Prevention of developmental delays among children at public healthcare facilities of Pakistan: protocol for a cluster Randomized Controlled Trial

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Abstract

Objectives: This cluster Randomized Controlled Trial (cRCT) aims to evaluate the effectiveness of an integrated ECD package in preventing developmental delays among children aged two years, in public health care centers, as compared to a control arm.

Methods: This is a parallel, two-arm, cluster randomized controlled trial. 768 mother-child pairs ('dyads') attending any of the 24-public health centers in two districts of Pakistan will be recruited, with an average of 32 participants per cluster. In the intervention arm, ECD based counselling sessions will be delivered to mother–child dyads by trained staff at public health care centers. Our primary outcome is reduction in prevalence of two or more developmental delays among children, from 38% to 23% in the intervention arm. Unit of randomization will be public health care center. 24 eligible clusters recruited will be randomized into intervention and control arms, using 1:1 allocation.

Discussion: The integrated model of child care into primary health care has the potential to provide a feasible and sustainable model for improving child developmental scale.

Key words: Early Child Development; Prevention; Developmental Delays; Public healthcare facilities

Introduction

In low-and-middle-income countries, 200 million young children are at risk of childhood developmental delays (1). In Pakistan, like most developing countries, early child development is a grossly neglected area of public health importance, with around 15% of children, suffering from a developmental delay (2). Exposure to risk factors or stressors such as malnutrition and lack of stimulation during first 2 years of life can place children at a higher risk of developmental delays (3) accounting for the higher 30% prevalence of developmental delays among children who are from disadvantaged families in Pakistan (4).

Evidence based programs in low resource settings have proven to be successful in improving childhood developmental by directly targeting the risk factors such as malnutrition and lack of stimulation for children under 2 years of age (5,6). Recognizing the established effectiveness of ECD care interventions, 'Advancing ECD series by the Lancet, 2017' highlights the need to integrate early childhood development programs into the existing public health services to enhance the reach and effectiveness of ECD packages in improving child development at a national level (7).

In Pakistan, public health facilities remain the most accessible and affordable source of health care especially for the less-advantaged, including the majority of the population who belongs to rural areas. The public health care doctors and health staff currently do not offer ECD care due, in part, to a lack of evidence-based contextualized care package and staff training for delivering integrated child development care. Therefore, we aim to address this need by developing an integrated ECD care package and evaluating its effectiveness in improving child development by embedding it within the already existing public health care centers.

Objectives of the study are:

1. To assess the effectiveness of integrated ECD care package in reducing prevalence of two or more developmental delays among children aged two years, from 38% to 23% in public health care centers and improving childhood stunting compared to usual care.

2. To explore acceptability and feasibility of ECD care package for both the providers and participants by conducting a mix-method process evaluation.

Materials and Methods

1. Study design, settings and participants

A parallel, two arm, cluster-randomized controlled trial will be conducted in public healthcare settings of Pakistan to evaluate the effectiveness of an integrated early child care package in reducing developmental delays among children as compared to treatment as usual. Each public health rural center or public hospital will serve as the cluster unit of randomization to avoid risk of contamination of intervention across arms. 24 clusters of public health centers will be randomized to intervention and control arm, using 1:1 allocation ratio.

Ethical approval for the study has been obtained from National Bioethics Committee (NBC) Pakistan (Ref No NBC255). The study will be conducted in public rural health care centers (RHCs) and sub-district hospitals of two districts i.e., Rawalpindi and Lahore, of Pakistan. In these two selected districts about one-third of the population live in rural and peri-urban areas (i.e., 4.5 million out of 14 million). People seeking medical care from public healthcare centers in Pakistan mostly belong to low socio-economic status. The average household size is around 6.5 persons with two out of five individuals being less than 12 years old. Four out of ten women in these two districts is illiterate. Women are mostly housewives; whereas the majority of men work on small sized farm lands, and supplement their earning by working for daily wages (when possible) (8,9). The rural and peri-urban population in these two districts is served by 24 public health facilities i.e., 16 rural health ECD care centers and 8 sub-district hospitals. Each rural health center and sub-district hospital has three or more doctors and lady health visitors (LHV, a nurse-midwife). The facility-based care is also supplemented by community-based health promotion care by community ('lady') health workers. The public health facilities are the main accessible and affordable source of healthcare for a majority of the target population.

The research participants will be 768 mother-child dyads recruited from 24 public health clusters from Rawalpindi and Lahore Districts. Mother-child dyads where the child is aged 12 to 13 months and the mother does not intend to move out of the area during study period will be considered eligible for participation in the study.

2. Package of Care in intervention and control arm

In the control arm, the designated LHVs at the selected public health facilities will be given a basic training on measurement of anthropometric measures and recording and reporting tools. This basic strengthening of the control facilities will be done to ensure standardized measurements and records across both arms and avoid any possible bias. Mother-child dyads will receive the usual treatment in control arm clusters.

In addition to the procedures listed above, in the intervention arm, a contextualized care package will be developed for the early child development. The care package will include a counselling tool (i.e. flipbook) and training module for LHVs. LHV will be given an additional 2-days training (along with the basic training given in the control arm for measurement and recording & reporting) by the research supervisors delivering standardized counselling sessions to mothers for early child development using the flipbook.

The ECD counselling sessions to mothers will be delivered by LHVs in public health centers on a quarterly basis to promote the early child development. Intervention components of ECD will include: a) infant nurturing and child brain development; b) weaning food and continued

breast feeding; and c) infection control e.g., food hygiene, sanitation, hand washing. Content of the materials used in counselling sessions has been developed in consultation with local and international ECD health experts. The LHVs will have quarterly sessions with the mothers and the ECD counselling will be divided into three sessions (i.e., at child age of 12, 16, and 20 months). Each counselling session to mothers will use 4-5 pages of the pictorial flipbook to deliver the core messages and will take at least 10-15 minutes.

3. Data collection and outcomes

Our primary outcome is reduction in prevalence of two or more childhood developmental delays of children aged 24 months, compared to treatment as usual using the adapted version of the Ages and Stages Questionnaire (10). ASQ is a brief, valid and reliable measure of childhood development that is widely used to assess childhood developmental difficulties ((11).

ASQ has 30 items, with 5 sub-scales measuring communication skills, fine motor, gross motor, problem solving and personal-social skills. Items are rated on a three-point Likert scale (0=No, 5= sometimes, 10=Yes). Total score is calculated by summing the responses of all items.

Secondary outcomes include anthropometric measures of child. Child's height (cm) and weight (kg) will be measured at baseline and endpoint by the research team to measure stunting.

4. Randomization and masking

All 24 health centers and sub-district hospitals in two selected districts will be invited to participate in the study. To minimize the risk of contamination, the unit of randomization will be a health center cluster. Clusters will be randomized before recruitment of research participants from each cluster. The clusters taking part in the study will be randomized to the intervention or control arm by an independent statistician, on a 1:1 allocation ratio. Statistical Package for the Social Sciences will be used to generate the randomization sequence code. Once a public health facility is allocated to a group, then all eligible clients attending the facility and agreeing to participate will receive the same child development care package (either the intervention or the usual care control), regardless of client social circumstances and/or preferences. The assessment team, Principal Investigators and the trial statistician will be blind to the allocation status of clusters.

5. Sample Size Calculations

A sample size of 11 clusters and 385 children per arm (i.e., a total of 22 clusters and 770 mother-child pairs) is required. The assumptions are as follows; decrease from 38% to 16% delays in child development domains; (12) at 80% power, 5% level of significance, average cluster size of 35 and an intra-class correlation coefficient of 0.04 (13) and assuming 10% loss to follow-up.

6. Data Management

Data management team will ensure data quality by running quality control checks to ensure there are not any outliers or missing fields in data. All data files will be encrypted and password protected while hard copy data will be kept under lock and key. Participant safety and confidentiality will be ensured by following Good Clinical Practices (GCP) guidelines (14) for data management.

7. Statistical analysis

Study results will be reported using CONSORT guidelines for cluster RCTs. (15). The data will be single entered and analyzed in SPSS version 21. To minimize data errors, data quality assurance procedures will be used, including training of data entry operators and checking data entry quality at regular intervals (16). The baseline characteristics will be compared across arms to assess baseline comparability of participant characteristics. The individual and cluster level analysis will be done following intention to treat principle. The binary and continuous outcomes will be analyzed by doing crude analysis which will calculate cluster level proportions and means respectively followed by an independent t-test to estimate the treatment effect (i.e., absolute difference in outcome proportions) between the two arms at endpoint using a 95% CI and significance value. Confounding variables will be adjusted by using logistic regression model for individual level data outcomes and covariate adjusted differences for cluster level outcomes. Z-scores for anthropometric measures will be calculated using the WHO child growth standards (17). No interim analysis is planned.

8. Process evaluation

A mix-method process evaluation will be conducted for the study following the guidelines of MRC (18). Quantitative data from study records and qualitative data from in-depth interviews with participants and providers will help inform the main factors associated with implementation of the intervention in public health care settings. Qualitative data will be analyzed using framework analyses to compare information from different participants.

9. Economic evaluation

An exploratory economic evaluation will be conducted to assess the cost-effectiveness of the integrated ECD program in public health care centers. Project budgets and expenditure reports will be used to estimate the costs of intervention. Incremental cost-effectiveness ratio will be calculated using the intervention costs.

10. Ethical considerations

All members of the research team will comply with Good Clinical Practices (14) to ensure safety and rights of participants. Voluntary participation will be ensured for all participants. Written informed consent will be obtained from the participants who are willing to participate in the study using the informed consent forms in local language. Participants' confidentiality will be ensured throughout the project. All reports and publications arising from the study will use anonymised and de-identified data to protect participants' privacy and confidentiality.

Discussion

Despite the established effectiveness of Early Childhood Development (ECD) care packages in improving child development, the majority of the population do not have access to these packages (19). To address poor child development outcomes in low and middle income countries, integration of early child development packages within private or public health care centers has the potential to improve child development at scale (20).

In Pakistan, there is a recognized gap in provision of child development care at public healthcare facilities (21). This study aims to address this gap by establishing the effectiveness of delivering an integrated child development care package in public health centers of two districts of Pakistan. This study will generate evidence for the effectiveness of delivering ECD care package in reducing childhood developmental delays by embedding it within public health care settings.

The intervention and relevant materials will be adapted for delivery in the context of public health centers in consultation with relevant stakeholders and international ECD experts. However, some potential challenges in intervention implementation may include; a) Low-attendance rate of mothers in follow-up sessions; in primary health care settings, patients are less likely to adhere to the follow-up schedule and tend to miss appointments with their healthcare providers which might lead to a lower effectiveness outcome due to less number of sessions attended by the mothers and b) Mothers in treatment arm might be more familiar with the development milestones of their child, leading to recall bias during the endpoint assessment. A process evaluation study will help explore these challenges in detail after completion of trial.

The study aims to create a public health impact by embedding the contextualized integrated package of early child care within the public health care system of the country. The findings from this study will be disseminated to relevant stakeholders including policymakers, researchers, program managers and national and international agencies using different platforms.

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Trial registration
The trial has been registered with the Current Controlled Trials ISRCTN14396904.

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