Protocol for a Systematic Review of Effects of Parenting Interventions on Early Childhood Development in Low- and Middle-Income Countries

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BACKGROUND
Recognizing approaches for spreading information on positive parenting to parents or caregivers can enhance early childhood development in low- and middle-income countries (LMICs). The purpose of the review is to assess effects of parenting interventions on early childhood development in LMICs.

METHODS
We will use The Cochrane Handbook for Systematic Reviews of Interventions and the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement to apprise the methodology of this review. We have conducted pilot searches considering controlled clinical trials only. We intend to undertake a comprehensive search of peer-reviewed as well as grey literature accessible up to 30th September 2018. We will search relevant electronic databases as well as prospective trial registries and reference lists of all potentially relevant publications. Two authors will independently screen studies detected by search strategy initially on the basis of title/abstract and then on the basis of full texts against predefined inclusion criteria. Discrepancies between primary reviewers will be settled through consensus and mediation by a third reviewer.

RESULTS
We will assess the effects of parenting interventions on socio-emotional development, physical development, language and motor development, learning (cognitive development, school readiness), and maternal depression. The results will be presented in the form of PRISMA flow diagram, ‘Characteristics of Studies’ table, Forest Plots, and ‘Summary of Findings’ Table.

CONCLUSIONS
We will disseminate the findings to relevant stakeholders through publications, conference presentation(s); etc. The systematic review can make a noteworthy contribution to the evidence of efficacy of parenting interventions for promoting early childhood development in LMICs.

KEY WORDS
Parenting Intervention, Socio-Emotional Development, Physical Development, Language and Motor Development, Learning

ABSTRACT

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BACKGROUND

Early child development (ECD) includes physical, social, emotional, cognitive and motor development in first eight years of life. (1) This period is very vital as maturation of brain ensues in all domains: cognitive, socio-emotional and physical. (2) Of 559 million children below the age of five years in developing countries, over 200 million children do not attain their developmental potential. (2,3) In low-income and middle-income countries (LMICs), 39% of children below the age of five years have compromised brain development. (2) Recent WHO 2016 estimations disclose that 250 million i.e. 43% of children in LMICs are not able to realize their full development potential usually due to insufficient nutrition and insufficient stimulus and because of adversities they face in their initial, formative years. (1) The greatest percentage of disadvantaged children reside in sub-Saharan African countries while highest number reside in south Asia. (6) The knowledge of ECD and its essential neurobiology are increasingly raised worldwide. (6) ECD is in the priority list for WHO, as it is provides a prospect to enhance wellbeing and equity. (1) The UN Sustainable Development Goals offers prospects to execute interventions to promote ECD. (5-9)

Various interventions have been undertaken to promote ECD. One such intervention is a Parenting programs which comprises community-based parent counselling or parent-group sessions, or center-based preschool and daycare programs that provide families with information and assistance to aid survival, growth, and well-being of children. (10-15) It delivers direct learning know-hows to children and their family members. (12,13) Along with health and nutrition support, parenting programs stress on encouraging stimulation of children. (10) Studies have exhibited moderate-to-large effect sizes for responsive parenting interventions on numerous attributes of ECD. (16,17) However, in other study, children who received only stimulation did not exhibit sizeable difference in either weight or height. (18) In another study, stimulation (either stimulation alone and blended with other interventions) promoted mental scores but had no effect on motor scores. (19)

Systematic reviews have been undertaken on childhood overweight or obesity, (20) non-progressive motor disorders, (21) prevention of unintentional injuries in childhood, for improving parental and infant mental health, for children with intellectual disability, (22-25) for the treatment of physical child abuse and neglect, for improving psychosocial outcomes for teenage parents and their children, (22-23) in children and adolescents with conduct disorder and delinquency, (26) for children with autism spectrum disorder, (27) for early-onset conduct problems, (28) for Attention Deficit Hyperactivity Disorder (12,13,29) for improving emotional and behavioural adjustment in young children, (12,13,23); etc. However; the effect of parenting programs for promoting ECD in LMICs especially with reference to South Asian countries has not been systematically reviewed.

Appraising and educating caregivers about the advantages of positive parenting can encourage and enable them to undertake effective parenting strategies, which in turn can promote early childhood development. Hence, it is necessary to recognize appropriate interventions for appraising and educating parents or caregivers about the importance of positive parenting for promoting ECD. There is a need to synthesis the evidence to decide whether parenting programs can be incorporated in aiding these children attain that potential by improving their physical, cognitive, and socio-emotional dimensions and, if data permit, to explore the best parenting intervention for this group of population. Therefore, systematic evaluation of the role of parenting programs in ECD is warranted. Findings of this review will assist paediatricians, caregivers, public health experts and policy makers alike for incorporating parenting interventions in improving early childhood development. This systematic review embodies a vital effort in exploring the existing evidence on parenting interventions for promoting ECD and will permit detection of grey areas for future research.

METHODS

This systematic review protocol has been registered in the International Prospective Register of Systematic Reviews (PROSPERO) and has been developed and reported as per the 'Preferred Reporting Items for Systematic reviews and Meta-Analysis - Protocol (PRISMA-P)' guidelines. This systematic review and meta-analysis will be conducted from October 2018 to January 2020. We will undertake meta-analysis for homogenous interventions and outcomes, incorporating random-effects model. We will assess statistical heterogeneity using $\chi^2$ test, quantify it using $I^2$ statistics and explore the cause of statistical heterogeneity through subgroup analysis. We will determine the quality of evidence using Grade Criteria. (12,13,30)

Inclusion Criteria

Types of Studies- We will include randomized control trials (RCTs) that assessed the effect of exposure of parenting interventions in LMICs on Early Childhood Development. We will include randomized controlled trials (RCTs), with randomization at individual or cluster level. We will only include cluster RCTs with a minimum of two intervention and two control clusters. We will exclude non-randomized trials, cross-over trials, trials with only one arm, case-control studies, cross-sectional studies and cohort studies. We will link multiple reports of the same study as a one study. We will include only studies undertaken in LMICs, as defined by the World Bank (World Bank, N.D.).

Types of Participants- This review will emphasize on participants who are caregivers (defined as parents, legal guardians or other persons assuming parental role) of children below three years of age to whom education about positive parenting is given.

Types of Interventions- We will emphasize on interventions to appraise or educate caregivers of children below three years of age about the significance of positive parenting practices which may include community-based parent counseling sessions or parent-group sessions or center-based preschool sessions or day-care programs or seminars or workshops, or one-on-one education that provide families with info and assistance to aid survival, growth, development and well-being of children. Appraisal and education about
parenting interventions may be provided either face-to-face, via mail, through phone calls or mobile text messages.

Types of Comparison- We intend to compare the effect of parenting interventions to no intervention or standard parenting practices in the study setting or alternative interventions or parenting interventions supplemented with other interventions.

Primary Outcomes
Main outcome measures will be outcomes related to early childhood development, in terms of socio-emotional development, physical development, language and motor development.

Secondary Outcomes
Secondary outcome will be outcomes related to maternal health like learning (cognitive development, school readiness) and maternal depression.

Search Methods for Identification of Studies
We will undertake an extensive search of peer-reviewed as well as grey literature existing up to 30th September 2018. We will search electronic databases like MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), Scopus,ISI Web of Science (Science Citation Index), Cumulative Index of Nursing and Allied Health (CINAHL) and other relevant databases for identifying studies. For ongoing clinical trials, we will search the WHO International Clinical Trials Registry Platform and Clinicaltrials.gov. Additionally, we will check reference lists of potentially eligible studies and will search for conference abstracts. We will contact investigators and experts associated with this field to obtain info on unpublished works or ongoing trials. For searching, we will use Medical subject headings (MeSH) and text word terms and will tailor searches to individual databases. We will not apply any language or date restrictions. We intend to re-run searches prior to final analyses, and retrieve further studies for inclusion.

Selection of Studies
We will employ systematic review methods developed by Cochrane Handbook of Systematic Reviews. Two reviewers will pre-screen studies identified in the electronic search for relevance using an on-line software Rayyan. Studies will be excluded from review if they are not from peer-reviewed journals, are not RCTs, or if the population, exposure/interventions and outcomes are not of interest to the review. Two reviewers will examine full papers for eligibility against the study inclusion criteria. Discrepancies will be resolved by discussion and consensus with a third reviewer. Multiple reports of the same study will be collated and assessed as one study.

Data Extraction and Management
Once the study is included in the review, two reviewers will then independently extract data using a pre-designed and pilot-tested data extraction form and the third reviewer will crosscheck the data. Data extraction from will include source of citation and other contact details, methods of the study (like study setting, study design, study duration, total groups or arms; etc.), details of participants (like participant number in each group, socio-demographic characteristics, eligibility criteria, etc.), details of interventions (like type of intervention, duration of intervention, frequency of intervention, description of control intervention(s); etc.), details of outcome measures (outcome measurement, outcome definition, scales used if any with time point of collection and reporting; etc.), and other relevant details (like sources of funding; etc.). These details will be tabulated in ‘Characteristics of included studies’ table. In cases of missing or incomplete information in included studies, we will contact corresponding authors for further information.

Assessment of Risk of Bias in Included Studies
We will use an approach proposed by Cochrane Collaboration for judging the risk of bias (Higgins JPT and Green S, 2011). Assessment of risk of bias (RoB) will be done at the outcome as well as study level. Two authors will independently assess RoB in each included study for selection bias (sequence generation, random allocation, allocation concealment; etc.), performance bias (measurement of outcomes, precision, other threats to validity), detection bias (blinding the outcome assessment, other threats to validity), attrition bias (completeness of the outcome data, number of dropouts; etc.), reporting bias (completeness of outcome reporting), and other sources of bias. For each domain, we will classify the risk of bias, as ‘low’ if the criterion is adequately addressed, ‘unclear’ if the information provided is insufficient to make an informed judgement or ‘high’ if the criterion is not sufficiently addressed. The risk of bias will be presented in the report as the risk of bias table and graph.

Measures of Treatment Effect
We will use the latest version of the Cochrane Collaboration Review Manager statistical software for conducting analysis (Review Manager, 2014). We will not perform Meta-analysis if there are variations in methods, intervention and outcomes reported. In such a case, we will describe the data narratively. We will use effect measures as Risk Ratio (RR) and its 95% confidence intervals (CIs) or Risk Difference (RD) for dichotomous variables, and Mean Difference (MD) or Standardized Mean Difference (SMD) for continuous variables. We anticipate heterogeneity of study designs and participants and hence we will pool RRs and 95% CIs of studies with identical interventions and outcomes using random-effects meta-analysis. We will incorporate data from cluster RCTs in meta-analyses after adjusting for design effect. For this we will use intra-cluster correlation coefficient obtained from same or a similar cluster RCT. In case of studies of long duration and with repeated observation, we will consider a single time point and analyse data at that time for studies in which it is presented. Alternatively, we will consider a longest follow up from each study. For studies with more than two intervention groups, we will undertake meta-analysis by creating different comparisons between all likely pairs of intervention groups. To avoid the unit-of-analysis problem care; we will avoid inclusion of same participants twice in the same meta-analysis.
Assessment of Heterogeneity
We will measure the extent of heterogeneity by $\chi^2$ test of homogeneity (with significance defined at the 10% $\alpha$-level). We will use I² statistics for quantifying inconsistency across studies and to assess its impact on the meta-analysis. If severe heterogeneity is observed, two reviewers will independently relook if data have been correctly extracted or entered into RevMan. We will investigate the cause of any pragmatic statistical heterogeneity through subgroup analysis.

Subgroup and Sensitivity Analysis
We will perform subgroup analysis for our primary outcomes. We have selected subgroups based on a explicit hypothesis. The impact of a parenting interventions may be arbitrated by cultural background and, in precise, by the approach in a specific culture. Hence, we will analyse, where possible, studies by regional characteristics of participants. We will undertake a separate subgroup analysis with regards to duration, timing and content of exposure to parenting interventions. To integrate the assessment of risk of bias in the review process; we will undertake a subgroup analysis for different primary outcomes stratified for risk. To determine the robustness of the findings of the review to risk of bias, we will undertake a sensitivity analysis by including and excluding studies with a high risk of bias).

Assessment of Reporting Biases
If meta-analysis involves ten or more than ten studies, we will use Funnel plots (plots of the effect estimate from each study against the standard error) to assess the possibility of bias associated to sample size of trials, which will suggest possible publication bias across studies.

Grading of Studies
Two reviewers will review the data on each primary outcome. GRADE approach will be used to assess the certainty of the evidence for each primary outcome which includes consideration of risk of bias, heterogeneity, directness of evidence, precision of effect estimates and risk of publication bias. We will use GRADE profiler (GRADEpro GDT, 2015) to assess the overall quality of the evidence and prepare Summary of Findings (SoF) table. Accordingly, we will grade studies as ‘High’ quality if further research is very unlikely to change our confidence in the estimate of effect), ‘Moderate’ quality (if further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate), ‘Low’ quality (if it is found that the further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate), and ‘Very low’ quality (if we are very uncertain about the estimate).

Ethics
No ethical issues are foreseen.

Dissemination
Findings of this study will be disseminated amongst relevant stakeholders through dissemination workshops, conference presentation(s), publications, plain language summaries, policy brief(s), etc. Findings of the review can make a noteworthy impact to the evidence base of interventions for promoting early childhood development in LMICs. The study will gather evidence on how parenting interventions can improve early childhood development. We foresee that this evidence will be valuable to national and international stakeholders involved in promoting early childhood development in LMICs.

Reporting of the Systematic Review and Meta-Analysis
The ‘Preferred Reporting Items for Systematic reviews and Meta-Analysis’ (PRISMA) guidelines will be used to report our review. (31-41)

Strengths and Limitations of This Study
- This study will further strengthen the evidence base on effective parenting interventions for promoting early childhood development in resource-limited settings.
- This protocol has been drafted as per the recently published PRISMA-P guidelines.
- We will use GRADE criteria to assess the strength of the evidence base for each primary outcome.
- The authors of this protocol are from different disciplines with different focuses like public health, child psychology, child health, biostatistics, clinical medicine, and nutrition.
- Despite using comprehensive search strategies, possibility of missing potentially relevant studies cannot be ruled out.

Funding
This project is supported by a grant from Grand Challenge Canada.

Competing Interests
All reviewers have completed ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf. All reviewers declare no financial interest in the proposed review and any associations or actions that could seem to have opinionated this work.

Search Strategy for PubMed
Search ((((((Children[Title/Abstract]) OR Child[Title/Abstract]) OR Under-five [Title/Abstract]) OR “Under five” [Title]) OR Infant* [Title/Abstract]) OR Toddler* [Title/Abstract]) OR Kid* [Title/Abstract]) OR childhood [Title/Abstract]) OR “Child” [Mesh]) AND (((((((((((“responsive care” [Title/Abstract]) OR “positive parenting” [Title/Abstract]) OR “parenting program” [Title/Abstract]) OR “parenting intervention” [Title/Abstract]) OR “child stimulation” [Title/Abstract]) OR “psychosocial stimulation” [Title/Abstract]) OR “early childhood development” [Title/Abstract]) OR ECD[Title/Abstract]) OR “early development”[Title/Abstract]) OR “child development intervention” [Title/Abstract]) OR “home Intervention” [Title/Abstract]) OR “home visiting” [Title/Abstract]) OR “responsive stimulation” [Title/Abstract]) OR “early childhood stimulation” [Title/Abstract]) OR “early stimulation” [Title/Abstract]) OR “caregiver training program” [Title/Abstract]) OR “environmental enrichment” [Title/Abstract]) OR “mother-infant relationship” [Title/Abstract]) OR “maternal education” [Title/Abstract]) OR
Search Strategy for Central
ID Search
# 1 Children
# 2 Child
# 3 Under-five
# 4 Under-five
# 5 infant
# 6 toddler
# 7 kid
# 8 MeSH descriptor: [Child] explode all trees
# 9 pre-school
# 10 preschool
# 11 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR
# 9 OR #10
# 12 "responsive care"
# 13 "responsive parenting"
# 14 "positive parenting"
# 15 "parenting program"
# 16 "parenting intervention"
# 17 "child stimulation"
# 18 "Psychosocial stimulation"
# 19 "early childhood development"
# 20 ECD
# 21 "early development"
# 22 "development program"
# 23 "child development intervention"
# 24 "home Intervention"
# 25 "home visiting"
# 26 "responsive stimulation"
# 27 "early childhood stimulation"
# 28 "early stimulation"
# 29 "caregiver training program"
# 30 "environmental enrichment"
# 31 "mother-infant relationship"
# 32 "maternal education"
# 33 "training of mothers"
# 34 "mother’s training"
# 35 MeSH descriptor: [Parenting] explode all trees
# 36 #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18
# OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR
# 26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33
# OR #34 OR #35
# 37#11 AND #36 in Trials

References


