Cognitive-Behavioral Counseling for Exclusive Breastfeeding in Rural Pediatrics: A Cluster RCT

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abstract

OBJECTIVE: To test the effectiveness of cognitive-behavioral counseling on the rate and duration of exclusive breastfeeding (EBF) during the first 6 months of an infant’s life compared with routine counseling.

METHODS: A single-blind cluster-randomized controlled trial was undertaken in 40 Union Councils of a rural district in the northwest province of Pakistan between May 2009 and April 2010. By simple unmatched randomization, 20 Union Councils were each allocated to intervention and control arms. Two hundred twenty-four third-trimester pregnant women in the intervention and 228 third-trimester pregnant women in the control arm were enrolled and followed-up biweekly until 6 months postpartum. Analyses were by intention to treat. Mothers in the intervention group received 7 sessions of cognitive-behavioral counseling from antenatal to 6 months postpartum, whereas the control group received an equal number of routine sessions. Proportion of mothers exclusively breastfeeding at 6 months postpartum and duration of EBF through these 6 months was assessed.

RESULTS: At 6 months postpartum, 59.6% of mothers in the intervention arm and 28.6% in the control arm were exclusively breastfeeding. This translates into a 60% reduced risk of stopping exclusively breastfeeding during the first 6 months (adjusted hazard ratio, 0.40 [95% confidence interval: 0.27–0.60], P < .001). Mothers in the intervention group were half as likely to use prelacteal feeds with their infants (adjusted relative risk, 0.51 [95% confidence interval: 0.34–0.78]).

CONCLUSIONS: Compared with routine counseling, cognitive-behavioral counseling significantly prolonged the duration of EBF, doubling the rates of EBF at 6 months postpartum.

WHAT’S KNOWN ON THIS SUBJECT: Exclusive breastfeeding until 6 months of an infant’s age is described as the safest, most powerful and cost-effective intervention to reduce infant morbidity and mortality globally. In developing countries, only ~25% of infants are exclusively breastfed for 6 months.

WHAT THIS STUDY ADDS: We developed a psycho-educational intervention combining education with techniques of cognitive-behavioral therapy, integrated it into the routine work of community health workers, which increased the rate and duration of exclusive breastfeeding until 6 months of an infant’s age.

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The practice of exclusive breastfeeding (EBF; ie, breast milk as sole source of food) to 6 months of age has been described as the safest, most powerful, and cost-effective intervention to reduce infant morbidity and mortality globally (endorsed by experts and advocated by the World Health Organization [WHO]). In developing countries, 25% of infants are exclusively breastfed for 6 months, whereas in Pakistan, where the infant mortality rate is 78:1000 live births, the rate is only 8%.4,5

A number of global initiatives to improve breastfeeding practices have been tried.6,7 Hospital-based programs are effective8 but of limited value in countries where the majority of infants are delivered at home. Community-based programs such as peer-counseling and health education delivered by community health workers have also been effective.9 Pakistan has 1 of the world’s best developed community health programs, but rates of EBF remain low. Three factors have been found to be important contributors to this: low levels of literacy, deeply ingrained cultural beliefs and practices that conflict with EBF guidelines, and high levels of psychological distress and disempowerment of women in disadvantaged rural communities.10 Mothers with high levels of psychological distress exclusively breastfeed for a shorter duration.11

We developed a culturally appropriate, feasible, and sustainable psycho-educational approach, in partnership with Pakistan’s Lady Health Workers (LHW) program. The approach was integrated into the LHW program and tailored to the needs of disadvantaged communities.12 We have demonstrated that cognitive-behavioral therapy (CBT) techniques can be taught to nonspecialist community health workers (LHWs) to bring about improvement in maternal well-being and child care, and that LHWs found these techniques to be very useful in communicating with “difficult to engage” families.14

The current intervention was designed to be integrated into the routine training, supervision, and day-to-day work of LHWs. In a 2-day (12 hours) training workshop, the research team trained the trainers of the LHW program. After a gap of 2 weeks, these trainers imparted the 2-day training to the LHWs. A participatory approach was adopted, with presentations, lectures, and role plays through which LHWs practiced simplified principles of CBT. After training, the LHWs implemented the counseling in their routine practice. The LHWs had routine monthly supervisions with their Lady Health Supervisors, which the research team observed. In all, the intervention involved 7 household visits integrated into the LHW’s routine work starting from the woman’s third trimester of pregnancy to the sixth month postpartum. The intervention had the following components:

- Developing an empathic relationship: a trusting, safe, alliance with the mother and other family members.
- Collaborating with the family in an equal partnership: the health worker brought skills and knowledge of health issues and the family brought their own experience and resources.
- Using guided discovery: a style of engagement to both gently probe for the individual and family’s health beliefs, and to stimulate alternative ideas. We made effective use of “imagery” techniques: culturally appropriate illustrations/pictures were used to facilitate this with mothers and families.
- Putting knowledge into practice and behavioral activation: the mother tried things out in between counseling sessions, putting what had been learned into practice. LHWs worked with key family members to motivate and encourage mothers to take small steps and then build on these.

- Problem solving: Problems and barriers in putting new knowledge and skills into practice were analyzed. The health workers used peer-supervision sessions to brainstorm for possible solutions and introduced these to mothers and families.

Structured feedback revealed that this intervention was accepted and found useful by both LHWs and mothers.13

The aim of the current study was to evaluate the impact of the intervention, delivered at scale, on both the rate and duration of EBF in the first 6 months of an infant’s life through an effectiveness trial. Secondary aims included evaluating impact on traditional practices impeding EBF and levels of psychosocial distress among mothers.

**METHOD**

**Study Area and Participants**

The study was conducted in Manserha district, located in the Khyber Pakhtunkhwa Province of Pakistan. Manserha is a resource-poor district with an infant mortality rate of 78:1000 live births and a mortality rate of 94:1000 live births for children younger than 5 years old.16 The literacy rate is 51% for men and 22% for women. Over 70% of deliveries take place at homes.16

The primary health care system is relatively well established. After a devastating earthquake in 2005, the government and the international community invested considerable resources in its upgrade.17 The first level primary health care facility called Basic Health Unit (BHU) covers a population of 1 Union Council (UC; smallest administrative unit; population: 15 000–20 000), has 2 to 5 facility-based staff, and 15 to 20 community-based LHWs. Each LHW covers ~100 to 120 households and
visits every household once every month to deliver basic education on maternal, newborn, and child health and family planning. Counseling for EBF is an important component of the LHWs’ routine training.

The trial profile is shown in Fig 1. A UC, the unit of randomization, is also the unit for training and supervision of LHWs working in that UC. LHWs from 1 UC do not have day-to-day contact with LHWs from another UC. Thus the risk of contamination was negligible. The study area comprised 59 UCs, with a population of ~1.5 million. The study was conducted in 40 randomly selected UCs (out of the 59 UCs of Mansehra district), which had LHW program coverage. LHWs were enrolled to participate before randomization. Using simple unmatched randomization, the 40 UCs were equally allocated to intervention and control arms by an independent researcher. Randomization was done before the recruitment of participants (Fig 1). All LHWs of the intervention arm received the training.

Participants were women aged 17 to 40 years, married, in their third trimester of pregnancy, and intending to reside in the study area for the duration of the study. They were enrolled and followed up from May 1, 2009, to April 30, 2010. Lists of potential women were compiled from official registers of the LHWs in the 40 UCs. To ensure coverage, we did an additional door-to-door survey to identify potential women not registered, and added them to the LHW lists. Women with diagnosed serious medical/psychiatric condition requiring treatment, pregnancy-related illness (except for common conditions, such as anemia), and substantial physical/learning disability, were excluded. Each UC (cluster) had ~15 to 20 LHWs. Each LHW, in turn, had 3 to 4 eligible women registered with them. For assessing trial outcomes, we randomly selected up to 3 LHWs (out of the 15–20 in each UC) and approached all eligible women on their lists to participate.

Informed written consent was obtained from participants. Ethical approval for the study was granted by the Institutional Review Board of the Human Development Research Foundation, Pakistan.

### Intervention and Control Arms

The intervention consisted of 7 psycho-educational sessions integrated into the routine work of LHWs and delivered to all women in their UC catchment areas. The first session was delivered before birth, the second session immediately after birth, and the remaining 5 sessions monthly thereafter. The control arm received an equal number of visits in exactly the same way as those in the intervention arm, but by routinely trained LHWs. Monitoring involved the LHW District Coordinator and the Lady Health Supervisors and was carried out in both arms to ensure that both intervention and control procedures were optimally delivered by using the existing approach of the LHW program.

### Methods

Outcomes were assessed through structured interviews with mothers in their households by 6 experienced assessors, blind to the allocation status of mothers. All assessors resided outside the study area. Mothers were assessed at baseline (third trimester of pregnancy), 2 weeks postpartum and thereafter biweekly until the infant reached 6 months of age. All instruments were translated and field-tested in the local population before study implementation.  

The primary outcome was EBF, as defined by the WHO guidelines. Assessors documented what the infant had been fed in the last 24 hours. This information was categorized as either EBF, partial breastfeeding (giving an infant some breastfeeding, and some artificial foods, either milk, cereal, or other food items), or no breastfeeding. If the infant was not exclusively breastfed, details of when (age of infant) and why EBF was discontinued were recorded. At the first follow-up immediately after delivery, details about early initiation, discarding colostrum, use of prelacteals, and reasons for delaying or not initiating breastfeeding were assessed. Psychological distress was assessed at baseline and 6 months postpartum by using the Self-Reporting Questionnaire (SRQ-20). This psychiatric screening instrument has been developed specifically for use in primary care by health workers in developing countries and has been validated in Pakistan.

We also gathered information on maternal age, education, maternal height and weight, number of children, and family structure. A family was considered poor if they were both in debt and rated in the poorest category by the LHW on a 5-point Likert scale (richest to poorest). Mothers were considered financially empowered if they (1) had been given a lump sum of money for day-to-day expenses by the main earner and (2) if they could make independent decisions about its use.

### Statistical Analysis

On the basis of our primary hypothesis, with 20 UCs in each arm, and assuming an intraclass correlation coefficient of 0.05, a significance level of 0.05, and a 2-sided hypothesis test, a sample size of 147 in each arm would give 90% power to detect a 20% absolute difference in rates of EBF in intervention versus control arm (28% vs 8%). Rates of EBF at 6 months in Pakistan vary greatly but have been reported to range from as low as 8% in settings similar to the district in which this trial was conducted. Due to additional concerns about migration out of the study area because of the study timing soon after the 2005 earthquake, and, to account for illness,
death, or conditions in infants rendering breastfeeding not possible (like cleft palate), we approached all third trimester pregnant women enlisted with up to 3 randomly selected LHWs in each of the 40 UCs, resulting in a total of 220 enrolled participants in each arm as our sample.

Summary baseline comparisons were conducted by using *t* tests for continuous variables and $\chi^2$ tests for categorical variables. All analyses were intention to treat (ITT). A mother was considered EBF at 6 months if she reported EBF during every follow-up interview including the final assessment at 6 months postpartum, whereas the duration of EBF was defined as time from birth to cessation of EBF calculated in weeks. As per the protocol, where there was stillbirth, infant death, congenital anomaly, or maternal death, these were not included in the analyses (Fig 1). The

FIGURE 1
Trial profile of participants in intervention and control arms.
At 6 months, 59.6% of mothers in the intervention arm (Tables 1 and 2). Empowerment, which was higher in empowerment, and family poverty. Four hundred forty pregnant women were asked to participate in the study. Of these, 1 refused and 1 was ineligible. Of the 452 women enrolled, 358 (79.2%) were assessed through to the end of the study at 6 months postpartum (Fig 1). No significant differences between arms were found in baseline comparisons, except for maternal financial empowerment, which was higher in the intervention arm (Tables 1 and 2). At 6 months, 59.6% of mothers in the intervention arm were exclusively breastfeeding, compared with 28.6% of mothers in the control arm. The median length of EBF in the control arm was 15 weeks (95% CI: 13–17 weeks); the median for intervention arm was 17 weeks (95% CI: 15–19 weeks); the median for intervention arm was 15 weeks (95% CI: 13–17 weeks); the median for intervention arm was 17 weeks (95% CI: 15–19 weeks); the median for intervention arm was 17 weeks (95% CI: 15–19 weeks); the median for intervention arm was 17 weeks (95% CI: 15–19 weeks); the median for intervention arm was 17 weeks (95% CI: 15–19 weeks). The impact of the intervention on duration of EBF was estimated by using the Cox proportional hazards approach: Kaplan-Meier survival curves were constructed and the shared frailty model with random effects adjusting for clustering at the UC level (PROC PHREG, SAS Institute, Inc, Cary, NC) was used to calculate hazard ratios (HRs) and 95% confidence intervals (CIs). Adjusting for clustering at UC level or at the health care worker level yielded identical results. Proportionality assumptions were verified graphically and by examining the significance of time dependent covariates (covariate with length of follow-up interaction terms).

### RESULTS

Four hundred fifty-four pregnant women were asked to participate in the study. Of these, 1 refused and 1 was ineligible. Of the 452 women enrolled, 358 (79.2%) were assessed through to the end of the study at 6 months postpartum (Fig 1). No significant differences between arms were found in baseline comparisons, except for maternal financial empowerment, which was higher in the intervention arm (Tables 1 and 2).

### TABLE 1 Baseline Characteristics of Participants in Intervention and Control Arms

<table>
<thead>
<tr>
<th>Variables</th>
<th>Control Arm, n = 211</th>
<th>Intervention Arm, n = 210</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%) or Mean (SD)</td>
<td>n (%) or Mean (SD)</td>
<td></td>
</tr>
<tr>
<td>Age of mother</td>
<td>26.22 (5.1)</td>
<td>28.62 (4.6)</td>
<td>.39</td>
</tr>
<tr>
<td>Number of children</td>
<td>2.37 (2.0)</td>
<td>2.07 (1.7)</td>
<td>.10</td>
</tr>
<tr>
<td>Number of female children</td>
<td>1.30 (1.4)</td>
<td>1.15 (1.2)</td>
<td>.26</td>
</tr>
<tr>
<td>Number of male children</td>
<td>1.09 (1.2)</td>
<td>0.95 (1.1)</td>
<td>.23</td>
</tr>
<tr>
<td>Height of mother, cm</td>
<td>154.79 (5.2)</td>
<td>155.28 (6.1)</td>
<td>.37</td>
</tr>
<tr>
<td>Weight of mother, kg</td>
<td>62.90 (10.4)</td>
<td>61.71 (11.1)</td>
<td>.26</td>
</tr>
<tr>
<td>Maternal education (number of years)</td>
<td>3.73 (4.4)</td>
<td>3.87 (4.3)</td>
<td>.74</td>
</tr>
<tr>
<td>Maternal levels of psychosocial distress (SRQ) scores out of 20</td>
<td>6.08 (5.7)</td>
<td>6.79 (5.6)</td>
<td>.20</td>
</tr>
<tr>
<td>Mother financially empowered, %</td>
<td>53.08</td>
<td>63.33</td>
<td>.03</td>
</tr>
<tr>
<td>Education of husband (number of years)</td>
<td>6.95 (4.6)</td>
<td>7.60 (4.6)</td>
<td>.15</td>
</tr>
<tr>
<td>Family structure, %</td>
<td>29.38</td>
<td>31.90</td>
<td>.67</td>
</tr>
<tr>
<td>Nuclear</td>
<td>6.95 (4.6)</td>
<td>7.60 (4.6)</td>
<td>.15</td>
</tr>
<tr>
<td>Joint/extended</td>
<td>9.95</td>
<td>10.00</td>
<td>.26</td>
</tr>
<tr>
<td>Multiple households</td>
<td>29.38</td>
<td>31.90</td>
<td>.67</td>
</tr>
<tr>
<td>Household in debt</td>
<td>68.67</td>
<td>68.57</td>
<td>.81</td>
</tr>
</tbody>
</table>

### TABLE 2 HRs Comparing the Duration of EBF Between Intervention and Control Arms

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>EBF at 6 mo, %</th>
<th>Raw Difference, %</th>
<th>Adjusted HR* (95% CI)</th>
<th>P</th>
<th>ICC, b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>28.6</td>
<td>31.0</td>
<td>Reference</td>
<td>&lt;.001</td>
<td>0.154</td>
</tr>
<tr>
<td>Intervention</td>
<td>59.6</td>
<td></td>
<td>0.40 (0.27–0.60)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Shared frailty models accounting for clustering.
arms at 6 months (3.52, SD [5.0] vs 3.90, SD [5.7], \( P = .51 \)) was seen.

**DISCUSSION**

This study reveals that an intervention using CBT-derived techniques was successful in significantly increasing the length of EBF in low literacy rural settings of Pakistan. Results reveal a doubling of the rate of EBF at the WHO recommended age of 6 months (59.6% vs 28.6%), compared with a control arm receiving routine breastfeeding counseling.

This community-based study had a high response rate. The mothers in the control arm also reported a somewhat higher level of EBF than in other studies in Pakistan, but still within an expected range. The cluster design allowed us to use the primary care and community setting for testing the intervention without risk of contamination. The allocation status of individual clusters was concealed from the team identifying pregnant women, as well as the assessors. Lastly, mothers were not informed of the study hypotheses.

The intervention was developed in partnership with an existing government health program, which ensured uptake and ownership, both essential for scale-up. Training and supervision were all carried out by government staff, so the results reflect “real-life” impacts of the intervention.

A number of studies from high income countries reveal that 1-to-1 professional or lay support increases the duration of any breastfeeding up to 6 months, with a greater effect for EBF. A recent systematic review of community-based interventions in low-income settings identified 4 randomized trials (in Syria, India, Pakistan, and Bangladesh), which assessed outcomes at 4 to 5 months. A random effects meta-analysis of the 4 studies revealed a pooled odds ratio of 5.90 (95% CI: 1.81–18.6) reflecting that available interventions were effective in improving EBF rates. A recent trial from Sub-Saharan Africa has revealed similar effects. Our findings are consistent with these studies, but differ in 4 important respects: Firstly, the intervention was adopted and rolled-out as part of the routine work of the LHW’s program. This is a rare example of an intervention fully integrated into an existing health system at the district-level. Other studies have used people outside the health systems imparting trainings that ranged from 20 to 40 hours alongside 2 months of field trainings; in comparison, we had 12 hours (2 days) of training. This has important policy implications for delivery of interventions at scale by using existing human resources, a challenge that has not been addressed in low-income settings. Secondly, we conducted our study in a very conservative community where women have little access to education.

![Kaplan-Meier estimates and 95% CIs of duration of EBF in the intervention and control arms.](image)

**TABLE 3** Comparison of Infant Feeding Practices Between Intervention and Control Arms

<table>
<thead>
<tr>
<th>Different Breastfeeding Behaviors</th>
<th>N(^a)</th>
<th>Percentage Engaging in Behaviors</th>
<th>Raw Difference, %</th>
<th>Crude RR (95% CI)</th>
<th>( P )</th>
<th>Adjusted RR (95% CI)</th>
<th>( P )</th>
<th>ICC, ( b )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colostrum</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>169</td>
<td>80.8</td>
<td>9.30</td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>180</td>
<td>90.1</td>
<td>1.98 (0.95–1.36)</td>
<td>.089</td>
<td></td>
<td>1.06 (0.92–1.19)</td>
<td>.12</td>
<td>.101</td>
</tr>
<tr>
<td>Prelacteal feeds</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>169</td>
<td>44.2</td>
<td>20.10</td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>180</td>
<td>24.3</td>
<td>0.51 (0.32–0.77)</td>
<td>&lt;.001</td>
<td></td>
<td>0.51 (0.33–0.75)</td>
<td>&lt;.01</td>
<td>.108</td>
</tr>
<tr>
<td>Early initiation (first hour)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>169</td>
<td>62.8</td>
<td>4.10</td>
<td>Reference</td>
<td></td>
<td>Reference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>180</td>
<td>68.9</td>
<td>1.07 (0.88–1.32)</td>
<td>.49</td>
<td></td>
<td>1.05 (0.85–1.29)</td>
<td>.65</td>
<td>.067</td>
</tr>
</tbody>
</table>

\( a \), Intra-cluster correlation coefficient.

\( b \), Forty-two women in the control arm and 30 in the intervention arm had missing values for early infant feeding practices.
or other sources of information outside of the family. Such societies tend to be very resistant to change.\(^{10}\)

Thirdly, other studies assessed EBF at 3 to 5 months,\(^{25,27,28}\) whereas we assessed it at 6 months, the period recommended by the WHO. Fourthly, all mothers were assessed biweekly until 6 months postpartum to document infant food intake in the last 24 hours, thus minimizing recall bias and enabling a much more accurate estimate of EBF duration.

The innovative aspect of our intervention was that it borrowed from the CBT approach and integrated components into routine counseling practiced by LHWs. Our formative research revealed that the LHWs’ counseling had been too didactic and authoritarian, undermining the confidence of many women.\(^{13}\) Using pictures to discuss traditional harmful practices rather than confronting the families, breaking tasks into manageable pieces, and helping mothers overcome problems in implementing behaviors made the LHWs much stronger agents for change. Although traditionally CBT techniques are used for the treatment of affective disorders such as depression, the current intervention did not have a significant impact on the levels of psychosocial distress. Further work is needed to refine the intervention so that it can simultaneously address behavior change, as well as improve psychosocial distress.

Community health workers are the back-bone of primary health care in low-income countries,\(^{30}\) and the most powerful tool in their kit is their ability to communicate positive health behaviors. This study reveals that seemingly sophisticated techniques of therapy can be simplified and incorporated into routine counseling practice. The techniques have much in common with other theory-based behavior change strategies,\(^{13}\) but pay particular attention to the mother who may be disempowered, illiterate, and psychologically distressed. Such techniques may have a role in enhancing the effectiveness of not only EBF programs but other preventive programs delivered at scale in similar settings.

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