<td>6</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Education (Years Completed)*</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>7</td>
<td>9</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Family Income in Rs*</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td>5000</td>
<td>4000</td>
<td>5000</td>
<td></td>
</tr>
</tbody>
</table>

*Median; ^p value: Kruskal Wallis Test

Group A: n=199, Group B: n = 202, Group C: n = 207
Socioeconomic Data
Midline Study: Post-Pregnancy

Mobile Ownership - Beneficiary %
- Group A: 8%
- Group B: 7.9%
- Group C: 13%

Mobile Ownership - Husband %
- Group A: 71.9%
- Group B: 55.9%
- Group C: 64.7%

Mobile Ownership - Other Family Members %
- Group A: 5%
- Group B: 5%
- Group C: 7.2%

Mobile Ownership - None %
- Group A: 15.1%
- Group B: 31.2%
- Group C: 14.9%

*p value for A, B, C: Chi Square Test

Group A: n=199, Group B: n = 202, Group C: n = 207
**Process Indicators**

**Midline Study: Post-Pregnancy**

**Gestational age in weeks at the time of enrolment**
- Group B: 15.64
- Group C: 13.86

*Median; \(^p\) value: Mann Whitney U Test

**Number of voice calls heard during pregnancy**
- Group B: 40
- Group C: 40

**Number of home visits made by Arogya Sakhi**
- Group B: 4

*Median; \(^p\) value: Mann Whitney U Test

Group B: n = 202, Group C: n = 207
Process Indicators
Midline Study: Post-Pregnancy

- **Proportion of women listening to the voice calls over family phone %**
  - Group B: 80.7% (n = 202)
  - Group C: 89.9% (n = 207)
  - p value: 0.008

- **Proportion of women accessing voice calls through Arogya Sakhi’s phone %**
  - Group B: 81.2% (n = 202)
  - Group C: 79.7% (n = 207)
  - p value: 0.706

- **Proportion of women who have been shown at least three animations during pregnancy %**
  - Group B: 93.1% (n = 202)
  - Group C: 94.7% (n = 207)
  - p value: 0.122

*p value for A, B, C: Chi Square Test*
Knowledge Recall
Midline Study: Post-Pregnancy

Proportion of women who knew the importance of taking 100 days of IFA tablets %
- Group A: 69.8
- Group B: 95.5
- Group C: 98.6

Proportion of women who knew at least three family planning methods other than male/female sterilization %
- Group A: 18.09
- Group B: 65.8
- Group C: 58.9

Proportion of women who knew that consistent use of condoms reduced the risk of HIV infection %
- Group A: 37.6
- Group B: 55.2
- Group C: 74.9

^p value for A, B, C: Chi Square Test; * p value for B & C: Chi Square Test

Group A: n=199, Group B: n = 202, Group C: n = 207
Behavior Change and Health Outcome
Midline Study: Post-Pregnancy

**Proportion of women who took IFA tablets during pregnancy %**

- Group A: 84.4%
- Group B: 95.5%
- Group C: 97.1%

**Proportion of women who took IFA tablets during pregnancy for 50-90 days %**

- Group A: 18.6%
- Group B: 23.4%
- Group C: 10.6%

**Proportion of women who took IFA tablets during pregnancy for 90 or more days %**

- Group A: 45.2%
- Group B: 70.1%
- Group C: 83.6%

*p value for A, B, C: Chi Square Test; *p value for B & C: Chi Square Test

Group A: n=199, Group B: n = 202, Group C: n = 207
Health Outcome

Midline Study: Post-Pregnancy

Proportion of women who delivered at a health facility %

Proportion of women who were referred for high blood pressure, who went for Rx %

^p value for A, B, C: Chi Square Test; * p value for B & C: Chi Square Test

Group A: n=199, Group B: n = 202, Group C: n = 207

^0.392
*0.999

^0.03
*0.286
Behavior Change and Health Outcome
Midline Study: Post-Pregnancy

Number of times weight was measured during pregnancy:
- Group A: 4
- Group B: 4
- Group C: 7

Number of times blood pressure was measured during pregnancy:
- Group A: 3
- Group B: 4
- Group C: 7

~Median; ^p value for A, B, C: Kruskal Wallis Test; * p value for B & C: Mann Whitney U test
User Satisfaction

Midline Study: Post-Pregnancy

Proportion of women satisfied with the voice calls %

- Group B: 95.5
- Group C: 97.1

Proportion of women who were satisfied with the animations %

- Group B: 94.6
- Group C: 96.1

Proportion of women satisfied with the home visits %

- Group B: 99
- Group C: 99

^p value for A, B, C: Chi Square Test

Group B: n = 202, Group C: n = 207
Study Population Groups

Endline Study: Post Pregnancy & Infancy

Women who got pregnancy and infancy messages/animations

Group A: Control

Group B: Messages+ Animations

Group C: Messages + Animations+ Home-based Care during pregnancy and infancy
Socioeconomic Data
Endline Study: Post-Pregnancy + Infancy

Age*
- Group A: 23
- Group B: 23
- Group C: 23

Household Size*
- Group A: 6
- Group B: 6
- Group C: 6

Education (Years Completed)*
- Group A: 9
- Group B: 10
- Group C: 10

Family Income in Rs*
- Group A: 5000
- Group B: 6000
- Group C: 6000

*Median  ^p value: Kruskal Wallis Test
Group A: n= 409, Group B: n = 475, Group C: n = 474
### Phone Use

**Endline Study: Post-Pregnancy + Infancy**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Group B</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of infancy care messages heard*</td>
<td>45</td>
<td>50</td>
</tr>
<tr>
<td>Number of infancy care messages heard through their own or family phone*</td>
<td>20</td>
<td>25</td>
</tr>
<tr>
<td>Number of infancy care messages heard through the AS phone*</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Number of home visits made by the Arogya Sakhi during infancy*</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Proportion of women who have heard 60% of the infancy voice calls</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of women who have been shown at least three animations during infancy %</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Median; ^p value: Mann-Whitney U Test

Group B: n = 475; Group C: n = 474
### Knowledge Recall: Breastfeeding

#### Endline Study: Post-Pregnancy + Infancy

<table>
<thead>
<tr>
<th>Category</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion of women who knew the need for exclusive breastfeeding for first six months %</td>
<td>72.9</td>
<td>93.1</td>
<td>94.3</td>
<td>^0.001</td>
</tr>
<tr>
<td>Proportion of women who knew the meaning of exclusive breastfeeding %</td>
<td>57.5</td>
<td>97.1</td>
<td>97.5</td>
<td>*0.001</td>
</tr>
<tr>
<td>Proportion of women who knew that prelacteal feeds can cause harm to infant %</td>
<td>72.1</td>
<td>98.1</td>
<td>97.9</td>
<td>^0.001</td>
</tr>
<tr>
<td>Proportion of women who knew the importance of early initiation of breastfeeding %</td>
<td>44.5</td>
<td>77.7</td>
<td>85.4</td>
<td>^0.001</td>
</tr>
<tr>
<td>Proportion of women who knew the importance of breastfeeding 8-12 times/day %</td>
<td>28.9</td>
<td>66.9</td>
<td>78.5</td>
<td>^0.001</td>
</tr>
</tbody>
</table>

^p value for A, B, C: Chi Square Test; * p value for B & C: Chi Square Test

Group A: n = 409; Group B: n = 475; Group C: n = 474
Knowledge Recall: Growth monitoring and Diarrhea

Endline Study: Post-Pregnancy + Infancy

- Proportion of women who knew the need for growth monitoring every month %
  - Group A: 45.2%
  - Group B: 73.7%
  - Group C: 71.9%

- Proportion of women who knew that weight loss in an infant is a danger sign %
  - Group A: 94.1%
  - Group B: 98.7%
  - Group C: 99.8%

- Proportion of women who knew the importance of giving ORS solution for diarrhoea management %
  - Group A: 84.3%
  - Group B: 99.6%
  - Group C: 100%

- Proportion of women who knew that delay in diarrhea treatment can lead to infant mortality %
  - Group A: 87.3%
  - Group B: 99.6%
  - Group C: 100%

^p value for A, B, C: Chi Square Test; * p value for B & C: Chi Square Test

Group A: n = 409; Group B: n = 475; Group C: n = 474
Proportion of infants under 6 months who were exclusively breastfed %

- Group A: 59.4%
- Group B: 85.7%
- Group C: 92.8%

Proportion of women who gave colostrum to the baby %

- Group A: 96%
- Group B: 98.1%
- Group C: 97.9%

Proportion of women who practiced early initiation of breastfeeding %

- Group A: 64.05%
- Group B: 85%
- Group C: 85.4%

Proportion of mothers who weaned the baby at 6-7 months of age %

- Group A: 75%
- Group B: 85.7%
- Group C: 88.6%

Proportion of mothers who did not give prelacteal feeds %

- Group A: 74.6%
- Group B: 86.7%
- Group C: 92.2%

^p value for A, B, C: Chi Square Test; * p value for B & C: Chi Square Test

Group A: n = 409; Group B: n = 475; Group C: n = 474
Behavior change and Health outcomes

Endline Study: Post-Pregnancy + Infancy

Proportion of women who made 4 or more ANC visits %

Proportion of infants (< 1 yr of age) who have had their weight checked more than three times in infancy %

Proportion of infants (< 1 yr of age) who have tripled their birth weight at the end of infancy (one year of age) %

Proportion of infants (< 1 year of age) who have had an episode of diarrhoea in the last six months who received Oral Rehydration Salts (ORS) %

^p value for A, B, C: Chi Square Test; * p value for B & C: Chi Square Test

Group A: n = 409; Group B: n = 475; Group C: n = 474
Health outcomes

Endline Study: Post-Pregnancy + Infancy

Proportion of infants given BCG %

Proportion of infants given measles, DTP, HEP B, OPV %

Proportion of women who took 2 TT injections %

^p value for A, B, C: Chi Square Test; * p value for B & C: Chi Square Test

Group A: n = 409; Group B: n = 475; Group C: n = 474
mMitra and Arogya Sakhi Home Based Care: User Satisfaction
Endline Study: Post-Pregnancy + Infancy

Proportion of women who were fully satisfied with the home based care %
- Group B: 99.4
- Group C: 98.9

Proportion of women who were satisfied with the voice calls during infancy %
- Group B: 97.5
- Group C: 97.9

Proportion of women who were satisfied with the animations %
- Group B: 98.9
- Group C: 98.3

\( p \text{ value for B & C: Chi Square Test} \)

Group B: n = 475; Group C: n = 474
Group B: Comparison between Baseline, Midline and Endline Study

- **Proportion of women who knew at least three family planning methods other than male/female sterilization %**
  - Baseline: 39.8
  - Midline: 65.8
  - Endline: 63.4
  - \(^{^p} < 0.00001\)
  - \(* 0.539\)

- **Proportion of women who knew that consistent use of condoms reduced the risk of HIV infection %**
  - Baseline: 8.6
  - Midline: 55.2
  - Endline: 59.4
  - \(^{^p} < 0.00001\)
  - \(* < 0.00001\)

- **Proportion of women who took IFA tablets for 90 or more days %**
  - Baseline: 63.6
  - Midline: 72
  - \(^{^p} < 0.00001\)

\(^{^p} p\) value for baseline, midline and endline: Chi Square Test  \(* p\) value for midline and endline  \(^{#} p\) value for baseline and midline

Baseline: n = 500; Midline n = 202; Endline: n = 475
Group C: Comparison between Baseline, Midline and Endline Study

- Proportion of women who knew at least three family planning methods other than male/female sterilization %
  - Baseline: 39.8%
  - Midline: 58.9%
  - Endline: 65.4%
  - ^ p value for baseline, midline and endline: Chi Square Test
  - * 0.107

- Proportion of women who knew that consistent use of condoms reduced the risk of HIV infection %
  - Baseline: 8.6%
  - Midline: 74.9%
  - Endline: 67.4%
  - ^ p value for baseline, midline and endline: Chi Square Test
  - * < 0.00001

- Proportion of women who took IFA tablets for 90 or more days %
  - Baseline: 63.6%
  - Midline: 85.6%
  - Endline: 85.6%
  - # p value for baseline and midline

Baseline: n = 500; Midline n = 202; Endline: n = 475
Sumitra Mishra  
Country Director  
iPartner India  
The Hub  
5 Torrens Street  
London EC1V 1NQ  

11 July 2016  

Dear Sumitra,

Project Ref: GPAF-INN-009  
mMitra Arogya Sakhis: Mobile phone enabled improved maternal and child health information access (voice messages and animations) and home based care for 2000 poor pregnant women and infants in India  

Many thanks for completing your Project Completion Report (PCR). Please find below a summary of our findings and recommendations for further information and action.

Narrative report  
The report is well written and easy to understand. Perhaps some issues or topics could have been reflected upon a bit more in detail, such as sustainability, the risk analysis and engagement with local actors. At the same time the format does not necessarily allow for this. After reading the report and the logframe, the reader is well aware of the achievements of the project and activities undertaken.

Given the level of evidence and achievement we are pleased to confirm we have rated this project as having achieved an outcome score of A+ (outcomes moderately exceeded expectations). Please see the full review report of your PCR in Annex One.

The key achievements of your project were as follows:  
1. Most outcome indicators have been met.  
2. Voice messages and animations created.  
3. 164 Aroqya Sakhis were transformed into health entrepreneurs.
In conclusion
UKAID Study Overview

• A timed and targeted preventive care voice call and animation film service leads to improved health outcomes among underprivileged rural women

• The impact of the same is comparable in multiple knowledge recall and behavior change indicators to home based provision of antenatal and infancy care

• The approach is cost effective at less than five dollars per woman and is strongly recommended for other resource poor settings
Proportion of women who sought treatment for complications during pregnancy %
- Baseline: 72%
- Endline: 96%

Proportion of women who suffered from pregnancy-related complications %
- Baseline: 38%
- Endline: 9%

Proportion of women who were aware of the importance of immunization during pregnancy %
- Baseline: 61%
- Endline: 97%

Proportion of women who were aware about immunization schedules during infancy %
- Baseline: 71%
- Endline: 93%

*p value < 0.05

*Results of an end-of-pregnancy survey (pre-post intervention study) conducted among mMitra beneficiaries at an urban tertiary care center (Sion Hospital) in Mumbai indicate that mMitra voice calls (without animations) have impact.
Results of an end-of-pregnancy survey (pre-post intervention study) conducted among mMitra beneficiaries at an urban tertiary care center (Sion Hospital) in Mumbai indicate that mMitra voice calls (without animations) have impact.

- Proportion of women who were aware about the period of exclusive breastfeeding: Baseline 66%, Endline 83%.
- Proportion of women who were aware of the importance of giving colostrum to the baby: Baseline 72%, Endline 91%.
- Proportion of women who were aware of the harmful effects of pre-lacteal feeds: Baseline 41.35%, Endline 88%.

^p value < 0.05