

Cluster randomized trial of a parent-based intervention to support early development of children in a low-income country

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Abstract

Background Programmes that promote early psychological development of children in the developed world have been found to be beneficial. However, such programmes are rare in underprivileged parts of the developing world. We adapted one such parent-based programme (Learning Through Play) for a rural Pakistani population and aimed to study if: (1) it was acceptable to community health workers; (2) the programme led to an improvement, after a period of 6 months, in mothers' knowledge and attitudes about early infant development; (3) it led to a reduction in the levels of maternal mental distress in the post-natal period.

Methods Using a cluster randomized design with villages as unit of randomization, 163 mothers from 24 villages in a rural sub-district of Rawalpindi, Pakistan, received the 'Learning Through Play' programme, whereas 146 mothers from 24 villages acted as controls. Twenty-four community health workers were trained to carry out the programme. Assessments were conducted using a specially developed 15-item Infant Development Questionnaire and the 20-item Self-Reporting Questionnaire (SRQ).

Results Over 80% of the community health workers trained found the programme to be relevant and were able to integrate it into their routine work. There was a significant increase in mothers' knowledge and positive attitudes about infant development in the intervention group, compared with the control group. Women in the intervention group answered correctly 4.3 (95% CI 3.7–14.9, $P < 0.001$) more questions than the control group. There was no difference in levels of mental distress measured by the SRQ.

Conclusions The 'Learning Through Play' programme was successfully integrated into the existing health system and accepted by community health workers. The programme succeeded in improving the knowledge and attitudes of mothers about infant development.

Keywords

child development, developing countries, early intervention, mental health, parent education, randomized trials

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Introduction

The recent *Lancet* series on child development highlights the fact that more than 200 million children under the age of 5 in developing countries do not reach their full developmental potential (Grantham-McGregor *et al.* 2007). Integration of early

child development programmes into health systems in resource-poor settings has been identified as one of the major challenges (Engle *et al.* 2007).

In the past few decades, numerous interventions aimed at improving the psychological development of children have been developed, mostly in the West (Karoly *et al.* 1998). These have

been classified as child-based, parent-based or joint-based (Meisels 1992). Child-based approaches involve high-intensity (frequent, many hours or weeks) direct interventions with children promoting cognitive, socio-emotional or linguistic development, whereas parent-based interventions involve direct contact with parents, with indirect benefits for children through improved parenting skills. Joint-based programmes include high-intensity components for both children and parents. There is evidence that parent-training programmes may also have beneficial psychological outcomes for mothers (Barlow & Coren 2002).

Owing to the lack of trained workers and resources, any intervention aimed at a disadvantaged population in a developing country needs to be inexpensive, simple to implement and easily integrated into the existing health infrastructure. The labour-intensive child- and joint-based programmes do not meet these criteria. Parent-based approaches are more feasible, and have the added advantage of providing support to mothers, many of whom might have post-natal depression.

In this paper we describe the experience of integrating a parent-based intervention (the 'Learning Through Play' Programme) into the existing health system in a resource-poor rural setting of a developing country.

The 'Learning Through Play' programme

The programme was originally developed in Toronto, Canada, for use by lay home visitors working with at-risk multi-ethnic parents and children and adapted for use in many developing countries (Bevc 2004). Starting in the last trimester of pregnancy, this parent-based programme provided centre-based parent groups, as well as fortnightly individual home visits. In addition, efforts were made to mobilize self-help groups of mothers to support each other and engage in fun child-focused activities, using the programme as a focal point.

The 'Learning Through Play' programme is intended to stimulate early child development. The central feature of the programme is a pictorial calendar devised for parents, depicting eight successive stages of child development from birth to 3 years, with illustrations of parent-child play and other activities that promote parental involvement, learning and attachment. In each stage, five key areas of child development are depicted: sense of self, physical, relationships, understanding and communication. Information about each area is written in simple, low-literacy language, with accompanying pictures that act as visual cues. The calendar is accompanied by a comprehensive training manual for workers (The Hincks-Dellcrest Centre 2002), which provides additional information on child devel-

opment and techniques on how to conduct groups or individual sessions for parents, using the calendar as a focus.

A key feature of the 'Learning Through Play' programme is its emphasis on the quality of the mother-infant interaction, and helping the mother read infant cues and develop sensitive responsiveness towards the infant through play, which can be pleasurable for both the mother and the infant.

The programme can be carried out by a variety of non-specialist staff (e.g. health workers, day care workers, lay home visitors) after appropriate training. The programme is flexible, and can be delivered in a variety of formats with individual parents or groups of parents (e.g. a 1-week workshop, integrated with routine antenatal and post-natal visits, or spread over the first 3 years of a child's life, with parent groups conducted at regular intervals). The 'Learning Through Play' calendar is a relatively inexpensive and simple tool that relies minimally on the literacy of the parents. These attributes make it suitable for use in developing countries. The programme has been introduced in 10 countries including India where 30 000 early childhood development workers have been trained. The programme was introduced in a rural area of Pakistan in 2002 and a non-randomized pre-post intervention study indicated that the programme was effective in increasing the knowledge of mothers about child development and led to a reduction in psychological symptoms in the mother (Bevc 2004).

The purpose of this study was to carry out a more robust assessment of the impact of the 'Learning Through Play' programme using a cluster randomized design. In order to minimize contamination, the unit of randomization was a village. The specific objectives of the study were to: (1) determine if the programme was acceptable to the community health workers; (2) evaluate if the programme increased mothers' knowledge of early infant development and fostered attitudes supportive of healthy development; (3) determine if the programme led to reduction in symptoms of maternal mental distress.

Methods

Geographical area and study sample

The study was conducted in Kaller Syedan, a rural sub-district of Rawalpindi, 40 km south-east of Rawalpindi City. It has an area of 350 km², a population of 150 000, and consists of about 60 villages (Government of Pakistan 1999). The average household consists of 6.2 members. Most families depend on subsistence farming, supported by earnings of one or more adult male members serving in the armed forces, or working as government employees, semi-skilled or unskilled labourers in

the cities. The average monthly income is about Rs 3000 (US\$ 50). The rate of post-natal depression in the study area, estimated in an earlier study, is 28% (Rahman *et al.* 2003). Government health facilities consist of 12 Basic Health Units and a Rural Health Centre, consisting of 14 doctors, 10 midwives (Lady Health Visitors, providing obstetrical care), 10 vaccinators (providing immunization) and 150 female primary health-care workers called Lady Health Workers (LHWs). LHWs are members of the local community, have completed secondary school and are trained to provide mainly preventive mother and child health care and education. Each LHW is responsible for about 1000 women in her catchment area.

The study was conducted in 48 villages (Fig. 1). Twelve villages not accessible by road were left out. Twenty-four villages were randomly allocated to the intervention group, and the remaining 24 acted as controls. Randomization was conducted by an independent Trial Centre in Rawalpindi. Villages were assigned by simple random allocation using a table of random numbers by a researcher not involved in the study and who was blind to the identity of the villages.

With the assistance of the local health centres, all healthy women aged 17–40, married, in their last trimester of pregnancy that were registered with LHWs were approached to participate in the study. Women with a complicated pregnancy or diagnosed medical condition were excluded. Out of 367

approached, 334 (91%) met the eligibility criteria and agreed to take part in the study.

Intervention

Twenty-four LHWs from the intervention villages were recruited to receive training in the 'Learning Through Play' programme from a trained psychologist. LHWs received one full-day training workshop and a refresher session of 1 h on the second birth month stage of child development. Each LHW was given the Urdu version of the manual for reference, along with suggested teaching guidelines. Training feedback was obtained from the LHWs, which showed that they found the training appropriate to their job, and relevant to the mothers they worked with.

After receiving training, each LHW conducted a half-day workshop on the second birth month stage of development with a group of mothers recruited from her area (each group comprised 6–8 mothers). Each mother was given a 'Learning Through Play' calendar to take home. Thereafter, during their routine fortnightly home visits, LHWs spent 15–20 min with the mothers to discuss their child's development, using the calendar as the basis for discussion. In addition, the mothers were encouraged to meet in groups on their own to support each other in the use of the techniques outlined in the calendar. The researchers monitored the training of LHWs and mothers to ensure that the programme was adhered to.

Outcomes

All assessments were carried out using instruments that had been translated, field-tested and validated in the local population through previous work. Assessments were carried out at baseline (third trimester) and 3 months post-natally.

Main outcome

Mothers' knowledge and attitudes about the second birth month stage of development was assessed using a specially developed Infant Development Questionnaire (IDQ).

Secondary outcome

The level of mental distress in mothers was measured using the World Health Organization's Self-Reporting Questionnaire (SRQ-20).

Data were also collected on demographic variables, family income, education and family structure. Using a specially devel-

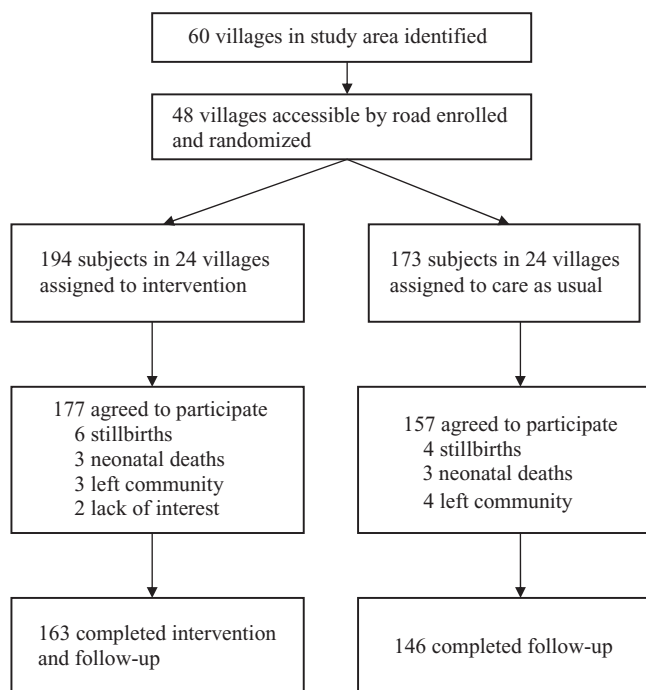


Figure 1. Flow of subjects through the trial.

oped questionnaire, feedback was obtained from LHWs about the training and intervention at the end of the study.

Instruments

Infant Development Questionnaire

Mothers' knowledge and attitudes about the birth to 2-month stage of development were assessed using a specially developed IDQ, written in Urdu and appropriate to the comprehension level of the mothers (Table 1). More than 40 items were developed initially. From these, 25 items were selected by experts in the field to fully represent the five content areas portrayed in the calendar. The items were then culturally adapted through lengthy unstructured interviews with health workers, midwives and mothers. The wording of each item was kept as simple as possible, so that further explanation, which might bias the response, could be kept to a minimum. In the final questionnaire, 15 items that were most relevant to the socio-cultural context were retained, based on the results of the pre-testing. Each item could be answered with a 'yes' or 'no' response. A correct response was scored as '1', and an incorrect response as '0'. Correct responses were then summed. Thus, the range of scores was from 0 to 15.

Table 1. The Infant Development Questionnaire

Questions	Correct response
1. When a baby cries he needs something, and his cries should not be ignored.	True
2. 1–2 month babies all have similar personalities.	False
3. Young babies need time to stretch and exercise their arms and legs.	True
4. It is not important to talk to a young baby.	False
5. 1- to 2-month-old babies try to follow slow movements with their eyes.	True
6. Babies can learn to love and trust from the time they are born.	True
7. Babies cannot hear at birth.	False
8. 2-month-old babies try to smile and make sounds when they see their mother's face.	True
9. Picking up a young baby every time he cries will spoil him.	False
10. 1- to 2-month-old babies are too young to have an emotional bond with their mother.	False
11. It is not important for a mother to make eye contact when holding her baby.	False
12. 1- to 2-month-old babies all behave in the same way.	False
13. Newborn babies are too young to learn.	False
14. A gentle massage can help soothe and relax young babies.	True
15. Newborn babies can see more than 3 feet away.	False

The Self-Reporting Questionnaire

The mental state of the mothers was measured using the World Health Organization's SRQ-20 (World Health Organization 1994). The SRQ-20 was developed specifically for use in primary care by health workers in developing countries, and can be verbally administered to non-literate persons. This standardized instrument has been in use in developing countries for over 20 years. It has been validated on the local population (Husain *et al.* 2006). The SRQ has 20 items, each item having a 'yes' or 'no' response to questions about psychological and somatic symptoms in the past 30 days. The range of scores is from 0 to 20.

Procedure

Demographic information was obtained on all respondents before the intervention. Mothers' mental state, and their knowledge and attitudes about infant development, were assessed before and 6 months after the start of the intervention. The baseline assessments were carried out in the antenatal period ($M = 12$ weeks before delivery). All women in the intervention group then received the programme, while the control group had routine follow-up visits. Both groups were reassessed in the post-natal period ($M = 12$ weeks after delivery). All questionnaires were administered individually to mothers in groups by workers who were blind to the control-intervention status of the two groups. As many respondents were illiterate, questions were read to all respondents.

Statistical analysis and sample size

No estimate of the intra-cluster size was available for the primary outcome when the trial was being designed. With 24 villages in each arm and six mothers per village the study had a power of over 90% to detect a standardized effect size equal to 0.5 assuming an intra-cluster correlation (ICC) equal to 0.1.

Statistical analysis was based on a random effects model with a random effects for village and mother (Donner & Klar 2000). For IDQ and SRQ covariates were included in the model for baseline value of the outcome, and mother's age and parity. Distributional assumptions were checked using normal probability plots of patient and village level residuals. Binary and ordinal outcomes were analysed using a random effects logistic regress model with the same covariates. Statistical analyses were carried out using STATA (StataCorp 2005).

Informed consent was obtained from all mothers participating in the study. Ethical approval was obtained from the ethical committee of Human Development Research Foundation.

Table 2. Comparison of subjects completing follow-up versus those not completing follow-up

Characteristic	Completed follow-up	Did not complete follow-up
Age (years)		
<i>n</i> *	305	25
Mean (SD)	27.3 (5.0)	27.8 (5.2)
Median	27	26
25th percentile	24	26
75th percentile	30	33
Mother's education (years)		
<i>n</i> *	290	25
Mean (SD)	5.9 (3.8)	5.0 (3.1)
Median	5	5
25th percentile	5	4
75th percentile	8	8
Family income (Pakistani rupees)		
<i>n</i> *	266	25
Mean (SD)	3097 (1646)	3380 (1716)
Median	3000	3000
25th percentile	2000	2500
75th percentile	4000	3500
Mother's score on IDQ		
<i>n</i>	309	25
Mean (SD)	7.80 (2.39)	6.72 (1.14)
Median	8	7
25th percentile	6	6
75th percentile	9	7
Mother's score on SRQ		
<i>n</i>	309	25
Mean (SD)	7.61 (4.94)	6.40 (2.58)
Median	7	6
25th percentile	4	5
75th percentile	12	7

*Data not available for some subjects.

IDQ, Infant Development Questionnaire; SRQ, Self-Reporting Questionnaire.

Results

Of those 334 women agreeing to participate in the study, 307 (93%) were followed up with complete follow-up in 37 of the 48 villages (Fig. 1). The follow-up rate was high because the programme was delivered at home by local village-based health workers who knew the women and their families well. Follow-up rate did not differ between study arms [intervention 93% (163/177) vs. control 93% (146/157)].

Table 2 compares the characteristics of patients followed up with those that were not. When a random effects logistic regression model was fitted to follow-up rate, there was evidence that women with higher IDQ scores at baseline were more likely to be followed ($P = 0.017$).

Table 3 gives the baseline characteristics according to study arm. These were broadly similar, although there were more primiparous mothers and fewer male babies in the intervention

Table 3. Comparison of intervention and control groups at baseline

Characteristic	Intervention group	Control group
Age (years)		
<i>n</i> *	141	161
Mean (SD)	27.3 (4.9)	27.3 (5.2)
Median	27	27
25th percentile	24	24
75th percentile	30	32
Mother's education (years)		
<i>n</i> *	119	161
Mean (SD)	6.3 (3.6)	5.9 (3.8)
Median	7	5
25th percentile	5	5
75th percentile	10	8
Family income (Pakistani rupees)		
<i>n</i> *	124	25
Mean (SD)	3060 (1598)	3160 (1719)
Median	3000	3000
25th percentile	2000	2500
75th percentile	3500	4000
Primiparous		
Frequency/ <i>n</i>	25/146	36/163
%	17	22
Male infant gender		
Frequency/ <i>n</i>	71/130	84/162
%	55	52
Living in joint family		
Frequency/ <i>n</i>	64/114	82/147
%	56	56

*Data not available for some subjects.

group. There were no statistically significant differences between the groups in age, years of education and family income.

Follow-up

Table 4 tabulates the primary and secondary outcome measures. For the primary outcome (maternal knowledge of infant development measured by the IDQ) there was evidence of a substantial increase in IDQ score at follow-up, with women in the intervention group answering correctly 4.3 (95% CI 3.7–14.9, $P < 0.001$) more questions than the control group. The ICC coefficient was 0.15. There was no evidence of the intervention effect for the secondary outcome (level of mental distress measured by SRQ).

Table 5 gives the results for the feedback from the health workers about the intervention.

Discussion

This pragmatic trial showed that a parent-based early intervention programme called 'Learning Through Play', after

Table 4. Comparison of outcome measures at baseline and follow-up with estimate of intervention effect (Intervention–Control)

	Control			Intervention			Intervention effect	95% CI	P	ICC
	Mean	SD	n	Mean	SD	n				
IDQ										
Baseline	7.49	2.26	157	7.92	2.39	177				
Follow-up	8.23	2.16	146	12.58	1.76	163	4.28*	3.68 to 4.89	<0.0001	0.16
SRQ										
Baseline	7.13	4.72	157	7.87	4.88	177				
Follow-up	7.51	4.90	146	7.37	4.36	163	–0.42†	–1.53 to 0.68	0.45	0.08

*Intervention–Control adjusted for baseline IDQ score, and mother's age and parity.

†Intervention–Control adjusted for baseline SRQ score, and mother's age and parity.

IDQ, Infant Development Questionnaire; SRQ, Self-Reporting Questionnaire.

Table 5. Health workers' feedback on intervention ($n = 24$)

Question	Response (N/%)				
	Definitely yes	Somewhat	Don't know	No	Absolutely not
Is the LTP training relevant to your own work?	18 (75)	3 (12.5)	2 (8.5)	1 (4)	0
Is LTP easily integrated into your routine work?	10 (42)	10 (42)	2 (8)	1 (4)	1 (4)
Are you able to understand the concepts explained in your training?	20 (83)	4 (17)	0	0	0
Are you able to communicate these concepts to the mothers you see?	10 (42)	10 (42)	3 (12.5)	1 (4)	0

LTP, Learning Through Play.

appropriate cultural adaptation, could be delivered by ordinary health workers in an underprivileged rural community in a developing country. The 6-month intervention succeeded in increasing the mothers' knowledge of infant development. The control group, in contrast, exhibited no increase in infant development knowledge.

The limitations of the study are that it does not examine the extent to which knowledge imparted through the programme produces a sustained change in mother–infant interactions, and whether this translates into actual psychological gains for the infant. In resource-poor settings, there are likely to be other factors influencing optimal child development, such as malnutrition, infections and poverty. Further studies, controlling for these factors, are required to quantify the impact of such programmes on child developmental outcomes before limited health resources are applied for their large-scale implementation.

Nevertheless, in addition to the impact of the programme on the mothers, the training of 24 LHWs who did not previously have exposure to information on the psychological development of children is itself a significant accomplishment. The training workshops also focused on developing LHWs' sensitivity towards mothers' issues, including post-natal depression that can interfere with their ability to respond appropriately to their infants. LHWs' involvement with the programme will undoubtedly have an impact on their subsequent work with mothers. Given that each LHW is responsible for 1000 women in her

catchment area, the impact of the 'Learning Through Play' programme on the community as a whole is potentially strong.

Although not measured in this study, such interventions may benefit the infant physically as well as psychologically. There is evidence that early stimulation is a protective factor for malnutrition in children (Grantham-McGregor *et al.* 2007). In a randomized controlled trial, growth-retarded Jamaican infants were given nutritional supplementation, psychosocial stimulation, or both. In the trial, only the children who received both stimulation and supplementation caught up with the non-growth retarded comparison group. Furthermore, benefits from nutritional supplementation were no longer apparent at 11 years of age, although benefits from stimulation remained (Walker *et al.* 2006).

A systematic review of parent-training programmes carried out in developed countries showed that these can also be effective in improving psychosocial and mental health of the mothers (Barlow & Coren 2004). However, 'Learning Through Play' did not bring about a reduction in levels of psychological distress in mothers. Similarly, in a pilot study of an intervention that addressed both mother–infant relationship and maternal mood in a disadvantaged South African population, the investigators found no impact on maternal mood but significant improvements in mother–infant relationship (Cooper *et al.* 1999). Poverty, poor education, lack of social status and family problems are important risk factors for depression in women in developing countries. Hence, multimodal interventions that

combine parenting with individual support for the mother may be more effective in reducing levels of mental distress in underprivileged populations than interventions focussing on mother–infant relationship alone.

It was beyond the scope of this study to examine the optimal length of the ‘Learning Through Play’ programme. The current intervention focused on the second birth month stage of child development. However, the programme provides information on each subsequent stage of child development, and it is likely that continued intervention would provide additional benefits as the mothers are faced with new developmental challenges.

The intervention relied on local health workers whom the subjects knew and trusted. In areas where there are no village-based health workers, gaining access to subjects might not be as successful as in this study.

Future research could assess whether the programme results in a change in mother–infant interaction, whether it has an impact on the psychological and physical development of infants, and whether continued intervention results in improvement of the mental health of the mother. Other modes of delivery, such as through peer groups or educated volunteers from the community, could also be tested. Most low-income countries have community health workers focusing on maternal and child health, and it can only be beneficial to have early child development on their agenda.

Key messages

- More than 200 million children under the age of 5 in the developing world do not fulfil their developmental potential.
- Integrating early child development interventions in resource-poor health systems remains a big challenge.
- A parent-focused intervention called ‘Learning Through Play’, developed in Canada, was adapted and successfully integrated into community-based health workers’ routine work in rural Pakistan.
- The programme succeeded in improving the mothers’ knowledge and attitudes towards infant development.

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