Cumulative Risk and Children's Developmental Outcomes: Evaluation of the 'Mentor Mothers' Perinatal Intervention in South Africa

Kamilla Mamedova

D.Clin.Psy. thesis (Volume 1), 2019

University College London

UCL Doctorate in Clinical Psychology

Thesis declaration form

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signature: 

Name: Kamilla Mamedova

Date: 3rd July 2019

Overview

This thesis explores the topic of early childhood development (ECD) interventions in low- and middle- income countries (LMICs) in three parts.

Part 1 is a systematic literature review of systematic reviews which has two aims. First, the review examines how effective psychosocial stimulation interventions are in relation to children's cognitive outcomes and parenting practices that facilitate children's cognitive development. Eight systematic reviews met the inclusion criteria and these demonstrated evidence of effectiveness of psychosocial stimulation interventions. Second, the review identifies the common techniques used across effective interventions. This is done by conducting common practice elements analysis of 16 intervention protocols.

Part 2 is an empirical study that used longitudinal data from a cluster randomised controlled trial of a perinatal home-visiting intervention in South Africa. Children's five-year follow up outcomes were evaluated to explore the long term effects of the intervention. The results showed no effects of the intervention at 5 years, in contrast to findings from earlier follow-up points, which showed benefits. Further, the cumulative risk framework was applied to investigate the moderation relationship between intervention, cumulative risk and children's outcomes. Cumulative risk exerted a moderating effect on the relationship between intervention and children's physical health outcomes. Children with higher levels of early cumulative risk benefited more from the intervention than children with lower levels of early cumulative risk. However, no moderating effects were observed on the relationship between intervention, cumulative risk and children's behavioural and cognitive outcomes.

Part 3 is a critical appraisal of the process of carrying out this research. It consists of reflections regarding the selection of the research topic and the gradual development of research questions; a discussion of the challenges associated with the process of conducting a systematic review of systematic reviews and a common elements analysis of intervention protocols; and considerations on the advantages and constraints of using secondary data analysis methodology.

Impact statement

The current project generated a number of insights that are applicable to academic research, development of community health services as well as policy considerations in low- and middle- income countries (LMICs).

The academic contribution of the study pertains to applying the cumulative risk theory of early childhood development to the global context. We tested the cumulative risk hypothesis by using longitudinal data available from a randomised controlled trial of a perinatal home-visiting intervention in a high-risk cohort of mothers in South Africa. We demonstrated support for the cumulative risk hypothesis in this context. This is an important finding that shows that cumulative risk metric holds predictive power not only in relatively well-resourced settings where the theory was developed (the UK and the USA), but also when exposure to adversity is significantly higher and resources are more scarce (LMICs).

Furthermore, the study evaluated the long term intervention effectiveness and the relationship between intervention and cumulative risk, i.e. the ability of the perinatal intervention to mitigate against the impact of early adversity. This work therefore adds to the evidence base of early childhood development interventions. We demonstrated a significant interaction between cumulative risk and children's physical health outcomes at 3 years post-birth. Children of mothers with higher cumulative risk during pregnancy benefitted more from being in the intervention condition, than children of mothers with lower levels of risks. This suggests that the most vulnerable benefit from the

intervention the most. Thus, the intervention's aim to protect children against early adversity was shown to be successful in relation to physical wellbeing.

This study further contributed to the understanding that the early intervention benefits are not maintained at longer term follow up of 5 years post-birth. In other words the intervention did not mitigate against psychosocial risks longitudinally. These findings are valuable, as they contribute to rigorous evaluation of such interventions. They can therefore help inform future planning of family support programmes, by considering strategies that can be employed to maintain the effects demonstrated at earlier time points. Future research will need to address this shortcoming of the intervention, possibly through techniques aimed at refreshing previously gained parenting skills and generalising parental knowledge to subsequent developmental stages of the child.

Elimination of risks in early childhood is a challenging task that requires a good understanding of the processes of child development, as well as the mechanisms through which interventions exert their effects. In this study, we investigated one such mechanism (cumulative risk) and this has implications for policy and practice. Cumulative risk can function as an important tool for identifying children most at risk in LMICs and offering support to these children as a matter of priority.

Finally, the current study contributes to the existing pool of knowledge which informs global strategies such as Sustainable Development Goals (SDGs) endorsed by most governments to improve health and wellbeing of their populations. Improving early child development is at the forefront of these efforts to tackle inequity, poverty and social injustice. We demonstrated some

challenges in maintaining these improvements following intervention, which confirms the need to invest more efforts into investigating what is required for family support interventions to work in the long term.

Table of Contents

PART 1: LITERATURE REVIEW 13

PSYCHOSOCIAL STIMULATION INTERVENTIONS FOR CHILDREN IN LOW- AND MIDDLE-INCOME COUNTRIES: AN OVERVIEW OF REVIEWS AND A COMMON ELEMENTS ANALYSIS..13

1. INTRODUCTION....16

1.1 The present review....19

2. METHOD....20

1.2 Search strategy....21

1.3 Quality assessment....22

1.4 Common Practice Elements: Data Extraction....25

1.5 Common Practice Elements: Coding....26

3. RESULTS....27

1.6 Description of reviews....27

1.6.1 Interventions....28

1.6.2 Child cognitive development....29

1.6.3 Parenting practices....31

1.7 Quality assessment of systematic reviews....33

1.8 Common elements analysis....34

4. DISCUSSION....55

1.9 Summary of findings: systematic review of reviews....55

1.10 Summary of findings: Common Elements analysis....58

1.11 Implications for practice and future directions....64

5. CONCLUSION....66

REFERENCES....67

PART 2: EMPIRICAL PAPER....74

CUMULATIVE RISK AND CHILDREN'S DEVELOPMENTAL OUTCOMES: EVALUATION OF THE 'MENTOR MOTHERS' PERINATAL INTERVENTION IN SOUTH AFRICA....74

1. INTRODUCTION....77

1.1. Cumulative risk and children's outcomes....77

1.2. Supporting women raising children in high-risk environments: perinatal interventions in LMIC context....80

1.3. Philani Mentor Mothers Programme....82

1.4. The present study....84

2. METHOD 86
2.1. Participants and Design 86
2.2. Measures 90
2.2.1. Maternal measures 90
2.2.2. Cumulative risk scale 93
2.2.3. Child outcomes 94
2.3. Statistical Analysis 95
3. RESULTS 97
3.1. Data preparation 97
3.2. Sample characteristics 98
3.3. Descriptive statistics 99
3.4. Effects of intervention on child outcomes at 5 years 104
3.5. Cumulative contextual risk 104
3.5.1. Children's outcomes at 5 years 105
3.5.2. Children's outcomes at 3 years 108
3.6. Subdomains of cumulative contextual risk 112
4. DISCUSSION 115
4.1. Summary of findings 115
4.1.1. Effectiveness of the intervention at 5 year follow up 115
4.1.2. Cumulative risk and behavioural outcomes 120
4.1.3. Cumulative risk and cognitive outcomes 121
4.1.4. Cumulative risk and physical health outcomes 123
4.1.5. Subdomains of risk 124
4.2. Strengths and limitations 125
4.3. Implications and future directions 127
5. CONCLUSIONS 131
REFERENCES 132

PART 3: CRITICAL APPRAISAL 142

1. INTRODUCTION 143
2. SELECTION OF TOPIC 143
3. LITERATURE REVIEW 144
Systematic review of reviews 144
Common elements analysis 147
4. EMPIRICAL PAPER 150
5. CONCLUSIONS 154
REFERENCES 155

APPENDICES 157

APPENDIX A – AMSTAR 2 158
APPENDIX B – ADAPTED PROTOCOL CODING SHEET 163
APPENDIX C – PRACTICE ELEMENTS DESCRIPTIONS 166

List of Tables

PART 1: Literature review

Table 1. Search Terms 22
Table 2. Broad themes of common practice elements 35
Table 3. Summary table of the scope of reviews of ECD psychosocial stimulation intervention studies. 39
Table 4. AMSTAR2 Quality appraisal of reviews 42
Table 5. Practice Elements occurring and their descriptions. Elements that did not occur in the protocols are excluded from this list. 45
Table 6. Intervention protocols included in the common elements analysis and information on the corresponding studies. 49

PART 2: Empirical paper

Table 1. Characteristics of the sample by Intervention (N=644) and Standard Care (SC) (N=500) groups 90
Table 2. Child outcomes at 3 years by Intervention and Standard Care groups 100
Table 3. Child outcomes at 5 years by Intervention and Standard Care groups 101
Table 4. Correlations between children's behavioural and cognitive outcomes, maternal depression, and cumulative risk. 102
Table 5. Effects of predictor and moderator variables on children's outcomes at 5 years. 108
Table 6. Effects of predictor and moderator variables on children's outcomes at 3 years. 111
Table 7. The relationships between subdomain of risks and children's outcomes at 3 years. 114

List of figures

PART 1: Literature Review

Figure 1. A flowchart of the search strategy. 23
Figure 2. Practice elements profile for ECD intervention protocols. 44

PART 2: Empirical Paper

Figure 1. Outline of the participant flow of the clustered randomised trial. 89
Figure 2. Conceptual and statistical diagrams of the relationships between the variables of the study. 105
Figure 3. Relationship between cumulative risk, intervention conditions and predicted hospitalisations at 3 years. 112
Figure 4. Relationship between maternal risk, intervention conditions and predicted hospitalisations at 3 years. 113

Acknowledgements

I would like to thank my supervisor Professor Pasco Fearon for his guidance throughout each stage of the research process and for directing me toward a study that aligned with my interests. I would like to express my gratitude to Professors Mark Tomlinson and Mary Jane Rotheram-Borus for agreeing to my involvement with their work. Special thanks to Ellen Almirol, data manager analyst, for her kind patience in helping me decipher the enormous dataset. I would also like to acknowledge the contributions to the process of protocol coding by our research volunteer Rosie Powell-Davies; and Dr Rob Saunders for offering his support during the foggiest phase of the statistical analyses.

I want to acknowledge the influence over the past three years of my clinical supervisors, particularly Dr Sarah Finnis, Dr Astrid Schepers and Dr Marion Bates who have shaped my professional thinking and were great sources of inspiration. I thank them for the learning and the wisdom they generously shared. Thanks to my fellow trainees for all the fun times in between the hard work; special mention goes to Kirsty Langley for being a calming presence and a friend throughout this training journey.

For my family, who have supported me always, I will be forever grateful. A big thank you to my mother, my own mentor and role model, who selflessly helped me make one of the most difficult decisions of my life 6 years ago and without whom this would not be possible.

Finally, to Sebastian - thank you for the head massages, for the oxytocin cuddles, and for keeping the coffee supplies flowing during the busiest writing times. Most of all, thank you for your love, for inspiring me to think big and always believing in me.

Part 1: Literature review

Psychosocial Stimulation Interventions for Children in Low- and Middle- Income Countries: A Review of Reviews and a Common Elements Analysis

Abstract

Aims. The aim of this paper is twofold. First, it reviews the evidence-base of psychosocial stimulation interventions conducted in low- and middle-income countries (LMIC) in relation to young children's cognitive outcomes and parenting practices that facilitate children's cognitive development. Second, the review identifies the common techniques being used across effective interventions.

Method. A systematic review of reviews of psychosocial stimulation interventions aimed at parents and children in LMIC was performed. Reviews were identified through academic database searches (PsycINFO and Web of Science), as well as subject-specific database searches (EPPI Centre, WHO Global Health Library, UNICEF Publications Database). The PracticeWise coding system was used to distil the practice elements from intervention protocols of interventions that showed effectiveness.

Results. Eight systematic reviews (4 of which were meta-analyses) that met inclusion criteria were identified. These demonstrated evidence of effectiveness of psychosocial stimulation interventions, carried out in LMIC, independently and as part of more comprehensive ECD programmes. Comprehensive interventions of higher intensity and longer duration yielded better results. From the reviews, 16 intervention protocols were identified and coded for common practice elements. The analysis of protocols revealed that three practice elements were found across all 16 intervention protocols: 'caregiver psychoeducation', 'talking to baby', and 'play/pretend'. Several practice elements were found in more than 80% of the protocols. These were:

'therapist praise', 'attachment building', 'responsive care/parenting', 'use of toys', and 'praise'.

Conclusions. Psychosocial stimulation interventions conducted in LMIC can be effective in improving children's cognitive development and support parenting practices that facilitate children's cognitive development. Identification of common practice elements of effective interventions can aid in informing future development and implementation of early child development programmes in low-resource settings.

1 Introduction

Early Childhood Development (ECD) interventions aim to mitigate the risks posed to physical and cognitive development in early childhood for children living in low-resource settings. These risks include poverty, undernourishment and stunting, lack of learning opportunities and other forms of early childhood adversity including parental depression, domestic violence and drug abuse. These risk factors can lead to significant developmental delays, health problems and prevent children reaching their full potential throughout their lives and their functioning as adults (Walker, Wachs, Grantham-McGregor, Black, Nelson, Huffman, et al., 2011).

Research has shown that environmental stimulation affects human brain development most critically in the early years (Grantham-McGregor, Cheung, Cueto, Glewwe, Richter & Strupp, 2007). Therefore interventions implemented during early childhood can have long term benefits for children, including an increased ability to learn, greater school achievement and overall quality of life (Britto, Lye, Proulx, Yousafzai, Matthews, Vaivada et al., 2017).

These interventions are often targeted at parents to promote developmentally appropriate nurturing care by providing learning opportunities for the young child and helping parents to engage the child in stimulating play activities (Eshel, Daelmans, Cabral de Mello, & Martines, 2006). These interventions further involve supporting caregivers to enhance parenting and caregiving knowledge, attitudes, practices and promoting positive parent-child interactions to improve children's physical and socio-emotional outcomes (Eshel et al., 2006).

Inadequate stimulation and interaction can affect child development through disrupting basic neural circuitry (Black, Walker, Fernald, Andersen, DiGirolamo, Lu, et al., 2017) whereas early stimulation may enhance neurocognitive processing and brain functioning, and compensate for developmental losses. The evidence for this is particularly strong for preterm babies (Grantham-McGregor et al., 2007; Spittle & Treyvaud, 2016). There is a growing evidence that parenting interventions that support parental psychosocial stimulation are effective in improving children's cognitive outcomes (Aboud & Yousafzai, 2015; Britto et al., 2017; Eshel et al., 2006). Studies from across the developed (Eshel et al., 2006; Hurt, Paranjothy, Lucas, Watson, Mann, Griffiths, et al., 2018) and developing world, including Jamaica, Pakistan, and Uganda have demonstrated that psychosocial stimulation improves childhood development outcomes across cognitive, socioemotional and motor development domains, and even later adult outcomes (Britto et al., 2017).

However there remain gaps in our knowledge regarding the impact of parental psychosocial stimulation programmes and interventions. The majority of the interventions delivered in LMIC are based on evidence from parenting programmes from high-income countries (Lipina & Colombo, 2009) where settings and level of resources differ considerably from low- and middle-income settings. Thus generalisability of findings to low resource settings of LMIC is often limited.

The existing effectiveness research on ECD interventions in low and middle income settings is further characterised by significant heterogeneity in the contents of interventions. What constitutes 'psychosocial stimulation'

interventions varies across different studies and countries. Psychosocial stimulation interventions have been described as facilitating children's non-health related outcomes, including elements of positive parent-child interactions, providing positive attention and responsiveness to cues and milestones, encouraging children's autonomy and exploration of the environment, as well as promoting attachment (Britto et al., 2015; Engle & Lhotska, 1999). What these interventions look like in practice however is not uniform or standardised, nor always easily inferred from the published literature.

As the evidence base for ECD interventions grows, there is an increasing need to systematically study and identify the necessary and sufficient components for effective early years psychosocial interventions. Moving away from pure effectiveness research, where treatments are often delivered as manualised packages, it is becoming more important to also consider the key intervention contents, in order to inform general practice. Understanding what the 'winning' ingredients of interventions are becomes particularly relevant when the aim is to scale up these interventions in the context of LMIC, where human resources, access to specialists, and training opportunities may be limited, and where the interventions are likely to be delivered by paraprofessionals in the community.

In recent years methodologies have arisen that allow researchers to assess the core elements of effective interventions. One such methodology is known as Distillation and Matching Model or Common Practice Elements analysis, developed by Chorpita, Daleiden, & Weisz (2005). Distillation is a method that allows interventions to be formulated not as single units of analysis

(as is common in systematic reviews), but rather as a collection of individual strategies, techniques or components that can be grouped empirically. This is done through systematic coding of key characteristics of intervention trials and protocols to identify common 'practice elements' (Chorpita, Daleiden, & Weisz, 2005). The matching method involves summarising client, setting or other factors that might be relevant considerations for selecting an intervention, allowing for the possibility of addressing the question of 'what works for whom and under what conditions?'. This approach is helpful in gaining a deeper understanding of strategies found in effective treatments, but it is important to note that this does not mean that such an analysis can identify the 'active ingredient' of an intervention (Chorpita, Daleiden, & Weisz, 2005).

This methodology may be useful for enhancing our understanding of the effective components of ECD interventions despite the heterogeneous nature of interventions tested across the world. To date, this methodology has not been applied to study common elements of psychosocial stimulation interventions in the early years. As such, this review is the first to distil the practice elements included in effective psychosocial stimulation interventions with a specific focus on early years parenting practices in LMIC.

1.1 The present review

The current review aims to identify effective ECD psychosocial stimulation interventions and systematically document their common practice elements. To identify the effective intervention programmes, I begin by reviewing existing systematic reviews and meta-analyses that have investigated the effectiveness of early childhood development interventions that included psychosocial

stimulation as part of the intervention. This systematic review of reviews focuses specifically on studies that have assessed impact on children's cognitive development in LMIC settings.

The second objective of the review is to extract the intervention protocols from the studies identified in high quality reviews as showing evidence of efficacy and conduct a common practice elements analysis of these to gain an understanding of the intervention elements shared by the effective interventions. The review focuses only on the distillation aspect of the common elements analysis methodology.

Thus, the review addressed two questions:

1. Are psychosocial stimulation interventions delivered in low and middle income countries effective in regards to children's cognitive development and parenting practices that support children's cognitive development?
2. What are the common practice elements in effective interventions?

2 Method

A systematic review of reviews was conducted using two electronic databases (PsycINFO and Web of Science) as well as three subject specific databases (EPPI Centre, WHO Global Health Library, UNICEF Publications Database). Reference lists of relevant reviews were consulted to identify any additional reviews not captured by the selected database searches.

2.1 Inclusion criteria

The current review included systematic reviews that met the following criteria:

(1) **Population:** The review examined studies of early childhood psychosocial interventions targeting parents of young children (up to 5 years old).

(2) **Intervention:** Included review articles must have assessed individual studies that delivered and evaluated psychosocial interventions either as a stand-alone psychosocial stimulation intervention or combined with other intervention strategies, such as nutritional programmes. The review included psychosocial interventions including group, individual, home visitation, family-based, or community-based interventions. It excluded interventions that focussed solely on basic needs such as nutrition.

(3) **Outcome:** The review examined the effects of ECD interventions on cognitive outcomes in children or parenting practices focused on providing cognitively stimulating environments for children. Reviews focussed on parenting practices and parental mental health were included if child cognitive outcomes were assessed in the studies.

(4) **Setting:** the review examined studies that aimed to assess ECD interventions in low- and middle-income countries.

2.2 Search strategy

To identify reviews meeting the inclusion criteria PsycINFO and Web of Science databases were searched for entries containing the following terms (and synonyms) in the title or abstracts: psychosocial stimulation, responsive parenting intervention, cognitive development, low- and middle-income countries, review or meta-analysis. A comprehensive list of key words is shown

in Table 1. The search terms selected were broadly inclusive with the purpose of finding reviews with a wide range of cognitive outcomes. No limits were set on date of retrieval for the reviews. No limits were applied to searches in terms of language. Hand searches of reference lists and the three additional subject specific databases were also conducted to identify additional reviews.

Table 1. Search Terms

Terms		Results
1	"early childhood development" OR "cognitive development" OR "language"	514,277
2	"parent*" OR "parent* sensitivity" OR "responsive caregiving" OR "responsive parent*" OR "sensitive parent*" OR "responsive care" OR "parent child relation*" OR "mother child relation*"	1,682,431
3	1 AND 2	22,065
4	"childrearing practices" OR "parent child communication" OR "parent* style"	2,789
5	4 OR 2	1,682,465
6	"psychosocial stimulation" OR "stimulation intervention*" OR "stimulation"	583,279
7	5 AND 1	22,069
8	7 AND 6	517
9	"review" OR "meta-analysis"	2,323,002
10	9 AND 8	92
11	"low- and middle- income countr*" OR "developing countr* OR "low resource setting*" OR "task shifting" OR "task sharing"	120,372
12	11 AND 10	41

Following identification of reviews through databases and reference list searches, records were screened for relevance on the basis of title and abstract. Thirty three reviews not relevant for the current review were thus excluded. The search strategy yielded 15 reviews that were assessed in detail. Of these, 8 reviews fulfilled the inclusion criteria set out above.

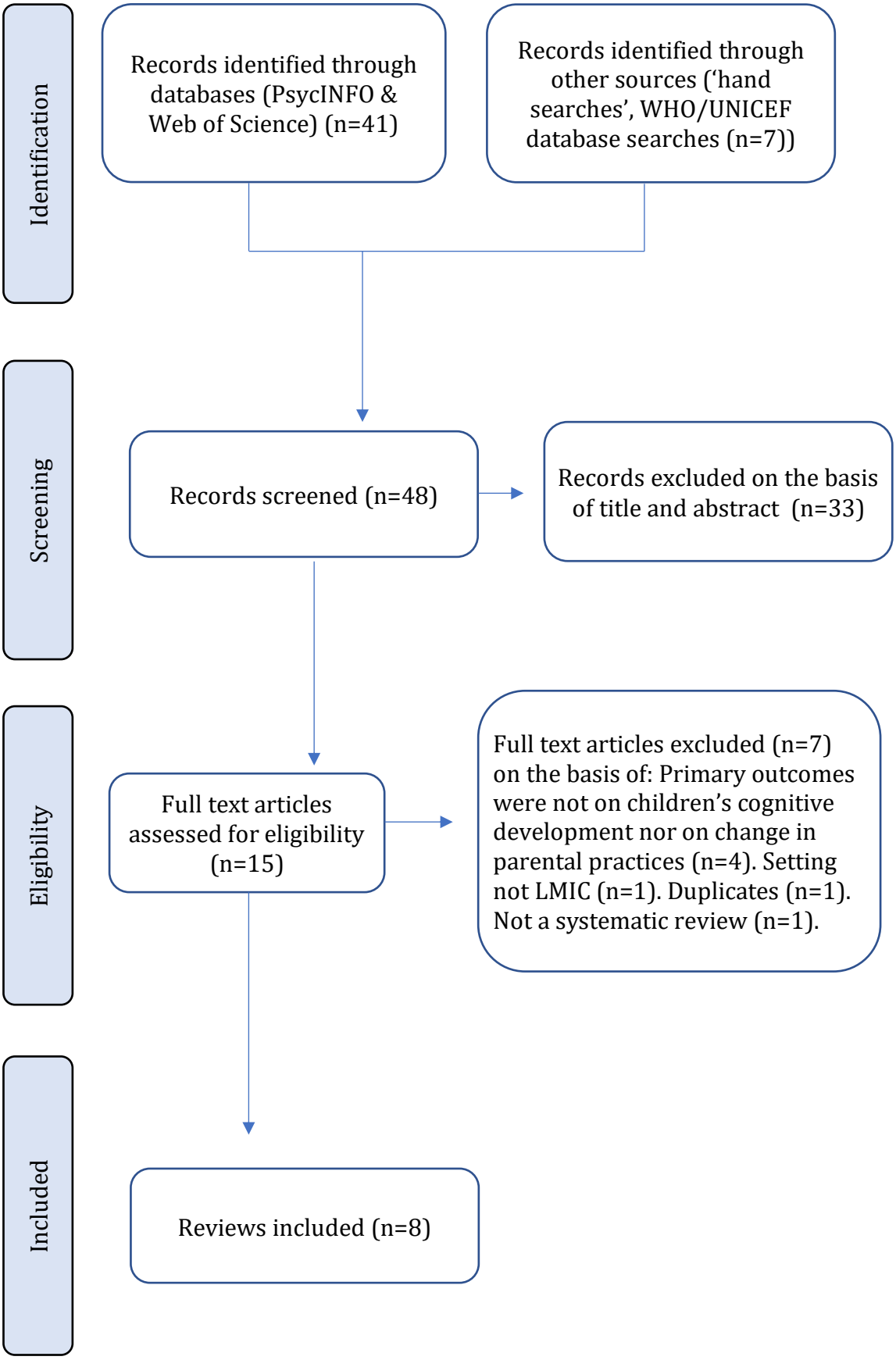

Figure 1. A flowchart of the search strategy.

2.3 Quality assessment

Two raters assessed the methodological quality of the included reviews using the validated tool for assessing systematic reviews – A MeaSurement Tool to Assess Systematic Reviews - AMSTAR2 (Shea, Reeves, Wells, Thuku, Hamel, Moran, et al., 2017). The AMSTAR2 tool is a recommended and validated method for evaluating the quality of systematic reviews of health care interventions (Smith, Devane, Begley, & Clarke, 2011).

AMSTAR2 tool does not calculate an overall score of quality of review, however it assesses weaknesses in several critical domains, and the overall qualitative rating is based on this assessment (Shea et al., 2017). The authors proposed seven 'critical' domains that can affect the validity of a review and its conclusions: 1) Protocol registered before commencement of review 2) Adequacy of the literature search 3) Justification for excluding individual studies 4) Risk of bias from individual studies being included in the review 5) Appropriateness of meta-analytical methods 6) Consideration of risk of bias when interpreting the results of the review 7) Assessment of presence and likely impact of publication bias (Shea et al., 2017).

For the purposes of the current literature review, the critical domain of registration of the review protocol was dropped due to the need for reviewers to consider the grey literature and government reports. The criteria for the third critical domain was loosened to accept as adequate if the review provided general reasons for exclusion of studies, rather than a list of individual studies and reasons for their exclusion as asked by the AMSTAR2 tool. It was found that no reviews provided detailed information on exclusion reasons for each individual study, therefore a more lenient criteria was considered sensible to

adopt. Not all reviews included a meta-analysis, and this was not considered a weakness due to heterogeneity of outcomes measured across studies, in particular if the review conducted showed high quality in other domains.

The overall judgement of the confidence in the review followed the rating system described by Shea et al., (2017) with some adjustments. *High confidence* rating was assigned to reviews that had none or one 'non-critical' weakness, but provided an accurate and comprehensive summary of the results of studies that addressed the question of interest. *Moderate confidence* was assigned to reviews that had two or more 'non-critical' weaknesses, providing an accurate summary of results of available studies included. *Low confidence* was assigned to reviews with one critical flaw with or without non-critical weaknesses, which may not provide an accurate or comprehensive summary of available studies.

Discrepancies in assessments between the two raters were solved through discussion. Inter-rater agreement was statistically calculated.

2.4 Common Practice Elements: Data Extraction

Following the identification of the reviews, the individual studies which demonstrated effectiveness and that were included in the reviews deemed to be of high quality were extracted. The authors of these studies were then contacted requesting the original intervention protocols on which the randomised trials were based (n=29). This strategy was adopted as it provided an efficient filtering procedure, with a focus on the robust interventions that were included in existing systematic reviews. Where the intervention protocols were not available, published papers of the studies were used to extract information

about the intervention content, with coding being based on the descriptions provided in the journal articles. Only articles which provided what was judged to be 'sufficient' information about the intervention were analysed for common practice elements.

2.5 Common Practice Elements: Coding

The original PracticeWise manual (Chorpita et al., 2005) for coding common elements was used. The original manual was developed for common practice elements analysis of interventions for older children and youth delivered in high income country contexts. Therefore significant adaptations had to be made to suit the purpose of the current review: a particular focus on the early years in the LMIC context, with additions made to the coding system.

Using the PracticeWise (2005) manual, the protocols of effective treatments were coded by two coders for the presence of absence of 62 practice element codes. The codes that were not relevant for the purpose of the current review were excluded.

Additional relevant codes were added to the coding structure through the procedure outlined in the manual, adding new elements as free text and then reviewing these for frequently occurring practice elements. Through this process 21 new elements were added: 'Emotion Regulation Skills', 'Parental self-care', 'Attachment building', 'Responsive care/parenting', 'Role-play', 'Use of toys', 'Talking to baby', 'Play/pretend', 'Story-telling', 'Reducing harsh discipline', 'Mentalising', 'Live/video demonstrations', 'Hygiene practices', 'Physically comforting baby', 'Community peers', 'Session aids', 'Peer support', 'Sleep hygiene/training', 'Antenatal support', 'Giving choices' and 'Synchrony

with baby'. Furthermore, some of the original codes were re-defined to be directed at caregiver rather than a young person, such as 'Activity Scheduling/Homework – Caregiver' or 'Assertiveness training – Caregiver'. Other definitions of codes were broadened to include early years specific aspects, for instance 'Caregiver-directed Nutrition' code was widened to include advice about breastfeeding, weaning and psychoeducation about portion sizes for young children. See Appendix D for the full list of practice elements codes with definitions and Table 4 for the elements that were coded in the protocols reviewed.

Once the additional codes were included, the practice elements coding was completed by two raters on a sample of 9 protocols to test for inter-rater reliability. This resulted in good inter-rater agreement at Cohen's *Kappa*=0.82. Through discussions the disagreements were reviewed and resolved.

3 Results

3.1 Description of reviews

The reviews that were included are summarised in Table 3. Of the included reviews 4 were meta-analyses, however only two of these were focused on cognitive outcomes in children, with the remaining two conducting a meta-analysis for nutritional interventions, but not cognitive outcomes. Psychosocial interventions in these were subjected to systematic review. The other 4 reviews were systematic reviews. Five of the reviews included studies that evaluated outcomes on child cognitive and language development. One review focussed specifically on maternal mental health outcomes with a secondary evaluation of

children's cognitive development outcomes. Five reviews included studies that evaluated the parent-child relationship.

The results of the systematic review are presented in three parts. First, the characteristics of the interventions included in the systematic reviews are discussed to give the reader an understanding of the nature of interventions of interest to the current review. Next the results of the review are discussed by outcome – children's cognitive outcomes and changes to parenting practices. The results from the review by Engle et al. (2011) are discussed under cognitive and parental outcomes, as review included outcomes within both of these domains. Where available statistical information is provided.

3.1.1 Interventions

Interventions assessed in the systematic reviews consisted of interventions in early infancy with a focus on promoting maternal-child interaction; stimulation interventions with disadvantaged children and their families, including with undernourished children; combined interventions for stimulation and health and nutrition programmes; interventions to increase parental responsiveness including in the area of feeding, as well as attachment and general parenting skills; interventions to encourage learning and play activities, positive discipline, and problem-solving. Some interventions reviewed were parent-focused, with a focus on improving maternal mental health with children's developmental and cognitive outcomes measured as secondary outcomes.

Interventions were delivered in various formats including home visits, group sessions and clinic appointments, often by paraprofessionals visiting the family weekly or monthly or delivering the sessions to a group of mothers, to

talk to and play directly with the child while the parents watched and coaching activities between the parent and child. Play materials were often provided or hand made in the sessions. Effectiveness of interventions was measured by the effect size of child outcome or the changes in parenting behaviour contributing to a more stimulating environment for the child.

3.1.2 Child cognitive development

Two meta-analyses (Aboud & Yousafzai, 2015; Rao, Sun, Chen, & Ip, 2017) described medium effects of psychosocial stimulation interventions on children's cognitive development, with both reviews highlighting that these effects are stronger when stimulation is provided in the context of comprehensive ECD programmes. In these reviews, studies were included which looked at effects of nutritional programmes on cognitive development, as well as combined nutrition and stimulation interventions.

The review and meta-analysis by Aboud and Yousafzai (2015) included 21 intervention studies which were designed as cluster or individual randomised controlled trials. The overall effect size they reported was $d = 0.42$ (95% CI 0.36, 0.48) for cognitive outcomes and $d = 0.47$ (95 % CI 0.37, 0.57) for language outcomes. The studies they reviewed were heterogeneous, and only 9 out of 21 stimulation studies analysed group samples sizes greater than 85, which meant that half of the studies they reviewed may have been underpowered. The overall sample size of the meta-analysis was not reported.

The review and meta-analysis by Rao et al., (2017) included 22 parent-focused interventions of education and support, 37 child-focused education and stimulation interventions, as well as 4 comprehensive programmes, which included various components (such as nutrition and health, and both child- and

parent- focussed psychosocial stimulation). They reported that comprehensive programmes showed the largest beneficial effects (g = 1.05, 95% CI 0.5, 1.61), followed by child-focused stimulation interventions (g = 0.64, 95% CI 042, 0.85), and parent-focused education and support interventions (g = 0.44, 95% CI 0.26, 0.61). They also included analyses of income supplementations and nutrition and health interventions in their review, which are not discussed in the current report.

The review by Engle, Fernald, Alderman, Behrman, Gara, Yousafzai et al., (2011) reviewed 42 effectiveness trials and included trials of parenting support and education, pre-primary and preschool centres, educational media for children and interventions for children at high risk. Out of these, 15 studies were relevant for the purposes of the current review – the programmes for parenting support and education. Within these, larger effect sizes were observed for interventions which included both parents and children (median d = 0.46, range 0.04 – 0.97), where parent-child interactions are encouraged, than for parent-only programmes (median d = 0.12, 0.03 – 0.34). The authors note that the most effective programmes were those with systematic training for workers who deliver the intervention, a structured curriculum and opportunities for parents to actively practice new strategies with children and receive feedback. Larger effects were observed in more disadvantaged populations (Engle et al., 2011).

Britto, Ponguta, Reyes, Karnati, Aboud, Bornstein et al., (2015) reviewed 105 studies of parenting programmes, which included interventions for parental practices and interactions with children, as well as knowledge, beliefs and attitudes toward parenting. The studies were reviewed for intensity,

delivery mode, approach, staffing and type of programme. The authors looked at childrens outcomes of physical, health and cognitive development as well as socio-emotional outcomes (although very few studies included outcomes withing this domain) or combined outcomes. The authors included studies from LMICs as well as parenting studies from HICs. For the purposes of the current review only results relevant to LMICs are discussed. Stimulation interventions were found to yield better results than interventions with a sole focus on nutrition. Studies (*n* = 14) with no impact of intervention were found to be delivered in a didactic manner and in low dosages; these were often interventions where parents did not have direct interactions with children during the intervention. This may mean that parental experiential learning of interacting with a child in new ways did not occur. Higher frequency of programme delivery was also associated with more effectiveness. The review concluded with a recommendation of 12 months parenting programme duration to achieve optimal levels of improved child's physical health, cognitive development and socio-emotional development (Britto et al., 2015).

The three systematic reviews (Baker-Henningham & Lopez Boo, 2010; Britto et al., 2015; Engle et al., 2011) also concluded that psychosocial stimulation interventions improve cognitive outcomes in children, in particular when interventions are of longer duration, aimed at younger children, and are more intensive.

3.1.3 Parenting practices

One meta-analysis (Jeong, Pitchik, & Yousafzai, 2018) specifically evaluated the effects of psychosocial stimulation interventions on parent caregiving practices and found medium to large positive effects on improving home caregiving

environment (*n* = 10; SMD = 0.57; 95% CI, 0.37, 0.77), mother-child interactions (*n* = 3; SMD = 0.44; 95% CI, 0.14, 0.74), and maternal knowledge of child development (n = 6; SMD = 0.91; 95% CI, 0.51 to 1.31). The pooled sample size of their meta-analysis was 6267 participants and there was significant heterogeneity in pooled effects for the outcome variables.

The review by Engle et al., 2011 described in the previous section also included two studies that showed improvements to parental knowledge of child development, improved home stimulation environment, and increased learning activities with the children (effect sizes were not available for these).

Baker-Henningham, (2014) concluded that there were benefits to caregiver practices following all 21 psychosocial stimulation interventions reviewed, in the areas of providing cognitively stimulating and emotionally supportive environments for the children.

The focus of the review by Rahman, Fisher, Bower, et al, 2013 was on maternal interventions for common mental health problems, with secondary outcomes consisting of child cognitive and physical development and mother-child interactions. The authors note that mothers participating in stimulation interventions showed better knowledge about children's needs and higher sensitivity, and provided improved home stimulation environments, as well as spending more time playing with their children.

Overall, positive effects of early childhood psychosocial stimulation interventions are reported by all of the systematic reviews included in the current review. Where stimulation interventions were reviewed alongside nutritional interventions, nutritional interventions alone did not benefit children's cognitive development to the same degree as psychosocial

stimulation or combined interventions with nutritional and psychosocial stimulation elements. Interventions that combine multiple methods, such as role plays, problem solving, provision of materials, and engagement of fathers and extended family members appear to be more effective than interventions that focus on isolated aspects of children's development. Interventions that include opportunities for practice with both the parent and the child were shown to be more effective than parent-only focussed interventions.

3.2 Quality assessment of systematic reviews

The results of the quality assessment using AMSTAR2 tool are summarised in Table 4. Two raters achieved acceptable inter-rater agreement, at Cohen's *kappa*=0.65 (95% CI 0.107, 1.207).

The confidence in the results of 4 reviews was judged to be *High*, with a further 3 reviews assessed to be of *Moderate* quality. One review was considered of *Low* quality. Most reviews commented on and considered the heterogeneity of the interventions included in these reviews, which limited the conclusions that could be drawn from the reviews. One of the most common weaknesses across the reviews was found to be a lack of assessment of the publication bias, and an insufficient consideration and discussion of the risk of bias and the impact of that on the conclusions of the review. In this respect the AMSTAR2 tool may provide for an overly harsh assessment of the systematic review evidence base considering that existing primary research in the ECD field is characterised by heterogeneity. Therefore the author adopted a more lenient approach in qualitatively rating the reviews based on whether there was a consideration of risk of bias and heterogeneity overall.

A further trend that was noticed was that no review provided a list of excluded studies and reasons for this as dictated by 'golden standard' criteria, and neither was the source of funding of individual interventions considered. Few reviews provided a clear indication that the study selection and data extraction was carried out in duplicate. For the purposes of current review these were deemed to be 'non-critical' weaknesses in assessing the strength of confidence in the findings of reviews.

3.3 Common elements analysis

The intervention studies which showed effectiveness in the systematic reviews (of Moderate or High confidence), that also yielded treatment effects on either children's cognitive outcomes or parenting practice outcomes, were extracted for common elements analysis. In total 29 effective interventions were identified and the authors of these were contacted with a request for the protocol or intervention manual. Five of these (n = 5) did not respond or were not able to provide the original protocol or description of the intervention. A further three (n = 3) were received but were written in a language other than English. Five (n = 5) referred to another protocol which was already included, stating that their intervention was based (with adaptations to local culture) on the original protocol.

In total 16 interventions protocols were coded for 62 individual codes. Table 6 summarises the study characteristics from which the protocols were drawn. Twelve of the protocols were an original intervention manual, two were described in a journal article, one in a book chapter and one in a published PhD thesis. Out of the 62 original codes, 48 practice elements were present in two or

more of the protocols. Figure 1 summarises the frequencies of practice elements across all protocols and Table 5 provides a list of the 48 practice elements with definitions.

Broadly, the common practice elements occurring in the protocol were grouped under five 'umbrella' themes, as can be seen from Table 2. These themes were 'Techniques', 'Psychoeducation', 'Enhancing parent-child interactions', 'Parent-focused elements', 'Session contents', 'Facilitator-focused elements'.

Table 2. Broad themes of common practice elements

Themes	Practice elements
Techniques	Problem-solving, Family engagement, Differential reinforcement, Sleep hygiene training, Motivational enhancement, Role-play, Attending, Giving choices, Support networking, Cognitive, Commands
Psychoeducation	Psychoeducation, Nutrition recommendation, Medical recommendation, Hygiene recommendations
Enhancing parent-child interactions	Play/pretend, Talking to baby, Attachment building, Responsive parenting, Toys use, Physically comfort, Story-telling, Mentalising, Synchrony with baby, Praise, Reducing harsh discipline
Parent-focussed elements	Therapist praise, Parenting skills, Homework, Communication skills, Caregiver coping, Parental self-monitoring, Individual therapy, Marital therapy, Antenatal support, Parental self-care, Emotional regulation skills
Session contents	Video/live demonstrations, Session aids, Delivery by community peers, Peer support
Facilitator-focussed elements	Accessibility promotion, Rapport building, Supportive listening, Coaching, Performance feedback, Modelling

As shown in Figure 2, the practice elements occurring in all of the protocols (n = 16) were the following: 'Play/Pretend' (parent-child activities using play to provide a learning experience for the child, or information provided to parents about the importance of play), 'Talking to baby' (any strategies to promote parental involvement in talking with baby, also in the pre-verbal stages, including babbling, singing, pointing, verbalising) and 'Psycho-education Caregiver' (information about early childhood development provided by facilitator to parents). Practice elements occurring in more than 80% of the protocols ($n \geq 13$) included the following: 'Therapist praise' (provision of social/verbal reinforcement to promote a desired behaviour in the caregiver, occurring in 15 protocols), 'Attachment building' (including psychoeducation, demonstrations or discussions about providing consistent loving care to the child, being responsive to the child's emotional needs, occurring in 15 protocols), 'Responsive care/parenting' (promotion of awareness of the importance of sensitive parenting and care; may involve activities to practice responding to child's words, actions, communications, following the child's lead; any strategies, including providing information to the parents, which encourage them to promote mediated learning or scaffolding, guiding the child's learning process; occurring in 14 protocols), 'Use of toys (strategies to promote use of toys in parenting practices; occurring in 13 protocols), 'Praise' (training parents in using praise and encouragement to promote desired behaviours; occurring in 13 protocols).

Practice elements occurring in more than 50% of the protocols ($n \geq 8$) were: 'Session aids' (materials for participants; occurring in 12 protocols), 'Physically comfort baby' (encouragement to provide soothing through touch,

including massage; occurring in 12 protocols), 'Live/video demonstrations' (if protocol includes demonstrations by facilitator or video; occurring in 12 protocols), 'Story-telling' (strategies promoting use of caregiver's story telling with the children, including with books or pictures; occurring in 12 protocols), 'Parenting skills' (strategies not already captured by other codes, may include attention to positive qualities of child, parental supervision, child rights education; occurring in 12 protocols), 'Rapport building' (instructions or strategies to increase quality of relationship between parents and facilitator; occurring in 11 protocols), 'Problem-solving' (strategies to bring about solutions to targeted problems, usually with the intention of imparting a skill for how to approach and solve future problems in a similar manner; occurring in 11 protocols), 'Family engagement' (facilitating family's positive interest in participation in an intervention; occurring in 11 protocols), 'Differential reinforcement' (ignoring 'problem' behaviours and selectively attending to positive behaviours; 11 protocols), 'Coaching' (providing feedback to parents as the activity is being carried out; occurring in 11 protocols), 'Homework' (activities outside sessions; occurring in 11 protocols), 'Mentalising' (facilitating caregiver's capacity to understand what their child is thinking and feeling; occurring in 10 protocols), 'Motivational enhancement' (increasing readiness to participate in programmes; occurring in 10 protocols), 'Community peers delivery' (intervention delivered by members of community, trained peer tutors; described explicitly in 9 protocols), 'Modelling' (demonstration to promote imitation of behaviour in parents; occurring in 9 protocols), 'Communication skills' (promoting more effective communication with others, including expressing emotions; occurring in 8 protocols).

In addition, 'Nutritional recommendation' and 'Caregiver-directed nutrition' codes also occurred in more than half of the intervention protocols. Five of these interventions explicitly combined psychosocial stimulation and a nutritional programme with a focus on responsive feeding practices.

Table 3. Summary table of the scope of reviews of ECD psychosocial stimulation intervention studies.

Review Year	Aim	Search Strategy	No. of studies included	Total no. of participants	Interventions reviewed	Outcome	Results/Comments	AMSTAR2 Quality Assessment Rating
Aboud & Yousafzai 2015	To review effectiveness (meta-analysis) of early interventions such as nutritional programmes and psychosocial stimulation on children's cognitive and language development (0-24 months)	Followed PRISMA, search terms provided, used 3 databases	21 cluster or individual RCTs (also 18 nutrition intervention studies)	Not provided	Included psychosocial stimulation interventions (as well as nutrition interventions)	Cognitive and language development	Effect size 0.42 for cognitive outcomes, 0.47 for language outcomes Review concludes that stimulation interventions show medium effects on children's cognitive and language development. Intervention groups compared to control families were shown to be more verbally responsive to children, providing a more stimulating environment for the child.	**Moderate** confidence in review. *Weaknesses:* review does not report on whether study selection and data extraction was performed in duplicate; does not provide a list of reasons for excluded studies; and does not report on the assessment of the publication bias.
Baker-Henningham 2014	To systematically review interventions/programmes that prevent child MH problems and promote wellbeing. Caregiver practices and caregiver MH also reviewed (up to 6 years old)	Up to December 2010, search terms provided, QA tools used	21 cluster or individual RCTs, or quasi-experimental design studies with a control condition.	Not provided	Educational interventions: parenting training, day-care, multi-component interventions in health settings	Child behaviour and mental health. Caregiver practices, parental skills to stimulate and provide emotional support	Benefits found for caregiver practices in 21 studies. Most benefits to child mental health when activities aim to increase child cognition, language, self-regulation and social emotional competence, when caregivers are trained in providing cognitively stimulating environments, and parental mental health is addressed.	**High** confidence in review. *Weaknesses:* review does not report on whether study selection and data extraction was performed in duplicate; does not provide a list of reasons for excluded studies.
Baker-Henningham & Boo 2010	To systematically review stimulation interventions in LMIC, with primary outcomes on children's cognitive development but	4 databases searched, outcomes explicitly stated	26 efficacy studies and large scale programme reports	Not provided	Cognitive stimulation interventions	Child cognitive development (IQ), child behaviour, schooling attainment, health and nutrition. Maternal	Review concludes that early stimulation interventions are effective in improving child and maternal outcomes. Most disadvantaged and younger children tend to benefit the most from the interventions. Interventions of	**Low** confidence in review *Weaknesses:* review does not report on whether study selection and data extraction was performed in duplicate; does not provide a list of reasons for

	also parental benefits (0-5 years)	prior to review				parenting, psychosocial function, mother child interactions	higher quality and longer duration are more effective.	excluded studies; does not assess risk of bias; does not assess or comment on heterogeneity of study results; does not comment on conflicts of interest.
Britto et al. 2015	To systematically review ECD parenting programmes conducted in LMIC (parents of children up to 8 years old)	10 databases used, 2001-2011, PICO criteria used, search terms provided	105 studies including cluster or individual RCTs, quasi-experimental design studies (minimum sample 100 for generalisability)	Not provided	Various ECD parenting interventions reviewed. Psychosocial stimulation studies (n=32)	Cognitive development and parenting practices outcomes. Also reviewed socio-emotional development and behavioural outcomes, however low frequency of studies looking at this.	Intensive (at least weekly for a period of one year) psychosocial stimulation programmes are effective in changing parental practices and the child's mental, social and emotional developmental outcomes.	**Moderate** confidence in review *Weaknesses:* review does not provide a list of reasons for excluded studies; does not comment on heterogeneity in results.
Engle et al. 2011	To systematically assess the effectiveness of early child development interventions, such as parenting support and preschool enrolment (0-5 years)	10 database, publications since 2006, PICO used, search terms provided, QA tools used, outcomes stated prior conducting of review	42 studies with a comparison group, including cluster or individual level RCTs, cohort analytic design studies (15 were parenting interventions)	Not provided	Included psychosocial stimulation interventions for parents, as well as stimulation in preschool programmes.	Child cognitive development, behaviour, attachment, parenting practices	Effect size 0.46 for parent-child interventions. Substantial positive effects on child development were identified in all 11 effectiveness studies; nine on cognitive or social–emotional development, and two on parent knowledge, home stimulation, and learning activities with children, which are associated with child development	**Moderate** confidence in review *Weaknesses*: review does not provide a list of reasons for excluded studies; does not comment on heterogeneity in results; does not comment on assessment of publication bias.

Jeong et al. 2018	To assess the effectiveness (meta-analysis) of stimulation interventions on improving parenting outcomes (0-2 years)	6 databases used, PRISMA followed, search terms provided	15 RCTs (cluster or individual)	6267	Psychosocial stimulation: Promotion of parenting behaviours and enhancing stimulation	Parental outcomes (mother-child interactions, knowledge of ECD, caregiving environment and maternal depression, opportunities for early stimulation and learning)	Found medium to large effects of stimulation interventions on improving home caregiving environment(0.57), observed mother-child interactions (0.44) and maternal knowledge of ECD (0.91). Non-significant results on maternal depression.	**High** confidence in review. *Weaknesses:* review does not provide a list of reasons for excluded studies.
Rahman et al. 2013	To assess effectiveness (meta-analysis) of interventions to improve MH in perinatal period, evaluate effect on health, growth and development of offspring in LMIC (3 weeks-3 years)	Used 7 databases, search terms provided, up to May 2012	13 RCTs (cluster or individual)	20092	Psychosocial stimulation/Maternal mental health interventions: 4 studies in the review addressed maternal depression.	Maternal mental health outcomes/Infant cognitive and physical development outcomes, mother-child relationship outcomes.	Review concludes that there is evidence that interventions aimed at relief of common mental health problems can be effectively implemented in LMIC. Child cognitive development was a secondary outcome not subjected to meta-analysis. Positive effects on infant cognitive development were noted.	**High** confidence in review. *Weaknesses:* review does not provide a list of reasons for excluded studies.
Rao et al. 2017	To assess effectiveness (meta-analysis) of different ECD interventions in enhancing cognitive development and to identify factors related to intervention efficacy (up to 8 years)	PRISMA followed, 9 databases used, search terms provided, hand searching outlined, specialist websites searches outlined	106 interventions, from 62 studies (RCTs, cluster or individual)	43696	Interventions designed to promote typical cognitive development (mental stimulation), along with nutritional and health interventions.	Cognitive and language development outcomes.	Effect sizes 1.05 for comprehensive programmes, 0.64 for children-focused interventions, and 0.44 for parent-focused interventions Review demonstrated a variation in overall effectiveness of ECD interventions for improving cognitive outcomes, with comprehensive programmes showing strongest effects.	**High** confidence in review. *Weaknesses:* review does not provide a list of reasons for excluded studies.

Table 4. AMSTAR2 Quality appraisal of reviews

	Aboud & Yousafzai 2015	Baker-Henningham 2014	Baker-Henningham & Boo 2010	Britto et al. 2015	Engle et al. 2011	Jeong et al. 2018	Rahman et al. 2013	Rao et al. 2017
1. Inclusion of PICO								
2. A priori design								
3. Explanation of study selection								
4. Comprehensive search strategy								
5. Study selection duplicate								
6. Data extraction duplicate								
7. List of excluded studies with reason								
8. Describes studies in adequate detail								
9. RoB assessment								

10. Report individual studies funding sources								
11. Appropriate methods for statistical combination		n/a	n/a	n/a	n/a			
12. Assess impact of RoB on synthesis.		n/a	n/a	n/a	n/a			
13. Account for RoB in interpretation of review								
14. Explanation of heterogeneity in results								
15. Assessed publication bias		n/a	n/a	n/a				
16. Sources of conflict								
Strength of confidence in review	Moderate	High	Low	Moderate	Moderate	High	High	High

Note: Yes Partial Yes No

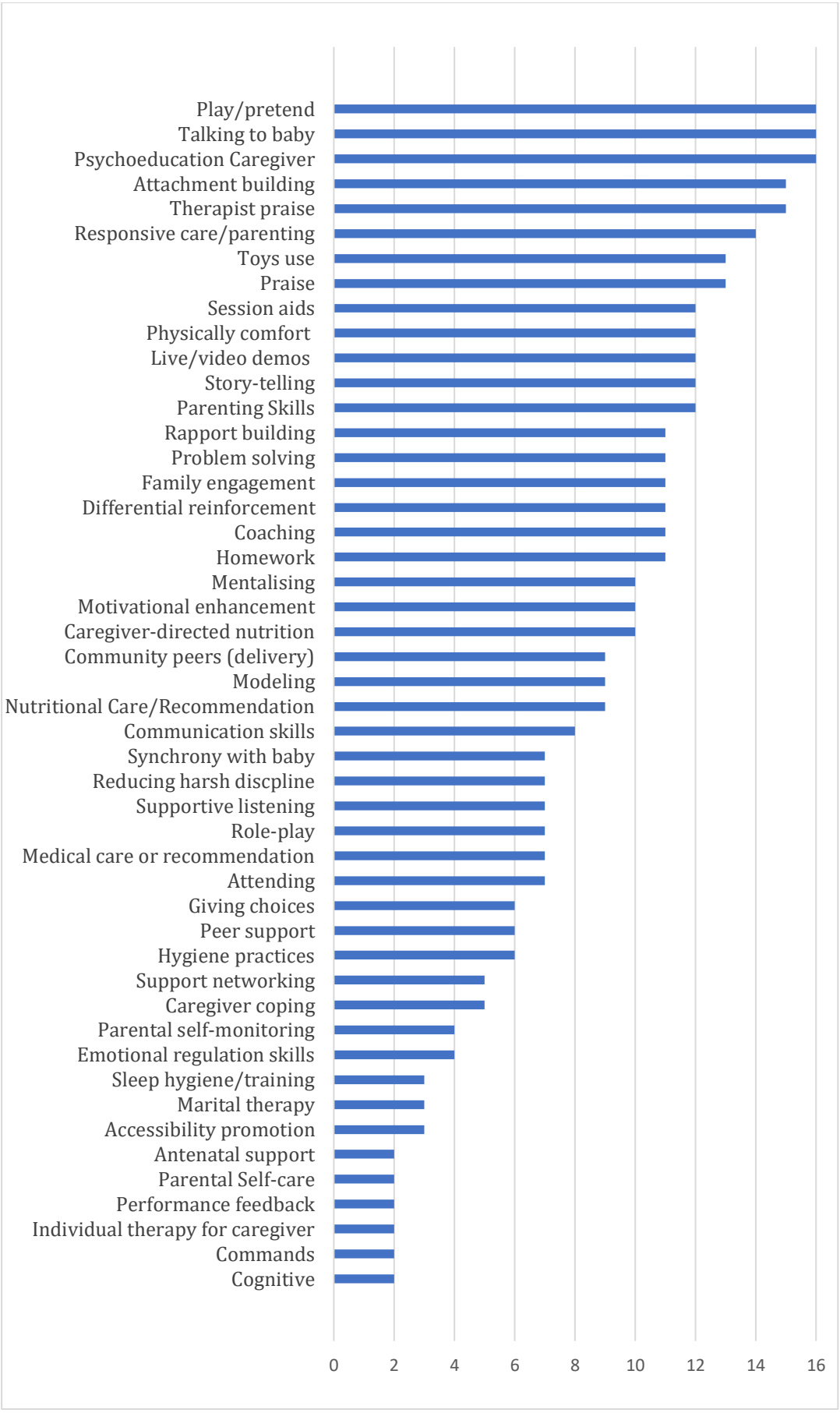

Figure 2. *Practice elements profile for ECD intervention protocols (n = 16).*

Table 5. Practice Elements occurring and their descriptions. Elements that did not occur in the protocols are excluded from this list.

Practice Element	Description
Accessibility promotion	Any strategy used to make services convenient and accessible or to proactively enhance treatment participation.
Attachment building	Provision of broader training in bonding with the child. This may include psychoeducation/demonstrations/discussions about providing consistent loving care to the child, being accessible to the child as a parent, being responsive to the child's emotional needs.
Attending	Exercises involving the child and caretaker playing together in a specific manner to facilitate their improved verbal communication and nonverbal interaction. Typically the caretaker is instructed to provide a running commentary or description on the child's activities
Antenatal support	Intervention including antenatal support or preparation for baby strategies to help parents.
Caregiver-directed nutrition	Setting an expectation for parents to take charge of eating and feeding, may include aspects of diet, feeding environment or behaviour. May also include advise about breastfeeding/weaning or portion sizes for children
Nutritional care or recommendation	Provision of counselling, education, professional services or recommendations for dietary or nutritional modification or supplementation.
Homework	The assignment or request that a child/caregiver participate in specific positive activities outside of sessions, with the goal of promoting or maintaining involvement in rewarding and enriching experiences.
Cognitive	Any techniques designed to alter interpretation of events through examination of the caregiver's reported thoughts, typically through the generation and rehearsal of more realistic, alternative counter-statements
Communication skills	Training for caretakers in how to communicate more effectively with others to increase positive functioning, increase consistency, or minimize stress. May also involve learning to express emotions more effectively
Coaching	Facilitator is encouraged to provide feedback to parents when they try new techniques out, praising where necessary and providing gentle suggestions when they need improvement – as the activity is being carried out
Community peers delivery	Intervention delivered by community peers, community health workers from the local population, or trained peer tutors.
Differential reinforcement	The training of caretakers, teachers, or others involved in the social milieu of the child to selectively ignore target behaviours and selectively attend to competing behaviours.

Emotion regulation skills	Techniques that are designed to promote learning to recognise and manage emotions and understanding emotion-behaviour-thoughts links. This may also involve psychoeducation about emotions (Code alongside Psychoeducation), and learning to differentiate between feelings and behaviours, and awareness of the choices to act or not to act on feelings constructively.
Family engagement	The use of skills and strategies to facilitate the family's positive interest in participation in an intervention
Giving choices	Encouraging parents to give children choices in play, feeding etc to promote child's autonomy and exploration
Hygiene practices	Information and instructions regarding safe, hygienic practices in the child's environment
Individual therapy for caregiver	Any therapy designed directly to target individual (non-dyadic) psychopathology
Marital therapy	Techniques used to improve the quality of the relationship between caregivers.
Medical care or recommendation	Provision of professional services, consultation, education, medications, or advice regarding adaptations to address physical health or well-being
Mentalising	Active discussions/questions that are aimed to facilitate/promote caregiver's capacity to mentalise (think and feel what the child thinks and feels) their child (Example: asking parents "What is your child feeling/thinking when you praise him/her?')
Modelling	Demonstration to the caregiver of a desired behaviour, typically performed by a therapist, confederates, peers, or other actors to promote the imitation and subsequent performance of that behaviour in parents
Motivational enhancement	Exercises designed to increase readiness to participate in additional therapeutic activity or programs
Performance feedback	Providing information about one's own or another's performance to the youth, parent, or others based on assessment or observation
Praise	The training of parents in the administration of social rewards to promote desired behaviours.
Parenting skills	Provision of broader training in parenting skills not captured by specific other codes – may involve child rights education, attention to positive qualities of the child, parental supervision and monitoring.
Problem solving	Training in the use of techniques, discussions, or activities designed to bring about solutions to targeted problems, usually with the intention of imparting a skill for how to approach and solve future problems in a similar manner
Psychoeducation - caregiver	The formal review of information with the caretaker(s) (Socratic or otherwise) about the child's early development.

Parental self-monitoring	Conducted by parents of their own behaviours, including mood charts, behaviour diaries etc.
Parental self-care	Any strategies that promote parental awareness of importance of their own wellbeing in caring for children, along with techniques aimed to increase parental psychological/physical wellbeing.
Play/pretend	Parent-child activities using play that provide a rich learning experience for the child
Physically comforting baby	Instructions/encouragement to provide physical comfort/soothing baby through touch (swaddling, picking up at distress, gentle touch). May also be coded if intervention includes baby massage as a strategy.
Peer support	If intervention involves a peer support element or group.
Supportive listening	Reflective discussion with the participant designed to demonstrate warmth, empathy, and positive regard, without suggesting solutions, actions, or alternative interpretations.
Support networking	Strategies to explicitly identify, engage, develop, or otherwise increase the involvement or effectiveness of individuals in the client's social ecology to provide instrumental or emotional support for the client or assist in the performance of therapeutic tasks or activities
Story telling	Any strategy that promotes the use and caregivers' ability to use story-telling with their children.
Session aids	Facilitation of intervention involves session aids, calendars for participants, or other objects or materials provided
Sleep hygiene/training	May include psychoeducation about sleep in young children. Can include sleep hygiene for parents.
Synchrony with baby	Parent and baby engaging in a give and take in their interactions and communications.
Therapist praise	The administration of tangible (i.e. rewards) or social (e.g., praise) reinforcers by the therapist to promote a desired behaviour in the caregiver.
Talking to baby	Any strategies to promote parental involvement in talking with baby, also in the pre-verbal stages. This may include imitating babble, singing to baby, expanding on what infant said, paying attention to what infant is looking at and labelling objects, pointing and verbalising.
Role play	Caregivers encouraged to act out (with facilitator or each other) either their routine practices (with the aim of understanding what behaviour currently looks like), or trying out new strategies/behaviours through role play with the aim to provide rehearsal for novel practices.

Reducing harsh discipline	Any instructions/strategies provided to caregivers aimed at reducing harsh/physical/aggressive discipline. Recommendations around more positive ways of dealing with children, reinforcing good behaviours. Information provision about negative effects of harsh discipline on child
Use of toys	Strategies (including psychoeducation around why it is important to provide toys for children) to promote the use of toys in parenting practices.
Video/live demonstrations	Code if protocol includes live/video demonstrations.

Table 6. Intervention protocols included in the common elements analysis and information on the corresponding studies.

Intervention Protocol	Study authors	Title	Population	Intervention	Comparison	Outcome	Results/Comments
Improving mother/child interactions to promote better psychosocial development in children (WHO, 1997)	Walker et al., 2004	*Psychosocial Intervention Improves the Development of Term Low-Birth-Weight Infants*	Jamaica Low birth weight infants up to 24 months	Weekly home visits for 19 months to demonstrate play and interaction with child	RCT, randomised at birth to intervention (stimulation) or control (health visits)	Cognitive language (Griffiths Mental Development scale) and fine motor skills tested at clinic	Effectiveness demonstrated, intervention group showed significant benefits to development compared to control group. Still lower developmental level than non-low birth weights infants.
Jamaica home visiting programme (1989)	Gardner et al., 2005	*Zinc supplementation and psychosocial stimulation: effects on the development of undernourished Jamaican children*	Jamaica Underweighted children 9-30 months old	Weekly home visits for 6 months demonstrating activities for play and zinc supplementation	Cluster RCT, randomised to stimulation group, zinc supplementation group, both interventions, and control (routine care only)	Griffiths Mental Development scale and length and weight	Zinc supplementation benefits development in undernourished children, and the benefits are enhanced if stimulation is also provided.
Care for Childhood Development (UNICEF/WHO 2012)	Jin et al., 2007	*'Care for Development' intervention in China - prospective follow up study*	China Infants up to 24 months	Clinic visits, twice over 6m to deliver messages and Card on play, talk and feeding.	RCT where mothers randomized to receive counselling and card or solely health check.	Gesell developmental schedule: Adaptive (cognitive) and Language test	Children in the intervention group significantly higher adaptive, language and social development quotients than control.

Home programme	Potterton et al., 2010	*The effect of basic home stimulation programme on the development of young children infected with HIV*	South Africa Infants up to 30 months infected with HIV	Stimulation program taught to caregivers when they visited the clinic, including how to talk and play with child during regular daily activities at home.	RCT, control group was no intervention	Bayley Scales of Infant Development II	Intervention group showed significantly better cognitive and motor development compared to control group, however mean scores at end of study period still showed significant developmental delay.
Responsive feeding and play programme (Plan Bangladesh 2008)	Aboud & Akhter, 2011	*A cluster randomised evaluation of a responsive stimulation and feeding intervention in Bangladesh*	Bangladesh Infants up to 20 months in rural areas	Group sessions provided demonstrations and mother-child practice on play, talk and responsive feeding.	Cluster RCT, Control mothers received 12 informational sessions on health and nutrition. The intervention groups received an additional 6 sessions where facilitators modeled and coached practice in self-feeding and verbal responsiveness with the child	Home Observation for Measurement of the Environment (HOME) inventory, mother-child responsive talk and language development (Bayley Language scales)	Responsive stimulation-feeding groups had better HOME inventory scores, responsive talking, language, mouthfuls eaten, and hand-washing.
No protocol available, book chapter on Mediational intervention for sensitizing caregivers (MISC) provided.	Boivin et al., 2013	*A year-long caregiver training program to improve neurocognition in preschool Ugandan HIV-exposed children.*	Uganda HIV infected children up to 48 months	25 home visits fortnightly for 12 months. Instruction, demonstration, practice how to interact with child. Feedback on videos of own interaction.	RCT, control group received instructions on health and nutrition, along with videos but no feedback.	Mullen Early learning scales: Visual-cognitive, receptive and expressive language	Intervention group showed greater gains on language development and cognitive ability.

Partners for Learning (Sparling, Lewis, Ramey et al 1991)	Carlo et al., 2013	*Randomized trial of early development intervention on outcomes in children after birth asphyxia in developing countries*	India, Pakistan & Zambia Infants after birth asphyxia	Home visits for 3 years (fortnightly) to promote play by helping parent practice and receive feedback.	RCT, Parallel groups of new-borns with asphyxia resuscitated at birth and normal new-borns without need for resuscitation. Both received health & safety counselling	Bayley Scales of Infant Development II	Children's cognitive and psychomotor abilities were significantly higher in the intervention group when compared to control group.
Responsive complementary feeding and play group	Vazir et al., 2014	*Cluster-randomized trial on complementary and responsive feeding education to caregivers found improved dietary intake, growth and development among rural India toddlers.*	India Infants from 3 to 15 months	Home visits with 19 Messages on feeding and 8 on stimulation, total of 30 visits.	Cluster RCT, control group standard care	Bayley Scales of Infant Development II	Cognitive development scores significantly higher in the intervention group compared to control, but not motor development scores.
Parenting programme in Health Centres (Walker et al 2016)	Chang et al., 2015	*Integrating a parenting intervention with routine primary health care: a cluster randomized trial*	Jamaica Children up to 18 months	Health centre visits, up to 5 sessions delivered at 3, 6, 8, 12, and 18 mo. Group sessions with child development messages through video and discussions.	Cluster RCT, control group routine care	Griffiths mental development scales, HOME inventory	Intervention group showed higher cognitive scores, no changes were seen on HOME scores

Thula Sana Programme (Based on The Social Baby UK programme)	Cooper et al., 2009	*Improving quality of mother-infant relationship and infant attachment in socioeconomically deprived community in South Africa: randomised controlled trial*	South Africa Mothers recruited during pregnancy	Home visits by local women, encouraging sensitive responsive interactions. 16 sessions over 6 months 1 h duration, weekly then fortnightly, then monthly.	RCT, control group routine care	Quality of mother child interactions at 6 and 12 months postpartum, maternal depression levels	Intervention associated with significant benefit to mother child relationships, mothers more sensitive in intervention group, less intrusive, in their interactions. No impact on depression at 12 months.
Plan Uganda	Singla et al., 2015	*Effects of a parenting intervention to address maternal psychological wellbeing and child development and growth in rural Uganda: a community based, cluster randomised trial*	Uganda Children up to 36 months	Group sessions and 2 home visits, encouraged parents to learn new parenting practices, play and communication, self-care. Every two weeks 12 sessions in total plus the HVs	Cluster RCT, control group routine care and waitlist for intervention	Bayley Scales of Infant Development II, EPDS for maternal depression, HOME inventory	Intervention significantly higher cognitive and language scores compared to control, mothers in intervention scores lower depression scores
Thinking Healthy (WHO 2015 – developed by Rahman et al. 2009)	Rahman, Iqbal, Roberts, & Husain, 2009)	*Cognitive behaviour therapy-based intervention by community health workers for mothers with depression and their infants in rural Pakistan: a cluster-randomised controlled trial*	Pakistan Women with depression recruited during pregnancy	Sessions every 4 weeks during pregnancy, then three sessions during first postnatal month, then 9 monthly sessions thereafter	Cluster RCT, control group received same number of sessions but routine health visits.	Maternal depression, infant physical development, Infant Development Questionnaire, time spent playing with infant.	Intervention group mothers showed lower depression scores, reported more time playing with their children. No impact on infant physical development.

Love, Play, Communication Uganda	Morris et al., 2012	*Does combining infant stimulation with emergency feeding improve psychosocial outcomes for displaced mothers and babies? A controlled evaluation from northern Uganda.*	Uganda Displaced children and mothers	Based on LTP programme and feeding, psychoeducation about childhood development, mother-infant group sessions, home visits (unspecified number)	RCT, control group	Maternal knowledge of childhood development, mother infant relationship HOME inventory, emotional responsiveness, maternal mood	Intervention group mothers showed higher HOME scores, showed greater involvement with babies and more responsiveness in interactions
Pehla Qadam - (based on CCD)	Yousafzai et al., 2014	*Effect of integrated responsive stimulation and nutrition interventions in the Lady Health Worker Programme in Pakistan on child development, growth, and health outcomes: a cluster randomized factorial effectiveness trial*.	Pakistan Children up to 3 months	Care for Child Development (UNICEF & WHO) responsive play and communication skills and activities Monthly group sessions and home visits	Cluster RCT, control group routine care	Bayley Scales of Infant Development II	Children who received responsive stimulation had significantly higher development scores on the cognitive, language, and motor scales at 12 and 24 months of age, and on the social–emotional scale at 12 months of age, than did those who did not receive the intervention.
Roving Caregivers Programme (2009)	Janssens, Rosemberg, & Spijk, 2009	*The impact of a home-visiting Early Childhood intervention in the Caribbean on cognitive and socio-emotional child development*	St Lucia Children up to 3 years	Home visits twice weekly, play activities with child and parent	Quasi-experimental, villages not included in intervention used as control group	HOME inventory, parent child interaction questionnaire, Mullen Scales of early learning, Vineland Socio-emotional early childhood instrument	No effects at 1 year follow up on children's cognitive and socio-emotional development. Significant positive effects on cognitive development of children between 6-18 months, but not 18-30 months when sub-divided for analysis.

Psychosocial stimulation and Nutrition Programme	Nahar et al., 2012	*Effects of a community based approach of food and psychosocial stimulation on growth and development of severely malnourished children in Bangladesh*	Bangladesh Malnourished children up to 24 months	Clinic workers delivered sessions comprising 1hr play sessions and parental education on stimulation and talk.	RCT, control group health and nutrition visits at clinic	Bayley Scales of Infant Development II	Children in the intervention group showed a significant benefit to cognitive development and growth in weight compared to control.

4 Discussion

The first aim of this review was to evaluate the effectiveness of psychosocial stimulation interventions in low- and middle-income countries on children's cognitive outcomes and on parenting practices that facilitate children's cognitive development. The second aim of the review was to explore the common practice elements of interventions that have demonstrated effectiveness.

4.1 Summary of findings: systematic review of reviews

The systematic reviews (n=8) considered in this report demonstrated evidence of effectiveness of psychosocial stimulation interventions, carried out in LMIC, independently and as part of more comprehensive ECD programmes, with effects on children's cognitive development outcomes or on parenting practices, or both.

Overall, psychosocial stimulation interventions delivered in these settings appear to be effective in randomised trials included in the reviews (Aboud & Yousafzai, 2015; Baker-Henningham, 2014; Britto et al., 2015; Engle et al., 2011; Jeong et al., 2018; Rahman et al., 2013; Rao et al., 2017). Comprehensive interventions of higher intensity and longer duration yielded better results (Engle et al., 2011; Baker-Henningham, 2014; Britto et al., 2015). Where stimulation interventions were reviewed alongside nutritional interventions, nutritional interventions alone did not benefit children's cognitive development to the same degree as psychosocial stimulation or combined interventions with nutritional and psychosocial stimulation elements

(Aboud & Yousafzai, 2015; Rao et al., 2017). Interventions that failed to show effectiveness were delivered in a didactic manner, did not incorporate child and parent practices, and were usually delivered in lower dosages (Britto et al., 2015). These were not included in the common practice elements analysis.

Interventions that addressed maternal mental health during the perinatal period also appear to be beneficial for children's cognitive development, especially when the intervention is positioned as a mother and child health promotion programme, as was done by the Thinking Healthy Programme in Pakistan which was included in the current review because the authors included infant development outcomes as well as parenting practices such as time spent playing with children (Rahman et al., 2013). Two reviews (Baker-Henningham & Lopez Boo, 2010; Engle et al., 2011) found stronger effects of interventions when the most disadvantaged groups and younger children were targeted. However, results of the review by Baker-Henning & Lopez Boo (2010) need to be considered tentatively as it was given a low confidence rating in the quality assessment.

Limitations. Five out of eight reviews reported heterogeneity in the results of the interventions, their designs and in the outcomes investigated. This limits generalisability of the findings. Nevertheless, the overall pattern of evidence presented strongly supports early cognitive stimulation interventions in facilitating children's cognitive abilities. Fidelity to intervention protocol was rarely considered in the systematic reviews included in this review, which presents another limitation of the review. This is a reflection of the

shortcomings of the original randomised studies which often did not report this information. Future research may need to address this gap.

The decision to conduct a systematic review of reviews meant that the quality of the systematic reviews was assessed, rather than the quality of the individual studies included in the reviews. This could be considered a limitation of the current review. However, within this framework the working assumption was made that through assessing the quality of the systematic review itself, a 'filtering out' of weaker studies would have been achieved, with a further evaluation step conducted by the author of the current review. Attention was paid to studies that showed effectiveness when extracting the protocols for the common practice elements analysis that followed. As long as the quality assessment of individual studies was carried out within the reviews, that meant that the review was presenting a balanced perspective of the evidence in the literature. This way, the methodological quality of the overall review was ensured within the time restraints of the project. In the future, it may also be useful to quality assess the individual studies.

Many cognitive stimulation interventions were delivered as part of larger programmes, often incorporating elements of improving parenting in general, parental sensitivity and responsiveness. It is therefore difficult to attribute separate effects of 'cognitive stimulation' on children's cognitive outcomes. Judging from the evidence presented in the current review and evidence from previous literature (Black et al., 2017; Lu, Black, & Richter, 2016; Walker et al., 2011), it is likely that benefits for children's cognitive outcomes accrue when interventions target children's needs holistically (nutrition, psychosocial stimulation, parental responsiveness, hygiene).

4.2 Summary of findings: Common Elements analysis

Based on the identified systematic reviews, randomised intervention trials that showed treatment effects and were considered of good quality (as assessed by authors of the reviews) were extracted (n=29). From these trials, 16 intervention protocols were obtained for further analysis. The common practice elements profiles of intervention protocols were then examined. Many of these interventions were delivered by non-specialist workers, as is common in low resource settings. Nine of the interventions explicitly stated community peer delivery in their intervention protocols.

Common practice elements analysis of these intervention protocols showed that the most commonly occurring elements were 'Talking to baby', 'Play/Pretend', 'Psychoeducation Caregiver', 'Attachment building', 'Therapist praise', 'Responsive parenting', 'Use of Toys', and 'Praise', occurring in more than 80% of the protocols.

'Psychoeducation - caregiver', 'Talking to baby' and 'Play/Pretend' codes were found in all protocols. Psychoeducation often included providing parents with information about stages of infant development. As an example, the Care for Child Development (WHO, 2012) manual highlighted helpful behaviours that parents can engage in to promote their child's optimal learning at each stage (new-born – 6 months, 6 months to 9 months, 9 months -12 months, and 12 months to 24 months). Parents were advised about how to best engage the child given their level of ability. Interventions that had a focus on responsive feeding with an element of psychosocial stimulation such as Responsive Feeding and

Play Programme Bangladesh (Plan Bangladesh, 2008) provided psychoeducation around what a child can learn from learning to feed themselves, such as motor coordination skills and mental development through learning different shapes and textures and tastes, gaining a sense of mastery of doing things by themselves.

The 'Talking to baby' practice element is simply described in the Jamaican Parenting Programme in Health Centres (Walker, Powell, Chang, Baker-Henningham, & Grantham-Mcgregor, 2016) as one of the key messages to parents: 'The more you talk to baby the better they will learn' with provided demonstrations and practice activities for the mothers. This practice element was also coded when singing, babbling, eye contact with babies were encouraged in parents – any form of communication that was facilitated, verbal or non-verbal between the parent and the child. Across different protocols there was an emphasis on communicating with the baby or young child with the desired outcome of their learning being enhanced through interactions with adults.

'Play/pretend' element was also present in all protocols, often being described to parents as children's 'work' through which they learn about themselves, others and the world. All protocols provided recommendations and suggestions for play activities mostly for children less than 2 years of age and the parents were often encouraged to continue these activities in their own time. Often this practice element was coded alongside 'Psychoeducation – Caregiver' as a significant amount of information was provided about the importance of play for children's healthy development through seeing, hearing, touch, movement and taste during play activities such as in Pehla Qadam

programme in Pakistan (Yousafzai, Rasheed, & Siyal, 2018). It was also often coded alongside 'Use of toys' as many interventions (n=13) made use of simple, often hand-made toys, sometimes crafted as part of the intervention activities.

The psychosocial programme Love, Play and Communication (IMC Uganda, 2009) conducted in Uganda provides a good example of 'Attachment building' for each of the developmental stages of an infant under the umbrella topic of 'Relationships'. The key message given to mothers is 'Love your children so they feel loved and secure and learn how to love, trust and get along with others'. At each stage of development it provides psychoeducation to mothers such as 'Babies learn to trust and love when they are responded to quickly and gently if they are upset, they become confident that that there will be someone to help them when they need it' (at birth to 2 months). Further mothers are encouraged to pay attention to baby's individual cues as they grow and to engage in 'gentle games together' whilst paying attention to baby's cues if they have had enough (2-5 months). Mothers are informed that at 6-8 months the baby will experience fear of strangers and prefer to be with their mothers above everyone else, showing sadness and upset if separated. Mothers are encouraged to treat this stage in a sensitive manner so that the child's feelings are respected.

'Responsive parenting' practice element was defined as promotion of awareness of the importance of sensitive parenting, including practical activities where responding to child's communications and actions; following the child's lead were encouraged; as well as other strategies that promote a mediated learning experience for the child. An example of this is demonstrated by an activity from the Plan Uganda Parenting Programme (Aboud & Singla, 2013) which asks the parents to engage in a two-way talk with their child about

a picture, highlighting that being 'responsive means that you respond to your child's interest and sounds' and that by following the child's lead the parent can expand on what the child is communicating into larger sentence, showing and interest and providing for a mediated learning experience. This practice element was also inclusive of the aspect of responsive physical care, such as responsive feeding. There is existing evidence that responsive parenting can be applied to the feeding context (Black & Aboud, 2011). Parental responsivity is important in promoting reciprocity in feeding interactions with the children, which can arguably be generalised to other forms of interactions. This is reflected in the use of responsive feeding strategies in combination with psychosocial stimulation strategies in the interventions protocols currently reviewed.

Most of the manuals (n=15) highlighted the importance of 'Therapist praise' in reinforcing parents' existing parenting skills as well as new behaviours that were recommended in the intervention. Similarly 'Praise' and encouragement of their children was taught to parents as a tool to enhance their learning in 13 protocols. The programme Improving Mother-Child Interaction to Promote Better Psychosocial Development in Children (WHO, 1997) incorporates praise as one of the eight guidelines for good interaction.

The most common elements of psychosocial stimulation interventions that emerged from the current analysis are consistent with the existing descriptions in the literature of what constitutes psychosocial stimulation (Britto et al., 2015; Engle & Lhotska, 1999), with elements such as 'Attachment building', 'Talking to baby', 'Responsive parenting', 'Praise' mapping onto aspects such as positive parent-child interactions, responsiveness,

encouragement of autonomy, and attachment. The current analysis further emphasises the importance of play and use of toys, as well as parent-directed elements of the interventions such as the reinforcement of existing parental skills and new skill building ('Therapist praise') and the importance of providing information to increase understanding of the early years developmental processes ('Psychoeducation – Caregiver').

Aboud & Yousafzai (2019) highlight the difference between two distinct aims of ECD psychosocial stimulation interventions: providing early learning opportunities for children or teaching responsive parenting. The first type of intervention is what the authors call 'milestone-focused' programmes , consisting of training children and parents how to engage with play materials, and encouraging this in the home; such interventions are often successful. The second type of intervention is based on responsive caregiving, guides parents to notice children's cues and respond to these appropriately. The authors highlight the importance of integrating both of these approaches in future programmes. Interestingly, from the current common elements profile it seems that the intervention protocols from effective studies reviewed, largely already incorporate both of these aims, with 'Responsive care' occurring in 14 protocols alongside 'Use of toys' and 'Play/pretend.'

Limitations. Some limitations of the current review need to be acknowledged. The methodology developed by Chorpita et al., (2005) was followed in the review, focussing on the distillation of the intervention protocols' content. The current review did not extract information from the individual studies, such as the frequency and duration of sessions, as part of the common elements coding. Intervention duration or what constituted control

groups in the trials is included for summary purposes (Table 6) but no further analysis of this information was carried out. These aspects (intensity of intervention) may play an important part in contributing to treatment effects and may also be relevant for the 'matching' process. However this was not the focus of the current review.

Further there are some existing limitations of the distillation and matching model itself, where key practice elements are identified based on their frequency. This simply represents what has been done more frequently across effective studies. The model does not take into consideration the degree of quality, and it is not possible to infer which practice elements are sufficient or are the 'active ingredients' of the intervention. Neither is it possible to determine what practice elements are more effective in driving the change process or improvement. Just because a practice element appears more frequently, does not necessarily mean it is better or more effective (Chorpita, Becker, Daleiden, & Hamilton, 2007).

Additionally, some of the protocols were cultural variations of a previously developed protocol, such as Pehla Qadam programme being an adaptation of the Caring for Childhood Development (WHO, 2012) for the country of Pakistan. As such it meant that the practice elements from these two protocols are represented several times in the frequency counts, despite their similarity and shared core methods. Therefore, the frequencies of practice elements should not be interpreted as a straightforward indication of their importance.

There are some further weaknesses to the analysis of the current common elements analysis. Protocols from several identified effective studies

were inaccessible, either due to lack of response to gaining access to them, or because they were written in other languages than English (Spanish, Urdu). Where the author relied on published papers for description of the intervention the coding was less detailed than where an intervention manual was available, and may not have been as rich in description, which means that some information about the contents of interventions may have been lost.

The current review did not specify or record information about supervision and training of facilitators, although some of the intervention provided guidance on this in their manuals. There was also a great variety in the quality of the protocols, with some providing a lot of information preparing facilitators for how the intervention should be 'set up', to others providing the bare minimum instructions about the content of the sessions with the parents.

Despite these limitations, the results of the review offer useful insights into what constitutes effective early years psychosocial stimulation interventions conducted in trials in LMIC. This may be valuable for informing future efforts to understand which elements are most effective for disseminating psychosocial programmes in new contexts or with new delivery methods.

4.3 Implications for practice and future directions

This review provides an initial step at distilling and unpacking the common practice elements of early child development interventions delivered in LMIC. Through synthesis of existing evidence and knowledge, the common practice elements approach offers an alternative empirically grounded understanding of what works. This is important in low-resource settings, where health care systems lack robust infrastructure. Identifying processes that may act as

mechanisms of change through dismantling studies would be an important future direction for research in this area to better understand what components work while maximising intervention impact. This can be helpful for future development of interventions aimed at promoting early child development, as well as implementing existing effective interventions at larger scale. In this way common practice elements model can be used to affect public policy and action with the usual considerations of cost-effectiveness (Rotheram-Borus, Swendeman, & Chorpita, 2014).

Future research would benefit from investigating how intensity and duration of interventions are linked with children's outcomes. Several reviews (Britto et al., 2015; Engle et al., 2011) described in the current review pointed to the capacity of psychosocial stimulation interventions to protect and buffer against developmental cognitive delay in the most disadvantaged child populations (undernourished, low birth weight, HIV positive) in particular with longer and more intensive interventions. Focussing future common elements methodology to investigate the 'dose-response' relationship between interventions and outcomes can aid with understanding of what constitutes minimal intensity and duration of interventions for them to remain effective, as it has been shown that longer exposure results in more consistent and larger effects on child development (Engle et al., 2007). This seems critical given that costs are likely to be higher for more intensive (i.e., longer-term) interventions. Similarly, longer-term follow-ups of the children who take part in the ECD interventions would be a necessary and important area to investigate in order to assess longer term effects of such interventions.

Building on the idea that evidence-based interventions share 'practice elements' that can be 'distilled' through common elements analysis, it would be of interest for future researchers to explore the 'matching' part of the Distillation and Matching Model developed by Chorpita et al., (2005) in relation to early years child development interventions in LMIC. The model suggests that following distillation, clinicians can select those practice elements that apply to a particular problem or particular target population as can be observed in the literature (Chorpita et al., 2007). In order to do this, in particular in relation to a LMIC context, common elements analysis would need to be applied not only to the intervention protocols and content, but also to the methodology of intervention implementation: including frequency, delivery method (group, individual, home visits), duration, training and supervision of those delivering the intervention, as well as characteristics of the populations receiving the interventions, and their contexts. Cultural adaptations, if such are made, would be of relevance to include in such an analysis in the future. Research on the process of adaptation to specific contexts should be a part of the work on identifying common elements of interventions to help the planning and replicating interventions in new settings.

5 Conclusion

The aim of the review was to evaluate effectiveness of psychosocial stimulation interventions conducted in LMIC on cognitive outcomes in children and changes in parenting practices that facilitate cognitive development. Despite the limitations, including significant heterogeneity in study characteristics and outcomes measures, the results of the review point to positive effects of psychosocial stimulation parenting programmes on measures of children's

cognitive and language development and on improving parent-child interactions.

The review also systematically assessed the contents of the psychosocial stimulation interventions delivered in LMIC which demonstrated effects in trials, through analysis of intervention protocols using common practice elements methodology. This process identified the most common practice elements that are shared across the intervention protocols. This showed that strengthening parents' knowledge and skills in providing responsive care to their children early in life is at the forefront of effective psychosocial stimulation interventions. It is important to continue building the evidence-base around the most effective ingredients in ECD interventions, in order to optimise and streamline these so that they can be made accessible to more people, while maintaining a holistic approach to child development where physical, emotional, and psychosocial needs of a child are met and parents are supported in achieving this. In the LMIC settings, these findings are of particular importance as it can aid more cost-effective planning and delivery of ECD interventions.

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Part 2: Empirical Paper

Cumulative Risk and Children's Developmental Outcomes: Evaluation of the 'Mentor Mothers' Perinatal Intervention in South Africa

Abstract

Introduction. Cumulative risk hypothesis postulates that increasing numbers of concurrent early life risk factors lead to adverse developmental outcomes . Children's exposure to multiple risk factors in low- and middle-income countries has not been widely studied from this perspective, yet the psychosocial adversity in this setting is a recognised problem.

Aims. The first aim of the project was to evaluate the follow up data from a cluster randomized control trial of a home visiting perinatal intervention delivered by community health workers, selected and trained specifically for their ability to successfully rear thriving children. The second aim was to investigate the impact of exposure to multiple risk factors on developmental outcomes. We adopted the cumulative risk framework to explore children's cognitive, behavioural and physical outcomes in the context of intervention and control groups.

Method. Longitudinal regression models were used to evaluate children's outcomes at 5 years post-birth . Further, a moderation relationship between cumulative risk factors at baseline and children's cognitive, behavioural and physical development outcomes was examined at 3 year and 5 year follow up.

Results. The mixed effects regression models demonstrated that early intervention benefits of the Philani Mentor Mothers Programme in relation to children's developmental outcomes are not maintained at 5 year follow-up. Moderated regression analysis showed that cumulative early risk did not exert a moderating effect on the relationship between intervention and child behaviour and cognitive outcomes. Cumulative risk did however exert a moderating effect

on the physical health domain as measured by the frequency of child hospitalisations.

Conclusions. The intervention did not mitigate against the detrimental impact of early psychosocial risks on children's cognitive and behavioural outcomes at 5 year follow up. The study found general support for the cumulative risk hypothesis. Children with higher levels of early cumulative risks benefited more from the intervention than those children with lower levels of early cumulative risk in the domain of physical wellbeing. This effect was not observed in relation to cognitive and behavioural outcomes. The findings highlight the challenge of maintaining effects from the efforts put in by communities to improve children's life chances in the long term.

1 Introduction

Experiences during the early childhood years lay the foundation for children's physical, cognitive and socio-emotional development and shape children's life chances and functioning as adults (Walker, Wachs, Grantham-McGregor, Black, Nelson, Huffman, et al., 2011). The 'first 1000 days' inclusive of conception, pregnancy and up to age 2 years is a critical developmental period that provides a window of opportunity for optimal health, growth and neurodevelopment (House of Commons Health and Social Care Committee, 2019). The evidence from longitudinal studies describes undesirable outcomes in later life for children who grow up exposed to adversity in the early years (Sabates & Dex, 2015). This poses a particular problem for children in low- and middle- income countries (LMIC). At least 200 million children in developing countries are not achieving their full developmental potential due to inequalities in social and economic determinants of health (Grantham-McGregor, Cheung, Cueto, Glewwe, Richer, & Strupp, 2007; Marmot, Friel, Bell, Houweling, & Taylor, 2008). Not only is this a loss of human potential, but it carries with it large economic losses for the communities in which these children are reared (Richter, Daelmans, Lombardi, Hemann, Boo, Behrmann, et al., 2017).

1.1. Cumulative risk and children's outcomes

Psychiatrist Michael Rutter (Rutter, 1981) observed that children exposed to single physical or psychosocial risk factors suffered little enduring harm, in contrast to children exposed to multiple risk factors who were more likely to develop psychological disorders. This led to the study of exposure to multiple risk factors in children and the power of these accumulated risks to interfere

with healthy child development (Evans, Li, & Whipple, 2013). Since then, it has been well established that children exposed to multiple risk factors face higher likelihood of adverse outcomes in psychological, behavioural, cognitive and physical health domains (McLaughlin & Sheridan, 2016). This is described as the cumulative risk hypothesis, which also postulates that increasing numbers of concurrent risk factors produce a cascade of deleterious effects on later developmental outcomes (Appleyard, Egeland, van Dulmen, & Sroufe, 2005).

A common approach to the study of cumulative risk and its effect on children's development includes formation of a composite measure where different risk factors are combined into one summary score. As the original measurements of individual risks use different metrics, the summation is done by dichotomising risk factor exposure (exposure = 1; no exposure = 0). The number of exposures are then summed across domains. This additive approach is straightforward, easy to interpret and allows identification of children at increased odds of developing maladaptive outcomes, including cognitive deficits, behavioural problems and poor physical health. Cumulative risk studies show a strong predictive power of this metric when it comes to a variety of developmental outcomes and this has been replicated across many studies (Evans et al., 2013).

Bronfenbrenner's (Bronfenbrenner & Evans, 2000) bio-ecological theory of human development provides an explanation for why cumulative risk predicts child development to a greater extent than singular risk factors. This framework proposes that human development is driven by transactions between the developing organism (child) and the persons and the environment surrounding the child. Exposure to multiple risk factors is more likely to disrupt

this process of development, because they interfere with the continuity and progressively more complex exchanges necessary to support healthy development, and there are fewer opportunities to find alternative sources of support for adaptation. These processes are said to be influenced by 'proximal' and 'distal' factors, with proximal factors influencing the day to day life of a child, such as in interactions with primary caregivers; and distal factors influencing the child's life indirectly via for example the constraints of the socio-economic status of the family (Bronfenbrenner & Evans, 2000). This ecological understanding of early child development is important in shaping interventions and policies, because it underlines the necessity to address multiple issues in order for interventions to be effective in enhancing children's life chances.

Exposure to poverty is one of the most recognised risk factors for children's development, along with parental mental illness, instability in relationship of parents, war, maltreatment and being born prematurely (Sabates & Dex, 2015). Poverty increases children's likelihood of exposure to multiple adversities, including family stress, food insecurity, exposure to violence – and this is exacerbated by living in communities with limited resources (Black, Walker, Fernald, Andersen, DiGirolamo, Lu, et al., 2017).

In LMICs, many children have poor access to health care and education and live with parents who contend with multiple stressors, like financial, health and mental health problems. Maternal depression in the perinatal period and beyond seems to be particularly important in relation to poorer cognitive development outcomes in children (Stein, Pearson, Goodman, Rapa, Rahman, McCallum, et al., 2014). Furthermore, a meta-analysis of 17 studies demonstrated that children of mothers with depression are more likely to be

underweight or stunted. Infant physical development is therefore compromised in the context of parental poverty and mental health problems which are widespread in LMICs (Walker et al., 2011). By late infancy, children's cognitive status is a good predictor of later cognitive functioning (Bornstein, 2014). In South Africa it is estimated that fewer than half of children in third grade are performing at grade level (Department of Basic Education, 2011). Thus, children's cognitive performance is of particular concern in LMICs due to the physical, psychosocial and mental health risks posed early on in life.

Considering the widespread exposure of children in LMICs to multiple risk factors it is important to take into account the effects of cumulative risk on children's developmental outcomes in this setting. Furthermore, it is valuable to study cumulative risk exposure among children in LMICs to help target interventions by identification of the most vulnerable populations and supporting these children in the first instance through early intervention. It is subsequently important to address the question of whether these early family support interventions are able to moderate and mitigate against the impact of cumulative risk on child development in this context.

1.2. Supporting women raising children in high-risk environments: perinatal interventions in LMIC context

Women in low- and middle- income countries (LMIC) are more likely to be exposed to risk factors such as poverty, low literacy, and lack of social support compared to women in high income countries (HIC) (Atif, Lovell, & Rahman, 2015). These factors contribute to a higher rate of maternal depression in LMICs (Affonso, De, Horowitz, & Mayberry, 2000). It is recognised that poor

maternal mental health has a detrimental impact on parenting, and infants' subsequent development, with most significant deficits seen in LMICs (Tomlinson, Cooper, & Murray, 2013).

Vulnerability in the early years is high, but it is argued that the potential benefits from early interventions that support child development can be substantial too (Darmstadt, Khan, Lombardi, & Richter, 2018). Early Childhood Development (ECD) interventions aim to mitigate the risks posed to physical and cognitive development in early childhood for children living in low-resource settings (Walker et al., 2011).

In LMIC settings these interventions are often delivered by paraprofessionals as an alternative delivery method, considering limitations in access to specialist professionals (Chowdhary, Sikander, Atif, Singh, Ahmad, Fuhr, et al., 2014). Given the range of challenges mothers in LMIC frequently face, especially in countries affected by HIV, alcohol abuse and malnutrition, community health workers (CHWs) need to support mothers in addressing multiple health challenges rather than focusing on single outcomes (Rotheram-Borus, Richter, van Heerden, van Rooyen, Tomlinson, Harwood, et al., 2014). Delivery of psychosocial support to promote physical and mental health in the perinatal period by non-specialist workers has emerged as a key way to improve access to health and mental health services (Padmanathan & De Silva, 2013). This method of delivery has been shown to be moderately effective in several systematic reviews in both LMICs and HICs (Gilmore & McAuliffe, 2013; Peacock, Konrad, Watson, Nickel, & Muhajarine, 2013).

Recent reviews (Aboud & Yousafzai, 2015; Britto et al., 2015; Britto et al., 2017; Rao, Sun, Chen, & Ip, 2017) of various psychosocial programmes

supporting parents and children in LMICs have found positive effects on measures of children's cognitive and language development, as well as some non-cognitive outcomes such as motor development. The delivery of these programmes varies in terms of length, setting, mode and frequency of contact. Some involve home visits, others are delivered as groups. Some of these programmes combine nutrition and stimulation elements and are effective in improving cognitive and language development in children. Overall, the evidence suggest that the cumulative developmental toll of adverse social and material circumstances on children can be reduced through perinatal and early years supportive interventions. The current study will explore the long term effects of one such programme.

1.3. Philani Mentor Mothers Programme

Philani Mentor Mothers Programme (PMMP) is a community-based perinatal supportive intervention and was evaluated in a cluster randomised controlled trial in Cape Town, South Africa (Le Roux, Tomlinson, Harwood, O'Connor, Worthman, Mbewu, et al., 2013). The programme was delivered by community health workers (CHW) called Mentor Mothers selected and trained from the community, in particular for their successful rearing of thriving children. These local women were trained to use cognitive behavioural skills to support mothers to manage daily activities and improve children's outcomes. The CHWs aimed to reduce multiple domains of risk rather than targeting single problems: including mothers' risk of acquiring HIV, following protocols to Prevent Maternal to Child Transmission (PMTCT) of HIV, improve maternal and child health including tuberculosis and illness detection; reduce maternal alcohol use;

improve child nutrition; foster children's growth and development. The CHWs were not trained to target depression specifically. The mothers in the control arm of this trial received regular antenatal care available in health clinics.

Earlier analyses of this trial demonstrated benefits of the Mother Mentors programme up to the age of 18 months for mothers and their children (Le Roux et al., 2013; Rotheram-Borus et al., 2011; Rotheram-Borus, Richter, et al., 2014), including fewer post-birth complications and hospitalisations for children, longer breastfeeding periods, improved health behaviours such as higher adherence to PMTCT tasks and higher rates of condom use; as well as better physical outcomes for children including less stunting and better growth (Tomlinson, Rotheram-Borus, Harwood, le Roux, O'Connor, & Worthmann, 2015). The outcomes for mothers did not show a reduction in depressive symptoms at 18 months.

Interestingly, at 36 months post-partum, intervention mothers were significantly less depressed (Tomlinson, Rotheram-Borus, le Roux, Youssef, Nelson, Scheffler, et al., 2016). Intervention children had better vocabularies and were less likely to be hospitalised compared to the control condition. This outcome was present despite continued exposure to poverty and other psychosocial stressors.

Together these findings suggest that there are benefits to intervening early to influence maternal and children outcomes by providing generalist support delivered by community-based peer health workers. The evaluation of the project (Le Roux et al., 2013; Rotherham-Borus et al., 2014; Tomlinson et al., 2016) has thus far only examined the effects of the intervention at 6, 18 and 36 months. It is unclear whether these benefits are maintained beyond the first

three years of life. Effects of cumulative risk have not been studied for this cohort of children. Moderation relationship between the intervention in relation to changes in perinatal risk factors and outcomes in children have not been examined. The current study will address these lines of inquiry.

1.4. The present study

The current study took advantage of the five-year follow up data, as well as the data from earlier time points, available from the Philani Mentor Mothers Programme and had a number of aims. Firstly, the study examines the effects of the Philani intervention on children's outcomes at 5 year post-birth. This will be carried out by conducting longitudinal regression analyses. It will allow understanding of the longer term effects of this perinatal home-visiting intervention.

The second aim is to investigate the impact of exposure to multiple risk factors on developmental outcomes, as located within a broad theoretical framework of the ecological model of child development. We adopted a cumulative risk framework to explore children's cognitive, behavioural and physical outcomes in the context of intervention and control groups. The question posed is whether the early family support intervention is able to prevent the negative impact of cumulative risk on child development. Another way of framing the question posed by this study is whether the intervention is moderated by cumulative risk - with effects assumed to be greatest for those facing the highest levels of cumulative adversity. These two approaches - intervention moderating the effects of cumulative risk or cumulative risk moderating the effects of intervention - lead to the same general prediction,

namely that intervention and cumulative risk will interact in their relationship with child outcomes.

This question will be investigated by constructing a cumulative risk index in accordance with previous literature on cumulative risk (Appleyard et al., 2005; Evans et al., 2013). The cumulative risk measure will be constructed at the point that mothers entered the Philani trial during pregnancy. Though limited, there is some research evidence looking at temporal effects of cumulative risk metrics showing that early childhood risks play a more significant role in predicting later child outcomes, than cumulative risks measured later on in life (Appleyard et al., 2005). This evidence provides the rationale for using the cumulative risk metric as measured at baseline as the moderating variable for children's outcomes at follow up points.

The individual risk factors that the cumulative risk measure consists of will be identified based on the study data available. These broadly map onto three sub-domains of risk that incorporate both 'proximal' and 'distal' factors that can exert an influence on child development: maternal risk – which includes maternal depression, physical ill health or disability, and problematic alcohol use; socio-economic risk – including poverty, experience of hunger, informal housing situation, unemployment and low level of education; and social risk – including factors such as lack of practical and emotional support, as well as experiences of intimate partner violence. The current study will investigate whether these sub-domains of risk play a particular part in predicting or moderating outcomes in children over time.

Statistically, mixed effects longitudinal regression models will be built to examine how perinatal risk factors predict and moderate the outcomes in the context of intervention and non-intervention as the children reach age 3 and 5.

In summary, the study will address the following research questions:

1. Does the Philani Mentor Mothers intervention improve children's behavioural, cognitive and physical outcomes at 5 years post-birth?
2. Does cumulative risk moderate the relationship between intervention effects and children's outcomes at 36 months and at 5 years? (Are the ones most at risk early in life benefiting the most from intervention?)
3. Which domains of risk are most important in moderating the intervention effect?

2 Method

2.1 Participants and Design

Data for this study are drawn from the Philani Mentor Mothers Programme (PMMP), a cluster randomised controlled trial of a perinatal home-visiting intervention which took place in Cape Town, South Africa. The original study was approved by the Institutional Review Boards of University of California Los Angeles and Stellenbosch University. The methods of the study have previously been published (Rotheram-Borus et al., 2011). Written voluntary informed consent was received from all study mothers. The randomised controlled trial is registered with ClinicalTrials.gov (NCT00996528).

The participants were recruited from neighbourhood clusters (N=24) of 450-600 households outside of Cape Town. These clusters were identified and matched based on housing type, presence of electricity, water sanitation, size

and density, alcohol bars, child care resources, distance to clinics, length of residence. The neighbourhoods were randomised in six blocked sets of four neighbourhoods each, resulting in 12 intervention (PMMP) neighbourhoods (N=644) and 12 standard care (SC) neighbourhoods (N=594). Standard care (SC) involved routine antenatal and postnatal care; Intervention (PMMP) included standard care and home visits by community health workers trained as generalists (mean=11 visits).

The pregnant women within neighbourhoods were identified by recruiters conducting house-to-house visits every other month to all households' in one intervention and one control neighbourhood. Participants were included if they were pregnant, above age 18 living in the neighbourhood. Pregnant women were at an average of 26 weeks of pregnancy (range 3-40) weeks at recruitment.

Figure 1 summarises the total numbers of participants flowing through the study, outlining the proportions lost to follow up or death at each assessment point. Almost all pregnant women were recruited and assessed during pregnancy (98%), two weeks post-birth (92%), 6 months post birth (88%), 18 months (91%), 36 months (85%) and 5 years (82.5%) post-birth.

The current secondary data analysis project excluded late-entry participants (n=94) who were recruited when the child was already born. Twin and triplet births were also excluded from current analyses (N=13) due to difficulty of comparability of multiple births. The total number of participants at baseline as included in the current study was N=1144. Demographic characteristics of these participants are summarised in Table 1. The current analysis draws primarily from assessments at three time points – baseline

(pregnancy), 3 years (36 months) and 5 years (60 months) with a focus on investigating the effects of the intervention on children's cognitive, behavioural and physical outcomes.

A power calculation was performed during the planning stages of the original trial (Rotheram-Borus et al., 2011) and found that in order to detect a standardized effect size of 0.4 (medium effect size) at 80% power the sample size per intervention arm needed to be 592, with a total sample size of 1184.

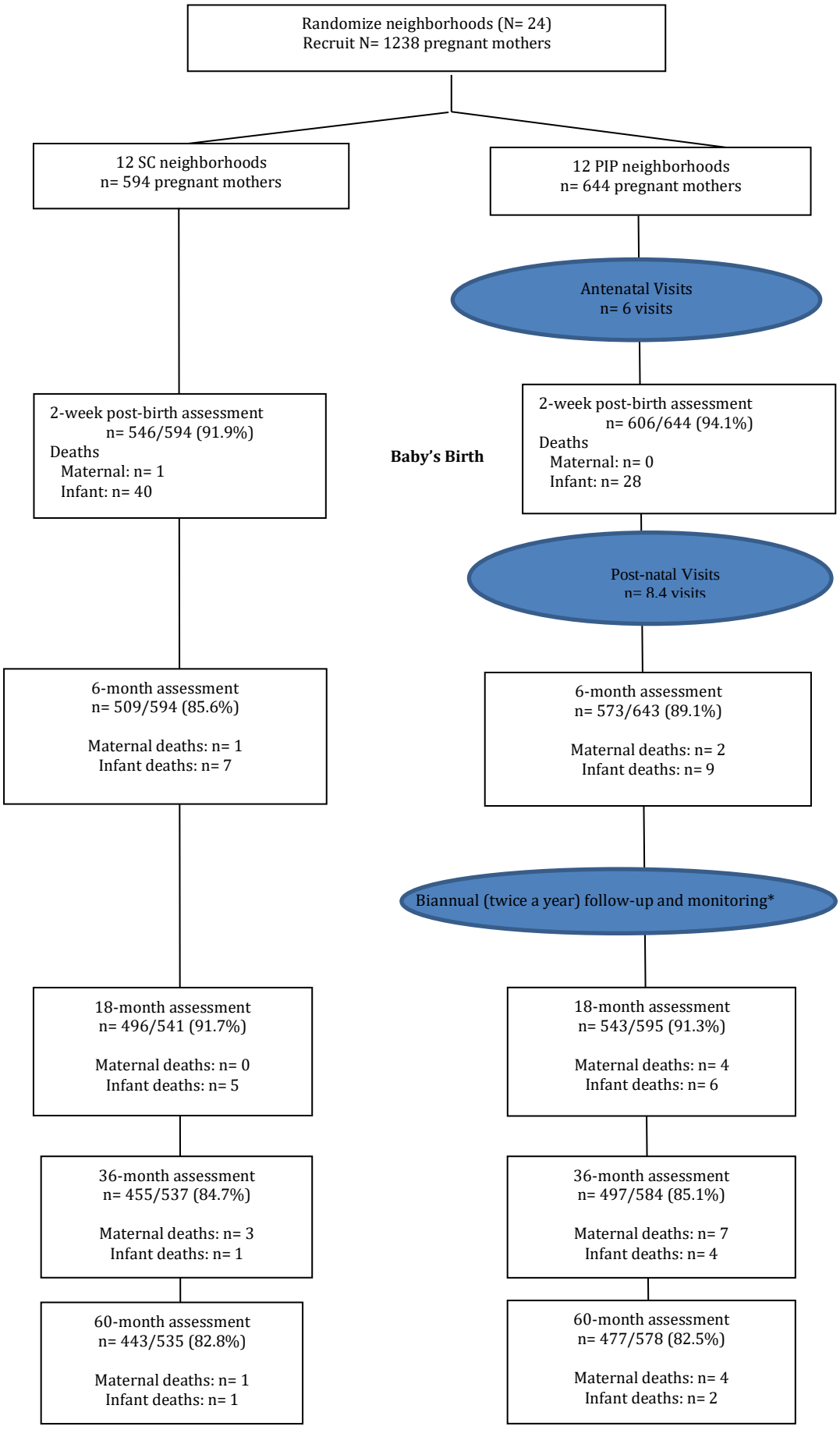


Figure 1. *Outline of the participant flow of the clustered randomised trial.*

Table 1. Characteristics of the sample by Intervention (N=644) and Standard Care (SC) (N=500) groups

	Intervention (N=644)		SC (N=500)		Total (N=1,144)	
	n	%	n	%	n	%
Demographic characteristics						
Age, mean (SD)	26.5 (5.5)		26.05 (5.4)		26.3 (5.5)	
Highest education level, mean (SD)	10.3 (1.8)		10.3 (1.8)		10.3 (1.8)	
Currently employed	129	20.0	89	17.8	218	19.1
Married or lives with partner	377	58.5	273	54.6	650	56.8
Monthly household income > 2000 rand	280	45.6	229	48.1	509	46.1
Formal housing	197	30.6	191	32.2	388	31.3
Mother hungry past week	312	48.4	301	50.7	613	49.5
Alcohol						
Use during pregnancy	56	8.7	49	9.8	105	9.2
AUDIT-C > 2, at pregnancy before discovery	113	17.5	101	20.2	214	18.7
AUDIT-C > 2, after pregnancy discovery	41	6.4	24	4.8	65	5.7
Maternal health and mental health						
Weeks pregnant at assessment, mean (SD)	26.0 (7.9)		25.8 (8.4)		25.9 (8.1)	
Ever tested for HIV	590	92.0	456	91.2	1,046	91.4
Mothers living with HIV	149	25.5	123	27.2	272	26.2
EPDS, mean (SD)	11.2 (6.9)		11.1 (6.9)		11.2 (6.9)	
EPDS > 13	238	37.0	181	36.2	419	36.6
EPDS > 18	109	17.0	81	16.2	190	16.6
Mothers living with a health problem (diabetes, asthma, hypertension, HIV+)	245	38.0	185	37	430	37.6
Cumulative risk, mean (SD)	4.8	(2.1)	4.8	(2.2)	4.8	(2.1)

2.2 Measures

2.2.1 Maternal measures

Demographic characteristics

Demographic characteristics were reported at baseline. Socio-economic factor variables of interest to the current project included: income level, whether the mother experienced hunger in the last week, housing situation (availability of

formal housing), employment status, education level, partnership status and financial involvement of the partner (father of the child).

Income level was reported in 6 categories: 1) 0-499 South African RAND, 2) 500-1000 RAND, 3) 1001-2000 RAND, 4) 2001-5000 RAND, 5) 5001-8000 RAND, 6) 8000 RAND and above. The official middle income poverty line in South Africa is at approximately 1000 RAND (Statistics South Africa, 2018). The current study assumed the same approach to the poverty risk threshold as the original research study of below 2000 RAND.

Alcohol use

The Derived Alcohol Use Disorder Identification Test (AUDIT-C) (Dawson, Grant, & Stinson, 2005) is a 3 - item questionnaire, including questions such as 'How often do you have a drink containing alcohol?', 'How many units of alcohol do you drink on a typical day that you are drinking?', 'How often have you had 6 or more units on a single occasion in the last year?'. Each item is rated on a scale from 0-4. Total scores above 5 indicate increasing risk of alcohol dependence. Scores 11-12 indicate possible dependence.

For the purposes of assessing problematic drinking in the current cohort in both the frequency of drinking and the scores from the AUDIT-C measure were used, in combination with the following questions: 1) Have close friends or relatives worried or complained about your drinking? 2) Do you sometimes take a drink in the morning when you first get up? 3) Has a friend or family member ever told you that things you said or did while you were drinking that you could not remember? Alcohol use was assessed at baseline and all follow up points.

Depression

Symptoms of depression were assessed at each time point of the trial using the Edinburgh Postnatal Depression Scale (EPDS) (Cox, Holden, & Sagovsky, 1987), with a cut-off score of higher than 13 to indicate depressed mood (Lawrie, Hofmeyr, De Jager, & Berk, 1998). Severe depression levels were identified at scores above 18 on EPDS.

Intimate Partner Violence

Domestic violence was assessed at baseline and each follow up point with four items adapted from Jewkes, Levin, & Penn-Kekana (2002) on women's experience of violence. Women were asked four items referring to the last 12 months: if they were slapped or had anything thrown at them; if they were pushed or shoved; were punched with a fist or another object; were attacked or threatened with a weapon by their partner. Responses ranged from never (1), once (2), few (3), to many (4).

Health

Health status was assessed by self-reports of diabetes, high blood pressure, and tuberculosis or other reported disability at baseline. HIV status and new pregnancies/childbirths were reported at each assessment.

Social support

Information was collected about practical and emotional support available to the mothers. This included emotional and practical support from partner, family

or friends in the past week, mother's involvement and support levels, and ability to turn to these people for support in difficulty. This was done by asking the mothers three questions about each source of potential support: whether the participant can trust their partner/mother, whether they receive practical support from partner/mother, and whether they can turn to them in difficulty. This information was collected at baseline and each assessment point.

2.2.2 Cumulative risk scale

Consistent with methodology from previous literature (Appleyard et al., 2005; Evans et al., 2013), each of the maternal risk factors, as assessed at baseline (during pregnancy), was transformed into a dichotomised variable and then summed into a cumulative risk scale. Baseline cumulative risk was chosen in contrast to later cumulative risk in order to mitigate against confounding effects of the risk measure and the intervention effects. The cumulative risk scale included three sub-domains: socio-economic risk, maternal risk and social risk scales.

Socioeconomic risk factors were: monthly income below 2000 South African RAND, mothers experiencing at least one instance of hunger in the past week, living in informal housing, unemployment, education level of less than 10 years at baseline, and receiving no financial support from the father of the child.

Maternal risk factors included presence of severe depression (score of 18 or above on EPDS), presence of disability or ill-health in the mother, and problematic use of alcohol during pregnancy. Problematic drinking was constructed from the AUDIT-C score, where the scores of participants indicated whether they have experienced heavy episodic drinking in the last month

(before or after finding out about pregnancy) and responded yes to at least one of the three following questions: 1) Have close friends or relatives worried or complained about your drinking? 2) Do you sometimes take a drink in the morning when you first get up? 3) Has a friend or family member ever told you that things you said or did while you were drinking that you could not remember?

Social risk factors included absence of practical support in the past week, absence of support from partner (practical and emotional), absence of support from own mother (practical and emotional), and exposure to intimate partner violence. Practical and emotional support from partner and own mother included three questions: whether the participant can trust their partner/mother, whether they receive practical support from partner/mother, whether they can turn to them in difficulty. Risk was coded when the participant did not respond yes to any of the three items. Intimate partner violence was reported by assessing whether the woman had been slapped, pushed or shoved, and/or threatened with a weapon by a current partner in the past 12 months.

Cumulative risk scale variable generated frequency scores which were approximately normally distributed across the sample, each participant could get a score between 0 (no risk factors) to 13 (13 risk factors) at baseline.

2.2.3 Child outcomes

Cognitive development

The Peabody Picture Vocabulary Test (PPVT) (Dunn, 1965) was administered at 36 months and 5 years, a version adapted for South Africa (Pakendorf & Alant,

1997) to assess child language. The Mental Processing Index (MPI) of the Kaufman Assessment Battery for children (KABC, Kaufman & Kaufman, 1983) was used at age 5 years to assess general mental processing ability, excluding the assessment of acquired knowledge.

Physical health outcomes

A government-issued Road to Health card for each child was used to record the number of clinic visits and hospitalisations. The number of hospitalisations between assessments were extracted from the Road to health card at 6 months, 18 months, 3 year and 5 year assessments.

Behavioural outcomes

The Child Behaviour Checklist (CBCL; Achenbach & Ruffle, 2000) was used to assess children's behavioural outcomes at 36 months. The CBCL consists of 99 items designed to measure the frequency of a child's problem behaviours in the past 6 months, rated by parents. At 5 years only the Aggressive Behaviour subscale scores of the CBCL were collected. Eyberg Child Behaviour Inventory (ECBI; (Eyberg & Pincus, 1999)) is a 36-item measure rating severity and frequency of behaviour problems completed by parents. It was used to assess behavioural outcomes at 5 years.

2.3 Statistical Analysis

The data collected from the trial has a hierarchical structure where assessments are 'nested' within clustered neighbourhoods. This dependency may have an effect on the relationships being studied, thus violating the homoskedasticity

assumption of traditional regression analyses, which postulates that residuals have equal variance, and the assumption that they are uncorrelated (Schwartz & Stone, 1998). To assess the relationship between the predictor variables and outcomes the current study used multilevel mixed linear regression models, which take into consideration the different levels of the data structure (Level 1 – Child outcomes, Level 2– Neighbourhood clusters) and accounts for the effects of these levels on the strength of modelled associations. Linear mixed models are also beneficial as they allow analyses to include missing data, as attrition is prevalent at long term follow up assessments.

The distribution of each child outcome measurement was examined by the intervention and control groups. Continuous outcomes were analysed using multilevel mixed-effects linear regression models with restricted maximum likelihood estimation (REML). Count outcomes were analysed using mixed-effects Poisson regression models.

The first research question was addressed by conducting a multilevel regression analysis evaluating overall effectiveness of the home-visiting intervention on child outcomes at 5 years.

The second research question was addressed by building a multilevel regression model with an added interaction term of cumulative risk by intervention group. Moderating effects of cumulative risk on child cognitive and behavioural outcomes by intervention at 3 and 5 years were thus explored separately.

Poisson regression analyses were conducted to explore the effects of intervention on the number of children's hospitalisations at 3 and 5 years

respectively, representing an exploration of effects of intervention on physical health outcomes in children.

Missing data were assumed missing at random. Random intercept modelling was assumed, taking into account the differential baseline levels of predictor variables such as cumulative risk scale. Where appropriate and where there was evidence that the variance in the regression slope effect was significant, random slope modelling was used. When the variance in the slopes was non-significant, fixed slope effects were assumed.

STATA SE software version 15.1 was used to perform all analyses.

3 Results

3.1 Data preparation

A cumulative risk measure was constructed as a sum of dichotomised (presence of risk) values based on the baseline risk factors. Mean cumulative risk frequencies were matched across the two conditions (see Table 1). The cumulative risk variable was centred prior to all analyses. This was done as very few mothers in the dataset (N=4) had a cumulative risk score of zero, which would make interpretations around the zero point less meaningful. Interpretation of cumulative risk scores around the mean of the predictor is more meaningful in this context.

Regression models do not require the outcome variables to be strictly normally distributed (Hayes, 2013). Nevertheless, distributions of children's outcome measures (behavioural and cognitive) were explored and examined for skewness and kurtosis, both visually and statistically (using the -sktest- command in STATA) . Where significant skewness and kurtosis were found,

logarithmic and square root transformations were tested. This did not make a large difference to the outcome distributions, thus untransformed outcome distributions were used for the final analyses.

3.2 Sample characteristics

Participants for intervention and control groups were similar across demographic characteristics and considered well-matched at baseline. Mothers were similar in age, education levels, socio-economic status, and had similar patterns of alcohol consumption.

Participants lost to follow up (N = 224) at 5 years constituted 19.6% of the baseline participants. Of those randomised to the intervention condition (N = 644), 26% were lost to follow up. Of those randomised to the standard care condition (N = 500), 11 % were lost to follow up.

Participants who took part in the follow up assessments at 5 years were compared to participants who were lost to follow up on their baseline characteristics using t-tests and tests of proportions. There were no significant differences between mothers who remained in the study and those who were lost to follow up on the following variables: depression as measured by EPDS ($t(1142) = -1.74$, $p = 0.082$), education levels ($t(1142) = -0.96$, $p = 0.33$), proportion of mothers with income below 2000 RAND ($z = -0.44$, $p = 0.65$), proportion of mothers living in informal housing ($z = 1.87$, $p = 0.062$), proportion of mothers with problematic drinking ($z = -0.83$, $p = 0.41$), proportion of mothers reporting no practical support ($z = -1.39$, $p = 0.16$), proportion of mothers living with a health condition ($z = -1.66$, $p = 0.096$), proportion of mothers exposed to intimate partner violence ($z = -0.62$, $p = 0.53$).

There was however a small but significant difference in the cumulative risk scale scores between the two groups ($t(1142) = -2.22$, $p = 0.026$), with mothers lost to follow up demonstrating a higher overall risk score ($M = 4.98$, $SD = 2.14$) than mothers who remained in the study ($M = 4.68$, $SD = 2.14$).

3.3 Descriptive statistics

The descriptive statistics with means and standard deviations for the main child outcome variables are summarised in Tables 2 and 3, for 3 year and 5 year outcomes respectively.

Preliminary correlation analyses between the study variables were performed and are presented in Table 4. Strong positive relationships were observed between behavioural outcomes (CBCL, ECBI, Aggressive Behaviour) at 3 years and 5 years as expected. Cognitive outcomes (PPVT) at 3 and 5 years showed a significant weak association between time points.

Cumulative risk measured at baseline showed a weak significant association with behavioural outcomes at 3 years (CBCL r = 0.17, p <0.001; Aggressive behaviour r = 0.15, $p < 0.001$). There was no association of cumulative risk to behavioural outcomes as measured by ECBI at 5 years (r = 0.04, $p = 1$), but there was a significant weak relationship with the Aggressive Behaviour scale (r = 0.13, $p < 0.05$). There was no relationship between the cumulative risk scale and cognitive outcomes (PPVT) at either 3 or 5 years. There was a weak negative association between the cumulative risk scale and cognitive function as measured by Kaufman Mental Processing Index at 5 years (r = -0.13, $p < 0.05$).

The measure of cumulative risk at baseline was moderately associated with maternal depression scores at baseline (r = 0.44, $p < 0.01$) and weakly associated with maternal depression scores at 3 years (r = 0.22, $p < 0.01$) and 5 years (r = 0.14, $p < 0.01$).

Table 2. Child outcomes at 3 years by Intervention and Standard Care groups

	Intervention (N=497)		**Standard Care (N=455)**	
	Mean	(SD)	Mean	(SD)
Behaviour (CBCL)	46.6	(23.5)	46.09	(23.0)
Behaviour (CBCL) Aggressive Behaviour Subscale	12.7	(7.16)	12.8	(7.2)
Language (PPVT)	20.0	(7.9)	19.1	(8.2)
Hospitalizations (number of admissions N/%)	n	%	n	%
None	352	71	283	62.33
One	100	20.2	112	24.7
Two	20	4.03	30	6.61
Three	11	2.22	15	3.3
Four+	13	2.61	14	3.1

Table 3. Child outcomes at 5 years by Intervention and Standard Care groups

	Intervention (N=477)		**Standard Care (N=443)**	
	Mean	(SD)	Mean	(SD)
Behaviour (ECBI)	86.0	(37.0)	88.5	(37.0)
Behaviour (CBCL) Aggressive Behaviour Subscale	10.6	(8.1)	10.7	(8.1)
Language (PPVT)	61.9	(18.8)	62.7	(17.8)
Cognitive function (KABC) Global Mental Scale Index (MPI) Standard score	83.1	(11.5)	83.2	(11.0)
Hospitalizations (number of admissions N/%)	n	%	n	%
None	303	66	242	56.8
One	93	20.2	100	23.5
Two	28	6.1	34	8.0
Three	15	3.26	26	6.1
Four+	21	4.57	24	5.6

Table 4. Correlations between children's behavioural and cognitive outcomes, maternal depression, and cumulative risk.

	1	2	3	4	5	6	7	8	9	10	11	12	13
Behavioural outcomes													
1. CBCL (3 years)	-												
2. Aggressive behaviour (3 years)	.87**	-											
3. ECBI (5 years)	.41**	.4**	-										
4. Aggressive Behaviour (5 years)	.47**	.48**	.67**	-									

Cognitive outcomes													
5. PPVT (3 years)	-.02	-.02	-.001	-.01	-								
6. PPVT (5 years)	.01	.002	.01	-.04	.28**	-							
7. Kaufman (5 years)	-.01	-.01	.07	.01	.3**	.47**	-						
Maternal variables													
8. EPDS (baseline)	.17**	.15**	.07	.14**	.02	.05	.002	-					
9. EPDS (3 years)	.27**	.23**	.15**	.21**	.02	.004	-.01	.13**	-				
10. EPDS (5 year)	.19**	.12*	.17**	.2**	.01	-.004	.08	.15**	.22**	-			
11. Cumulative risk (baseline)	.17**	.15**	.04	.13*	-.01	-.07	-.13*	.44**	.22**	.14**	-		
12. Cumulative risk (3 years)	.20**	.16**	.09	.14**	.03	-.06	-.1	.20**	.5**	.17**	.43**	-	
13. Cumulative risk (5 years)	.21**	.17**	.15**	.22**	-.02	-.07	-.09	.16**	.24**	.43**	.36**	.48**	-

Note: * p<0.05
**p<0.01

3.4 Effects of intervention on child outcomes at 5 years

To answer the first research question, multilevel mixed effects regressions were performed to investigate predictive effects of the home-visiting intervention during the perinatal period on children's behavioural, cognitive and physical outcomes at 5 years. Intervention did not significantly predict children's behaviour at 5 years as measured by ECBI (B = -2.88 95% CI [-8.54, 2.77], p = 0.33), or aggressive behaviour as measured by the Aggressive Subscale of CBCL (B = 0.05 95% CI [-1.21, 1.31], p = 0.93). There was no significant effect of intervention on children's language and cognitive outcomes as measured by PPVT (B = -0.76 95% CI [-3.43, 1.91], p = 0.58) and Kaufman Assessment Battery for Children, Mental Processing Index scale (B = - 0.33 95% CI [-2.18, 1.52], p = 0.73).

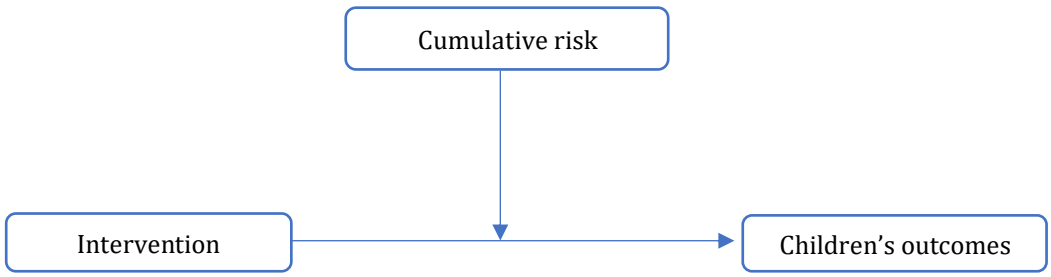
Poisson regression analysis was run to predict the number of children's hospitalisations since birth. There was no significant predictive effect of intervention on children's hospitalisations counts (B = -0.27, 95% CI [-0.55, 0.008], p = 0.06).

These analyses confirmed the unpublished findings by (Tomlinson et al., 2019) that were completed during the time the current study was conducted.

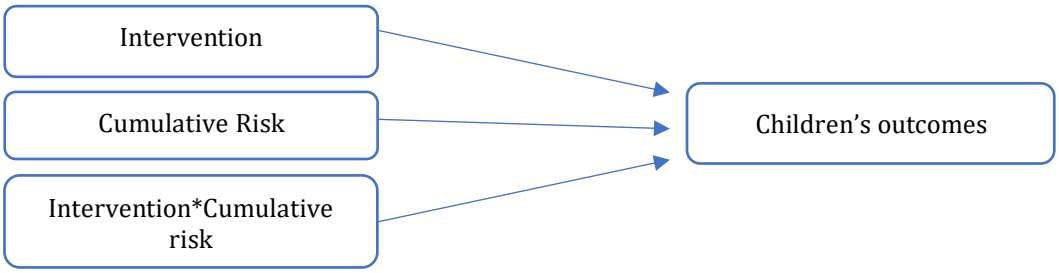
3.5 Cumulative contextual risk

In order to investigate the second research question, multilevel moderated regressions were performed testing moderating effects of cumulative contextual risk on the relationship between the intervention and children's outcomes at 3 years and 5 years post-birth. Figure 2 demonstrates the relationships tested. Independent variables in the model included intervention and cumulative risk,

with an added interaction term. Gender was entered into the models as a covariate. Children's outcomes were treated as dependent variables in every model. The results are presented in Table 5.



a. Conceptual diagram of the relationship between intervention, cumulative contextual risk at baseline (pregnancy) and children's outcomes at follow up.



b. Statistical diagram of the relationship between intervention, cumulative contextual risk at baseline (pregnancy) and children's outcomes at follow up.

Figure 2*. Conceptual and statistical diagrams of the relationships between the variables of the study.*

3.5.1 Children's outcomes at 5 years

Moderated regressions were run for children's outcomes at 5 year post-birth. No significant effects of intervention on any of the outcomes (behavioural, cognitive, and physical) were found. No significant interactions between the cumulative risk variable and children's outcomes were observed, indicating that cumulative risk did not have a moderating effect on children's outcomes by intervention as observed at 5 years post-birth. Each model is described in more detail below. Gender was controlled for in all models.

ECBI as DV: In this model, fitted with random intercepts and fixed slopes, no predictive effects of intervention were observed, despite overall significance of the model (Wald $\chi 2 = 10.1$, $p < 0.05$). Cumulative risk did not moderate the effects of intervention on the levels of behavioural difficulties in children at 5 years (B = 0.69 95% CI [-2.53, 2.84], $p = 0.91$). The significance of the overall model was carried by the covariate of gender which was predictive.

Aggressive behaviour as DV: This model, fitted with random intercepts and fixed slopes, showed an overall significance (Wald $\chi 2 = 30.62$, $p < 0.01$). No predictive effects of intervention on aggressive behaviour were found, and cumulative risk did not moderate the relationship between intervention and children's aggressive behaviours (B = 0.39 95% CI [-0.15, 0.94], $p = 0.16$). Notably, when the interaction term was removed from the model, Cumulative risk acquired a predictive significant effect (B = .55, 95% CI [0.27, 0.82], $p < 0.01$), which is consistent with the positive correlational relationship between these two variables observed in Table 4.

PPVT as DV: This model fitted with random intercepts and fixed slopes, showed no overall significance (Wald $\chi 2 = 3.99$, $p = 0.41$), no significant predictive effects of intervention (B = -0.86 95% CI [-7.42, 5.7], $p = 0.798$), nor any moderating effects of cumulative risk (B = 0.01, 95% CI [-1.24, 1.26], $p = 0.98$).

Kaufman MPI as DV: In this model, fitted with random intercepts and fixed slopes, no significant predictive effects of intervention were found (B = 3.29 95% CI [-1.03, 7.62], $p = 0.13$) despite overall model significance (Wald $\chi 2 = 15.39$, $p < 0.01$). No moderating effect of cumulative risk was seen (B = -0.72, 95%CI [-1.54, 0.09], $p = 0.08$). Similarly to behavioural outcomes described above, when the interaction term was removed from the model, cumulative risk was observed to have significant predictive effects on children's mental processing scores effect (B = -0.71, 95% CI [-1.12, - .31], $p < 0.01$). This is consistent with the correlational relationship between these variables seen in Table 4.

Hospitalisations as DV: This model fitted with random intercepts and random slopes, showed no overall significance (Wald $\chi 2 = 8.45$, $p = 0.076$). There was no interaction between cumulative risk and intervention conditions (B = -0.01, 95%CI [-.08, 0.06], $p = 0.837$). When the interaction was removed from the model – the predictive effect of cumulative risk was significant.

Table 5. Effects of predictor and moderator variables on children's outcomes at 5 years.

Variable	Coef.	95% *CI*	*SE*	Wald	*p*
Outcome 1 – ECBI (behaviour)				10.1	0.038*
Intervention	-3.26	-17.25 – 10.7	7.14		0.648
Cumulative risk	.69	-1.18 – 2.72	1.02		0.497
Intervention*Cumulative risk	.16	-2.53 – 2.84	1.37		0.91
Outcome 2 – Aggressive Behaviour				30.62	0.000**
Intervention	-1.75	-4.64 – 1.14	1.47		0.236
Cumulative risk	.34	-.071 – .74	.21		0.138
Intervention*Cumulative risk	.39	-.16 – .94	.28		0.164
Cumulative risk (interaction term removed from model)	0.55	.27 – .82	.14		0.000**
Outcome 3 – PPVT (language)				3.99	0.41
Intervention	-.86	-7.42 – 5.71	3.27		0.798
Cumulative risk	-.59	-1.5 – .33	.47		0.21
Intervention*Cumulative risk	-.01	-1.24 – 1.26	.64		0.98
Outcome 4 – Kaufman MPI (cognitive function)				15.39	0.004**
Intervention	3.29	-1.03 – 7.62	2.21		0.135
Cumulative risk	-.33	-.92 – .27	.31		0.283
Intervention*Cumulative risk	-.72	-1.54 – .09	.41		0.082
Cumulative risk (interaction term removed from model)	-.71	-1.12 – - .31	.21		0.001**
Outcome 5 - Hospitalisations			8.45	0.076	
Intervention	-.23	-.72 – .22	.23		0.322
Cumulative risk	.04	-.01 – .09	.03		0.106
Intervention*Cumulative risk	-.01	-.08 – .06	.04		0.837
Cumulative risk (interaction term removed from model)	.04	.001 – .071	.02		0.043*

Note: * p<0.05 **p<0.01

3.5.2 Children's outcomes at 3 years

Further moderated regressions were run to explore the moderating effects of cumulative risk on children's outcomes earlier on, at 36 months post-birth. No

significant predictive effects of intervention on any of the children's outcomes (behavioural, cognitive, and physical) were found. Baseline cumulative risk was found to be predictive of behavioural and physical outcomes at 3 years. Cumulative risk also had a moderating effect on the relationship between intervention conditions and number of children's hospitalisations, as will be described in detail below.

CBCL as DV: In this model, fitted with random intercepts and random slopes, the overall model showed significance (Wald $\chi 2 = 33.5$, $p < 0.01$). There was a predictive effect of cumulative risk on behavioural outcomes (B = 2.16 95% CI [1.08, 3.25, $p < 0.01$), remaining significant with the interaction term included in the model. There was no significant interaction between cumulative risk and intervention, indicating no moderation effect (B = -0.45 95% CI [-1.9, 0.99], $p = 0.54$).

Aggressive behaviour as DV: This model, fitted with random intercepts and fixed slopes, showed an overall significance (Wald $\chi 2 = 30.6$, $p < 0.01$), and a significant predictive effect of cumulative risk on aggressive behaviour (B = 0.52 95% CI [0.19, 0.86, $p < 0.01$). There was no significant interaction between cumulative risk and intervention, indicating no moderation effect (B = 0.01 95% CI [-0.44, 0.46], $p = 0.96$).

PPVT as DV: This model, fitted with random intercepts and fixed slopes, showed an overall significance (Wald $\chi 2 = 11.04$, $p < 0.05$). There were no significant

predictive effects of cumulative risk on cognitive outcomes (B = 0.15 95% CI [-0.25, 0.55, p = 0.45), with or without interaction term included in the model. There was no moderating effect of cumulative risk on the relationship between intervention and language outcomes in children (B = - 0.37 95% CI [- 0.91, 0.16, p = 0.18). Cumulative risk remained non predictive when the interaction term was removed from the model. The significance of the overall model was carried by the covariate of gender which was predictive.

Hospitalisations as DV: This model fitted with random intercepts and random slopes, showed an overall significance (Wald $\chi 2$ = 11.04, p < 0.05). Cumulative risk was predictive of the number of hospitalisations at 3 years (B = 0.08 95% CI [0.02, 0.13], p < 0.01) in the full model. The model showed a significant moderating effect of cumulative risk on the relationship between intervention conditions and the frequency of children's hospitalisations (B = -.09 95% CI [-0.17, -0.006], p < 0.05). Marginal slopes were plotted to assess the interaction effect. The relationship is demonstrated in Figure 3. Marginal predicted mean contrasts were performed showing a significant difference between Intervention and Standard Care conditions at 1SD above the predicted mean, representing higher contextual risk at baseline ($\chi 2$ = 6.6, p < 0.05), compared to no significant difference between the two conditions at 1SD below the predicted mean, representing lower contextual risk at baseline ($\chi 2$ = 0.04, p = 0.84). In other words, children in the Standard Care condition from mothers with higher levels of cumulative contextual risk at baseline were admitted to hospital more often (B = 0.75, 95% CI [0.59, 0.9], p < 0.01) compared to the children in the

intervention condition (B = 0.49, 95% CI [0.38, 0.61], $p < 0.01$). Children of mothers whose contextual risk factors were lower at baseline, did not benefit from the intervention to the same degree in relation to number of times hospitalised during the first 3 years of life.

Table 6. Effects of predictor and moderator variables on children's outcomes at 3 years.

Variable	Coef.	95% *CI*	*SE*	Wald	*p*
Outcome 1 – CBCL (behaviour)				33.5	0.0000**
Intervention	3.58	-4.28 – 11.46	4.01		0.372
Cumulative risk	2.16	1.07 – 3.25	.55		0.000**
Intervention*Cumulative risk	-.45	-1.9 – .99	.74		0.541
Outcome 2 – Aggressive Behaviour				30.6	0.0000**
Intervention	.32	-2.13 – 2.76	1.24		0.797
Cumulative risk	.52	.18 – .86	.17		0.002**
Intervention*Cumulative risk	-.01	-.44 – .46	.23		0.96
Outcome 3 – PPVT (language)				11.04	0.026*
Intervention	2.6	-.32 – 5.36	1.45		0.082
Cumulative risk	.16	-.24 – .57	.21		0.427
Intervention*Cumulative risk	-.35	-.89 – .18	.28		0.199
Outcome 4 – Hospitalisations				11.26	0.024*
Intervention	.21	-.27 –.68	.24		0.398
Cumulative risk	.08	.02 –.13	.03		0.009**
Intervention*Cumulative risk	-.09	-.17 – -.006	.04		0.035*

Note: * p<0.05 **p<0.01

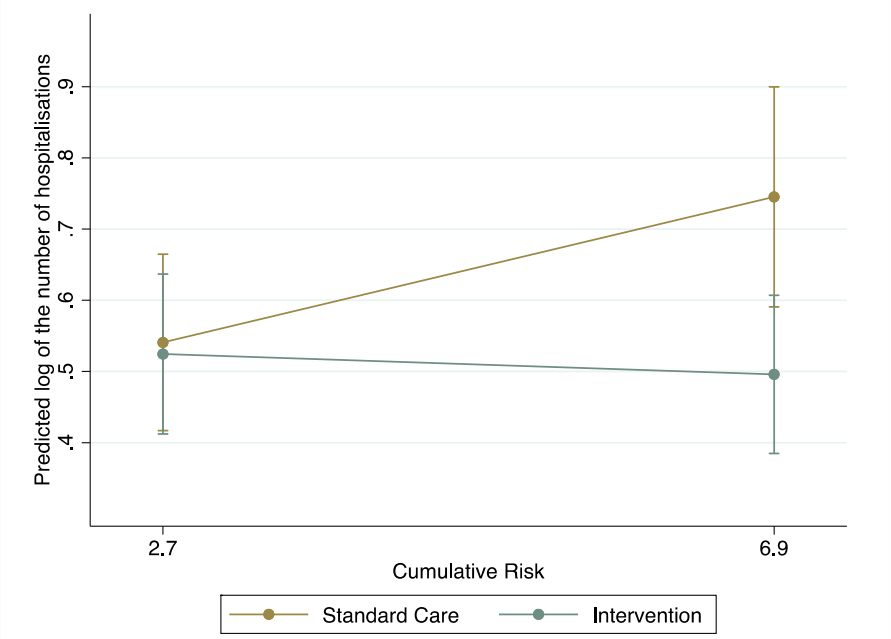


Figure 3. *Relationship between cumulative risk, intervention conditions and predicted hospitalisations at 3 years.*

3.6 Subdomains of cumulative contextual risk

Further moderated regression analyses were run to investigate the subdomains of the cumulative risk scale (socio-economic risks, maternal risks, and social risks). There were no moderating effects of the subdomains on intervention-related change in children's outcomes at 5 years post-birth, consistent with the overall findings for 5 year outcomes. These results are therefore not reported further.

Table 7 summarises the models that were run for 3 year outcomes. At 3 years post-birth, behavioural outcomes (CBCL and Aggressive behaviour scales) were predicted by the subdomains of risk, however no moderation effects of subdomains on risk on the relationship between intervention and children's outcomes were observed. There were no predictive effects of subdomains of risk on cognitive outcomes as measured by PPVT. For physical health outcomes, frequency of hospitalisations was significantly predicted only by the Maternal risk domain, and there was a significant moderating effect observed in this model as seen by the significant interaction term. Marginal predicted mean

contrasts were performed showing a significant difference between Intervention and Standard Care conditions at 1SD above the predicted mean, representing higher Maternal risk at baseline ($\chi 2 = 6.93, p < 0.01$), in contrast to no significant difference between the two conditions at 1SD below the predicted mean, representing lower Maternal risk at baseline ($\chi 2 = 0.01, p = 0.9$). The plotted relationship is demonstrated in Figure 4 and is consistent with the relationship seen between Cumulative risk, Hospitalisations and Intervention conditions presented in Figure 3. This suggests that the moderation effect of the cumulative risk scale on physical health outcomes in children is driven mainly by the maternal risks.

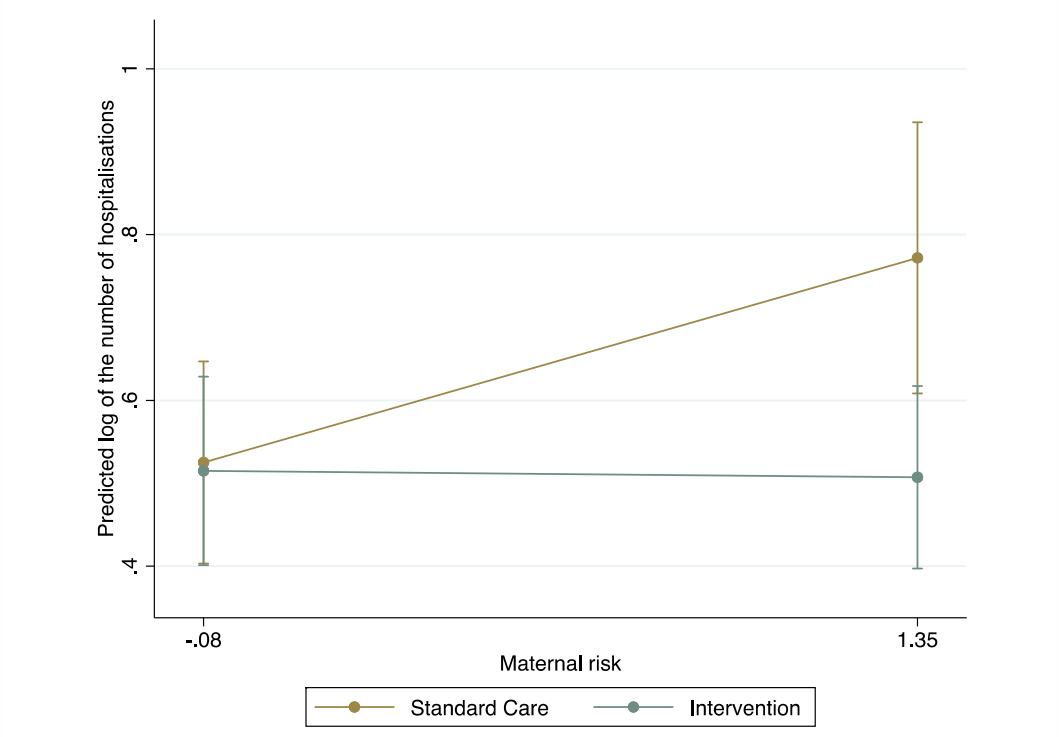


Figure 4. *Relationship between Maternal risk, intervention conditions and predicted hospitalisations at 3 years.*

Table 7. The relationships between subdomain of risks and children's outcomes at 3 years.

Variable	Coef.	95% *CI*	*SE*	*p*
Outcome 1 – CBCL (behaviour)				
Socio-economic risk	3.14	1.11 – 5.19	1.04	0.002**
Maternal risk	5.36	1.95 – 8.77	1.74	0.002**
Social risk	3.27	.85 - 5.68	1.23	0.008**
Note: no moderating effects of risk subdomains were observed in the models				
Outcome 2 – Aggressive Behaviour				
Socio-economic risk	.65	.01 – 1.28	.32	0.045*
Maternal risk	1.64	.58 – 2.7	.54	0.002**
Social risk	.92	.17 – 1.67	.23	0.016*
Note: no moderating effects of risk subdomains were observed in the models				
Outcome 3 – PPVT (language)				
Socio-economic risk	-.04	-.79 – .70	.38	0.908
Maternal risk	.31	-.96 – 1.59	.65	0.634
Social risk	.73	-.15 – 1.61	.45	0.103
Note: no moderating effects of risk subdomains were observed in the models				
Outcome 4 – Hospitalisations				
Socio-economic risk	.1	-.004 – .21	.05	0.059
Maternal risk	.27	.1 – .44	.09	0.002**
Intervention*Maternal risk	-.28	-.52 – -.04	.12	0.024*
Social risk	.12	-.01 – .24	.06	0.068
Note: no moderating effects were found for Socio-economic and Social risk domains				

Note: * p<0.05 **p<0.01

4 Discussion

The aim of the current study was to evaluate the effects of a perinatal home-visiting intervention delivered in South Africa (Philani Mentors Mothers Programme) on children's behavioural, cognitive and physical outcomes at 5 years post-birth. A key question we addressed was whether early intervention moderated the impact of cumulative adversity on children's health and psychological outcomes. This was done by constructing a cumulative risk scale from the demographic data available at baseline as well as the risk factors assessed in mothers during pregnancy.

The summary of the findings are discussed in light of previously published findings from the Philani trial, as well as evidence from other perinatal and early years interventions. The results are also discussed from the perspective of cumulative risk hypothesis and the broader theoretical framework of ecological model to child development.

4.1 Summary of findings

4.1.1 Effectiveness of the intervention at 5 year follow up

The results of the study showed that there was no effect of intervention on children's cognitive, behavioural or physical health outcomes at 5 years post-birth as assessed by the longitudinal mixed effects regression models. This was contrary to what the hope for such an intervention might be, but it is an important finding which indicates that benefits of the intervention in relation to children's outcomes seem to have tapered off at longer term follow up. This finding confirmed the results that were completed by Tomlinson et al., (2019) who also found that children in the intervention and standard care conditions

were equally likely to be hospitalised, and scored similarly on other physical health indicators: scores for height and weight – for age as well as similar odds of being stunted or malnourished. They also found that children scored similarly on behavioural and cognitive measures, indicating no intervention effect on these domains at 5 year follow up.

In contrast to the current 5 year follow up findings, there were beneficial effects of intervention on children's physical development outcomes at earlier time points as described earlier in the paper. At 18 months, fewer post-birth complications and hospitalisations for children were observed in the intervention condition, mothers showed improved health behaviours such as higher adherence to HIV transmission prevention tasks and longer breastfeeding periods; physical outcomes for children such as less stunting and better growth (Le Roux et al., 2013; Rotheram-Borus, Tomlinson, et al., 2014; Tomlinson et al., 2015) were seen. In relation to cognitive outcomes, at 18 months no intervention effect was seen as measured by Bayley Scale II cognitive and motor domains; however intervention-related differences in cognitive scores were observed between children of antenatally depressed mothers and mothers who were not depressed (Tomlinson, Rotheram-Borus, Scheffler, & Le Roux, 2017). This suggested that the intervention at this earlier time point did not exert an overall effect on cognitive development, however it may have protected the children from further cognitive developmental delays when the risk factor of maternal depression was present.

It appears that the benefits of intervention at earlier time-points for children were mostly observed in the physical health domain, in addition to benefits to maternal outcomes, such as reduced levels of depression at 36

months (Tomlinson et al., 2016). Maternal outcomes were not examined as part of the current investigation. Interestingly, Tomlinson et al., (2019)reported that intervention mothers consumed less alcohol at 5 year follow up than did mothers in the standard care condition, but there were no intervention effects on depression levels in mothers at 5 years.

In light of the current null findings in relation to children's outcomes, the content of the intervention needs to be considered. The Philani Mentor Mothers programme promoted wellbeing for mothers and children, with several 'health messages' delivered by peer mothers trained in cognitive behavioural principles, problem solving and supportive counselling. The health messages consisted of HIV transmission prevention practices, alcohol use reduction practices, nutrition practices, assistance with gaining financial grants for the children, self-care and social support for mothers (Rotheram-Borus et al., 2011). Considering that the intervention did not set out to improve cognitive and behavioural outcomes for children, it may be understandable why the benefits would be accrued around children's physical health domain at earlier assessment points, rather than on children's cognitive and behavioural outcomes later on. The Philani intervention did not directly target children's cognitive development such as through psychosocial cognitive stimulation or improving parent-child interactions. Stimulation approach is well established in the early childhood development (ECD) field (Aboud & Yousafzai, 2015; Engle et al., 2011; Obradovíc, Yousafzai, Finch, & Rasheed, 2016; Potterton, Stewart, Cooper, & Becker, 2010) with evidence from countries such as Pakistan and Jamaica that this approach is effective in enhancing children's cognitive outcomes in low-resource settings. Such an addition of a stimulation element to

the Philani programme may be worth considering in order to more directly target cognitive development.

The dose and intensity of the intervention must also be considered in evaluating longer term impact of a home-visiting intervention. On average the community health workers in the Philani trial made six antenatal visits, five postnatal visits between birth and 2 month post-birth, and 1.4 visits a month until the children were 18 months old. After 18 months visits only occurred every 6 months (Rotheram-Borus, Tomlinson, le Roux, & Stein, 2015). At the 5 year follow up point none of the intervention mothers were receiving any type of support or input from the mentor mothers. A review of early parenting interventions carried out in Turkey, Brazil, Jamaica, South Africa, Belarus, Philippines and others (Britto, Ponguta, Reyes, Karnati, Aboud, Bornstein, et al., 2015) suggests that 12 months duration is the minimum time recommended to improve a child's physical health, cognitive development and socio-emotional development, and that programmes that lasted over 2 years had a more consistent impact among the most vulnerable and disadvantaged populations. It also concluded that more intensive approaches that include direct interactions with the child are needed to improve both parent-level outcomes (responsiveness) and child level outcomes (language abilities) (Britto et al., 2015). In light of this, the current intervention may benefit from a longer, more intensive intervention, with more explicit focus on children's cognitive development, such as via psychosocial stimulation or enhanced parent-child interaction approaches in the future to see an effect on children's cognitive and behavioural outcomes.

Considering the findings through the lens of cumulative risk hypothesis it is important to acknowledge that there may be increasing demands associated with raising children across the developmental periods and the changing needs of a child. This might intersect with the lack of support previously available in the context of continued psychosocial adversity. Illustrating this, there was a significant positive relationship between cumulative risk as assessed at 5 years and maternal depression levels ($r = 0.43$, $p < 0.01$) as seen in Table 4. This suggests that concurrent psychosocial stress continues to account for a substantial amount of variability in maternal depressive mood, which in turn may influence mothers' ability to provide responsive care. It is likely therefore, that cumulative risk, inclusive of maternal depression, coupled with reduced social support (no longer provided by mentor mothers), continues to shape children's development after the intervention comes to an end.

Obradovíc et al., (2016) studied the mediational effects of a parenting intervention in Pakistan, and showed two underlying mechanisms through which intervention predicted measures of intelligence and executive function skills longitudinally, the quality of home stimulation and maternal scaffolding. Their study also reported a waning effect of intervention over time and the need to specifically target these processes to enhance intervention effects. The authors suggest that there is a need to study the effect of 'booster sessions' in early years interventions to enhance their longitudinal effects. This may be of relevance for our understanding of the lack of a longitudinal intervention effect at 5 year follow up in the current study. The waning effect of the home-visiting intervention on children's developmental outcomes suggests a need for future

programmes to explicitly address the issues of adapting the knowledge and skills learnt during the postnatal period to later developmental periods.

4.1.2 Cumulative risk and behavioural outcomes

Baseline cumulative risk was significantly predictive of aggressive behaviour at both 3 and 5 years, and it was predictive of total behavioural difficulties as measured by CBCL at 3 years. Higher early cumulative risk was positively associated with higher levels of behavioural challenges at later time points. This finding is important for the context of LMICs, where the overall level of adversity is very high, and the environment is harsher (Stein et al., 2014). The average amount of psychosocial risks in the current sample was at 4.8, which means that the variation in cumulation risk is reflective of greater degrees of adversity than in relatively well-resourced settings of HICs. As such the current results seem to support existing evidence from HICs showing that greater cumulative risk predicts later adverse behavioural outcomes in early childhood (Crnic, Gaze, & Hoffman, 2005; Trentacosta et al., 2008), middle childhood (Ribeaud & Eisner, 2010) and adolescence (Appleyard et al., 2005). Aggressive behaviours seem to be particularly strongly predicted by early psychosocial risks (Ribeaud & Eisner, 2010). Cross sectional studies also support the notion of cumulative risk being associated with higher problem behaviours (Atzaba-Poria, Pike, & Deater-Deckard, 2003).

The lack of a moderating effect of cumulative risk on the relationship between intervention and later behavioural outcomes is interesting. It may be worth investigating other moderators and mediators between cumulative risk and children's behavioural outcomes. For instance, one study found that cumulative risk in early childhood is a predictor of nurturing parenting which in

itself is a predictor of later externalising and internalising difficulties (Trentacosta et al., 2008). Parenting therefore accounted for the 'indirect' mediational effect between cumulative risk and behavioural problems in that study. On the other hand, other studies have failed to find such a mediational effect of parenting on the relationship between cumulative risk and child behaviour, despite finding that cumulative risk has an effect on children's behavioural outcomes (Crnic et al., 2005), indicating a more direct effect of cumulative risk. Parenting practices were not measured as part of the current intervention study, however future research would benefit from looking at this potential mechanism between early psychosocial risks and later behavioural outcomes in children.

4.1.3 Cumulative risk and cognitive outcomes

Cumulative risk was not predictive of children's language outcomes as measured by PPVT at both 3 and 5 years. This is somewhat surprising, as there is evidence in the literature of the impact of cumulative risk on language outcomes in children (Burchinal, Vernon-Feagans, & Cox, 2008; Laucht, Esser, & Schmidt, 1997; Stanton-Chapman, Chapman, Kaiser, & Hancock, 2004; Wade et al., 2018). It is possible that previous studies of impact of cumulative risk on cognitive development in children used different instruments, measuring various domains of cognitive function. In support of this idea, there was a predictive effect of cumulative risk on the scores of the Kaufman Mental Processing Index (MPI), which was used at 5 years only, a measure which focuses on executive function and fluid ability, rather than language ability. As such, perhaps different domains of cognitive function are differentially affected.

A recent longitudinal study (Wade, Madigan, Plamondon, Rodrigues, Brown & Jenskins, 2018) conducted in a high income country, showed that cumulative risk of mothers in infancy was associated with poor parenting competencies which were in turn associated with children's compromised executive function, theory of mind and language ability at age 4.5. This mediating effect of parenting competencies on cognitive development is an important area to explore with further research, to understand better the pathways that lead from early psychosocial stresses to reduced child cognitive functioning in children in LMIC settings too.

It is worth highlighting that the mean score on Kaufman MPI for children in both conditions was 83 at age 5, which is contrasted against an expected normative score of 100 (Laher & Cockcroft, 2013; Lichtenberger, Volker, Kaufman, & Kaufman, 2012); similarly the mean score on PPVT in this cohort of children was 62 at age 5, contrasted against the mean expected normative score of 100 (Meers, State, & Haven, 2013). These scores indicate a lower than expected cognitive functioning and vocabularies for children of age 5, suggesting that regardless of intervention or levels of cumulative risk the children in this cohort and setting are failing to reach their full developmental potential. As such, this also contributes to the evidence that shows that there is an association between poverty, early learning in the home and later children's cognitive skills as demonstrated in other countries such as Zambia (McCoy, Zulikowski, & Fink, 2015), Bangladesh (Hamadani, Tofail, Huda, Alam, Ridout, Attanasio et al., 2014), Nepal (Patel, Murray-Kolb, LeClerq, Khatry, Tielsch, Katz, et al., 2013). This highlights the great challenge that preventative efforts face in this context.

4.1.4 Cumulative risk and physical health outcomes

A significant moderating effect of cumulative risk was found on the number of children's hospitalisations as assessed at 3 years, as seen from a significant interaction effect. Children in the Standard Care condition from mothers with higher levels of cumulative contextual risk at baseline were admitted to hospital more often, in contrast to children in the intervention condition. At the same time, there was no benefit of intervention for those children whose mothers experienced lower levels of risk at baseline. This suggests that those with higher cumulative risk have benefitted more from being in the intervention condition. It could be argued that intervention provided a 'buffering' against negative effects of cumulative risks on children's health. However this interpretation is tentative as this effect was only observed on one aspect of children's physical health, and was not seen in behavioural or cognitive domains. Nevertheless, it makes sense that physical health outcomes improve most clearly, as supporting parents to promote their children's physical wellbeing was the primary focus of the current intervention.

The positive finding of an intervention effect on protecting children against hospitalisations at age 3, along with other positive effects on children's health as seen from earlier findings from the trial, suggests that the intervention's aim to protect children against early adversity by supporting mothers through the perinatal period is successful when it comes to physical wellbeing of children in the early childhood. However this intervention effect seems to disappear by the time that children reach age 5, which is a concerning outcome for those children exposed to highest levels of risk. Research on adverse childhood experiences (ACE) is clear about the detrimental impacts of

toxic stressors early in life on individuals' ill-health in childhood and adulthood (Felitti, 2009; Hughes, Bellis, Hardcastle, Sethi, Butchart, Mikton, et al., 2017; Shonkoff & Garner, 2012). There is limited research on the impact of ACEs in LMIC settings, but there is some indication that ACEs are associated with substance abuse, mental illness and HIV risk in South Africa (Jewkes, Dunkle, Nduna, Jama, & Puren, 2010). This suggests that cumulative risk seen in this population of children may put them on a trajectory of higher susceptibility to developing diseases later on in life.

4.1.5 Subdomains of risk

Analyses of subdomains of risk revealed that there were no significant moderating effects of domains of socio-economic and social risks. There was however a significant moderator effect of the maternal risk at 3 years. This suggests that the moderating effect of cumulative risk on children's hospitalisations was driven mainly by the maternal risk subdomain. The maternal risk domain included factors such as maternal depression at baseline, problematic drinking during pregnancy, and maternal ill-health or disability, which also included mothers living with HIV. Interestingly, this finding seems to partially map onto the results of a systematic review of effects of ACEs (measured retrospectively) on adult health (Hughes et al., 2017), which found that the strongest relations with multiple ACEs were mental illness, problematic substance use and violence. This suggests that these particular risks (parental mental illness and substance misuse) represent strong intergenerational effects that perpetuate familial cycles of adversity and ill-health.

Thinking about the broader ecological framework (Bronfenbrenner & Evans, 2000), one can extrapolate on the finding of maternal risk being the

'carrier' of the interaction between intervention and children's physical health outcomes. It is possible that the maternal risks as conceptualised to include maternal factors in this study, account for the 'proximal' factors influencing the child's development. The 'distal' factors of socio-economic risk and social risk – may not directly contribute to children's physical development as seen in the current null findings of these domains on child outcomes, but they may be exerting an indirect effect via the mother. It is known for instance that psychosocial stresses such as poor socio-economic conditions and interpersonal problems and adverse life events are contributing factors for maternal depression in LMIC (Atif, Lovell & Rahman, 2015). This mechanism was not explored in the current study, but may be a fruitful area to investigate in future research.

4.2 Strengths and limitations

A major strength of the current analyses included the use of the data from the Philani Mentors Mother Programme, which is a large representative sample of mothers and children living in impoverished peri-urban settings in South Africa. The mothers and children were consistently followed up at several time points with a high follow up rate (82,5%), which is impressive considering that attrition rate often presents a problem in intervention study follow-ups. The study was a randomised controlled trial which is generally believed to be the gold standard in study design, and the cluster randomisation was clearly outlined and described by the original research group. The data utilised in the current secondary data analysis included detailed information on the socio-demographics characteristics of the cohort of mothers at baseline (as well as

follow up assessments), which allowed the construction of the early cumulative risk variable for the current study investigating the effects of cumulative risk. Children's behavioural, cognitive and physical health outcomes were assessed across different developmental periods which allowed for a longitudinal evaluation of the intervention effectiveness on children's longer term outcomes, as well as allowing for a more general epidemiological analysis of association between early risks and child outcomes.

One limitation of this study is the conceptualisation of cumulative risk through dichotomisation of individual risk variables to collate a summarised risk variable. Some researchers (McLaughlin & Sheridan, 2016; O'Hara, Legano, Homel, Walker-Descartes, Rojas & Laraque, 2015) critique this methodology as lacking explanatory power, in particular when attempting to explore the mechanisms that link childhood adversity with developmental outcomes, as cumulative risk hypothesis implicitly assumes that all adverse experiences influence development through the same underlying mechanisms in an additive manner. In contrast to this assumption, O'Hara et al. (2015) demonstrated in their study that children who were at risk of neglect showed worse cognitive/language outcomes than children who were at risk of both neglect and physical abuse, which contradicts the cumulative risk hypothesis. Further, McLaughlin & Sheridan (2016) propose to distil adverse experiences into dimensions of adversity and differentiate between experiences of *threat* (witnessing violence or experiencing abuse) and experiences of *deprivation* (lack of expected inputs from environment, neglect) in order to study differential mechanisms by which adversity impacts development.

These criticisms highlight the need to better understand the underlying mechanisms by which early risks effect children's development over time. In the current study, the cumulative risk variable was also separated into 'subdomains of risk' in an attempt to further understanding about which particular risks are more important for the variables of interest in the study. Through these analyses it was shown that maternal risk sub-domain was the 'carrier' of the effects of the interaction between cumulative risk and the number of hospitalisations. Although a tentative finding, this method of grouping risk factors by type, goes some way to address the challenge of delineating the mechanisms by which cumulative risk operates on developmental processes. More consideration would need to be given to this in future research however.

A further constraint of the study data in relation to the current research question was the lack of measurement of parenting practices or parent-child interactions, which would have been an interesting variable to include in the moderator analyses. In addition, gender was controlled for as a covariate, but as gender differences were not the focus of the current investigation this was not explored further. Future research can address this gap, as it seemed that gender offered a significant contribution in explaining a proportion of the variance in some of the models tested in the current study.

4.3 Implications and future directions

The waning effect of the home-visiting intervention on children's developmental outcomes suggests a need for future programmes to explicitly address the issues of maintaining intervention effects longitudinally. Longer, more intensive interventions with possible 'booster' sessions aimed at generalising previously

gained knowledge to new developmental phases may be necessary to see prolonged effects, especially in the context of continued psychosocial adversity. The lack of intervention effect on cognitive and behavioural outcomes in children may be reflected in the nature of the intervention which focussed on child general wellbeing. Whilst this focus, which was already broad in its scope to address multiple issues, is understandable and logical in the harsher LMIC context, future programmes may benefit by including explicit components of psychosocial stimulation and enhancement of parent-child interactions in order to see improvement in children's cognitive and behavioural development to ensure the developmental potential is reached across all of these domains.

In light of the limitations of the current analyses, future research would benefit from testing other potential moderators of the relationship between early risks and children's outcomes. As proposed earlier, parenting competencies and behaviours may be of particular interest to investigate as a potential moderators and mediators of children's outcomes, in particular as research into the mechanisms of change in intervention studies is scarce in LMIC settings.

4.4 Reflections on cultural differences in research

Considering cultural differences in research conducted across national borders is important. For instance, the regular issues of reliability, validity and norms of the psychometric measures arise when used in contexts other than where they were initially developed and standardised (Lonner, 1985).

Within the research questions asked by the current study and the dataset used to answer them, there was an assumption of universality of constructs

investigated. These constructs included among others the cumulative risk framework and the assessments of cognitive development, such as executive function and language, as well as behavioural measures. Cultural adaptations of these measures and adaptations for use in communities of interest are often necessary to conduct good quality research in new settings.

Majority of the measures used included in the study have been widely used internationally, and where possible culturally adapted versions of measures were employed. Furthermore, the research was enhanced by the inclusion of measurements of physical health outcomes, such as problematic alcohol use, frequency of hospitalisation (and therefore illness), or absence or presence of disability. It can be argued that these measures accomplish a level of equivalence across different contexts. For example, there is extensive evidence that supports the use of AUDIT-C to measure alcohol use problems in various settings and with diverse populations (Reinert & Allen, 2007). The language measure (PPVT) was specifically adapted for use in South Africa (Pakendorf & Allen, 1997).

A further consideration in relation to cultural differences relates to the involvement of researchers from wealthier countries and well-resourced universities with the research conducted in low resource settings. In the case of the current secondary data analysis the researcher's position outside of the geographical and cultural context of the original study meant there was only a limited awareness of the cultural context in which the study took place. This may be seen as a challenge to the overall process of research. On the other hand, the distance between the researcher and the intervention could also contribute

to a less biased stance in relation to the evaluation of intervention, with less investment into the success of the intervention.

In general, externally-sponsored research carried out in low and middle income countries often involves cultural differences between those organising or funding the research and the research workers and participants in the host country (Nufflield Council on Bioethics, 2002). Inequality of power and advantage between wealthier countries funding the researches and LMICs hosting the research inevitably creates the conditions of unintentional misuse of this power even when perceived through the benevolent lens in healthcare research (Nufflield Council on Bioethics, 2002). Considerations around research being sensitive to cultural differences, the moral imperative of not exploiting the vulnerable populations, and the continuation of the standards of care post-research are all relevant when conducting research in LMICs.

Appropriate weight needs to be given to the interest of participants and local communities. Ethical guidelines stress the importance of researchers having a duty to enable participant communities to benefit from the research conducted on them (Nufflield Council on Bioethics, 2002).

The South African research group which oversees the current randomised control trial and who collected and recorded the data have a good knowledge of the local community and language. Thus, the methodology of the randomised control trial can be said to be culturally sensitive in this respect. The local community seems also to benefit from the research conducted in that the women from the community receive opportunities for employment and opportunities to improve the health and wellbeing of their community.

Considering the principles of international research in the context of the current study, it is important to note the history of the Philani project. One of the key ideas behind The Philani Mentor Mothers Programme is to engage women who thrive despite adversity in the task of improving the lives of families in their own communities. These women are employed and trained to deliver the intervention. Philani as a project has been in operation for over 30 years, with the research evaluation of the Mentor Mothers programme growing out of the original project (Philani, 2013). In this way the delivery of intervention is not done 'to' the participants but 'with' them, achieving a level of sustainability, which is a common challenge in low resource settings. The Philani project does not stop when the research evaluation stops, which is a positive aspect of this study seeking to delineate the aspects of intervention that are most effective.

5 Conclusions

The findings of this study add to the current research investigating the long term effectiveness of early years home visiting interventions in LMIC. It demonstrated that early intervention benefits of the Philani Mentor Mothers Programme in relation to children's developmental outcomes are not maintained at 5 year follow-up.

Separately, the study found general support for the cumulative risk hypothesis, consistent to previous research in this area. The cumulative early risk did not exert a moderating effect on the relationship between intervention and child behaviour and cognitive outcomes. Put differently, the intervention did not mitigate against the detrimental impact of early psychosocial risks on

children's cognitive and behavioural outcomes in the long term. Cumulative risk did however exert a moderating effect on physical health domain as measured by the frequency of child hospitalisations. Those children with higher levels of early cumulative risks benefited more from the intervention than those children with lower levels of early cumulative risk. This effect was shown to be largely carried by the maternal risk subdomain of the cumulative risk scale.

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Part 3: Critical Appraisal

1 Introduction

This critical appraisal will reflect on relevant issues and challenges associated with this research project. I will consider the personal and theoretical perspectives that motivated and informed my choice of topic for the literature review and empirical paper. I will comment on my learning points from undertaking a systematic review of reviews and a common elements analysis of intervention protocols, and discuss the implications of this methodology for future research. I will then consider my experience of conducting my empirical project, with particular reference to the process of utilising the secondary data analysis methodology and the advantages and constraints of this approach. The appraisal will conclude with a discussion of the findings within a broader early childhood development (ECD) context.

2 Selection of topic

During the initial research topic selection I was curious about the area of perinatal mental health. My work experiences in a health psychology team in a hospital at the time fuelled this interest. I was predominantly involved in cases of antenatal anxiety and depression referred from maternity wards. I wanted my research to provide me with the opportunity to learn more about maternal mental health and the consequences of maternal mental ill-health. By engaging in initial literature searches, I discovered that globally, in women of child-bearing age, anxiety and depression accounts for the largest proportion of the burden associated with mental and neurological disorders (Vos, Flaxman, & Naghavi, 2012) and that mental health problems are more prevalent in low and middle income countries (LMICs) than in high income countries (HICs) (Atif et

al., 2015). As my thinking around this subject developed my research questions shifted to incorporate the impact of maternal mental health on children's developmental outcomes as is considered by the early childhood development (ECD) research. There is strong evidence indicating the link between maternal depression and compromised child development through mechanisms of disturbances in early mother-infant relationships (Patel, Chowdhary, Rahman, & Verdeli, 2011). It was therefore difficult to disentangle perinatal mental health from infant mental, physical and cognitive development. This is one of the reasons why perinatal mental health is currently a growing field in both research and clinical settings. Supporting mothers during this critical period is seen as a window of opportunity in preventing detrimental outcomes for children later on in life.

Upon consultation with my supervisor, he identified a dataset from a randomised controlled trial of a perinatal home-visiting intervention from South Africa as a potential source of empirical data. Fortunately, the South African research team allowed me to use the data to investigate the impact of maternal depression on children's outcomes, as well as other psychosocial risks that may interfere with healthy child development. It also provided me with the possibility to empirically evaluate the long term outcomes of an intervention designed to support mothers in the perinatal period.

3 Literature review

Systematic review of systematic reviews

Making the decision to conduct a systematic review of reviews, rather than a systematic review of individual studies allowed me both to narrow down the

focus of my searches while maintaining a 'birds eye'-view of the topic and the conclusions that were drawn from the reviews I was considering. In the last decade this method has emerged as a way to help decision-makers in health care planning to get the information they need in shorter time frames and to allow the findings from separate systematic reviews to be compared and contrasted (Smith, Devane, Begley, & Clarke, 2011). At the same time, it seems that this approach is still in its infancy, as evidenced by the fact that the tools for evaluating the quality of these 'overviews' are still developing. AMSTAR and the revised AMSTAR-2 (Shea et al., 2017) tools which I used for quality appraisal are the only validated tools available that are adapted in particular to assess the methodological quality of systematic reviews (rather than individual studies).

I was not familiar with this method upon embarking on this process and there were useful learning points and challenges associated with this for me. The AMSTAR tool provides guidance on evaluating the strengths of reviews and proposes several 'critical' domains that can affect the validity of the review, but it also allows for some flexibility in deciding beforehand which domains are most important for the overview that one is carrying out. I had to adapt the criteria for the purposes of my review, for instance allowing for heterogeneity in outcomes in primary studies, and dropping the criterion of pre-registration of the review as I sometimes made use of organisational reports and the grey literature. Making these decisions required some consideration and rationale, and the process of this was thought provoking as it appeared to deviate from the criteria of a systematic review.

Many reviews assemble information from the studies that may have been considered robust but also from ones less so. I therefore had to be mindful of

taking a 'meta' perspective: I was reviewing the quality of the 'review' itself, rather than the 'studies' that were included within the review, and as long as the issue was thought about this meant that the review presented a balanced perspective on the evidence in the literature. This also allowed for a 'filtering out' of weaker intervention studies for the second part of my literature review.

The heterogeneity in outcome measures between intervention studies included in the reviews made it difficult to compare and contrast the findings, and this was a difficulty both for the authors of the reviews, as well as for me in drawing conclusions from the reviews regarding effectiveness of psychosocial stimulation interventions in general. Many psychosocial interventions for early years in LMICs were delivered alongside nutritional programmes (Aboud & Yousafzai, 2015), and measured physical health outcomes as their primary outcome, with cognitive outcomes being their secondary outcomes. Other psychosocial interventions included changes in parenting practices as their outcome measure. I made the decision to include both children's cognitive outcomes and parenting practices as my outcomes of interest to get a fuller picture of stimulation interventions in LMIC and to capture more fully the scope of developmental research currently being carried out in these settings. This diversity in outcome measures, as well as the breadth of intervention targets often delivered as comprehensive programmes (nutrition, parenting, cognitive stimulation) is reflective of the challenge of comparing findings on psychosocial parenting interventions across different countries.

Overall, conducting a systematic review of reviews taught me to think more broadly about how to assemble and organise the evidence to draw conclusions about effectiveness of interventions. This is particularly relevant

when individual reviews are reporting discordant results. I have learnt that putting these findings together in one document and comparing the quality of the reviews provides a definitive summary that can be helpful in informing decisions (Shea et al., 2017).

Common elements analysis

My literature review was a two stage process, with the second stage looking more closely at the content of the interventions through the common elements analysis methodology. Common practice elements were extracted from the studies that showed effectiveness included in the systematic reviews. Going through this process offered me valuable insights into what the interventions that I was evaluating through a systematic review of reviews look like 'on the ground'. I also gained a deeper understanding of the principles and theoretical underpinnings of these interventions.

Common elements analysis was an existing methodology which I adapted for the purposes of my review. This involved developing a set of new code definitions which were to be used for coding the interventions manuals. The original PracticeWise manual was used for the initial framework (Chorpita, Daleiden, & Weisz, 2005). This manual was developed for deriving common elements of interventions for children and youth in HICs. Significant adaptations had to be made to suit the purpose of my review which looked at early years parent-directed interventions in LMICs, where interventions take a much broader approach to early childhood development as there are more environmental risks to contend with. This was evident for instance in a lot of intervention protocols including nutrition and feeding practices as well as

hygiene practice information for parents. These new elements had to be described and defined.

I found that during the process of adaptation and development of the coding system I drew on my own knowledge of early child development, from the teaching I received throughout the three years of training as well as my clinical experiences. This included behavioural theories, attachment theory, and cognitive-behavioural theories. The knowledge helped me operationalise the definitions of the 'practice elements' included in the intervention manuals of the early years psychosocial stimulation interventions. Incidentally, my clinical placement during this process was in a perinatal mental health team, and I found this beneficial in two ways – the intervention protocols gave me a more thorough understanding of the stages of infant development which helped me in my clinical work. For example, a child's cognitive and emotional abilities and needs in the first year of life broken down by months helped me think about the mother-child relationship in the context of child age. At the same time, the clinical work I was engaging in with mothers and babies informed my thinking in relation to ascribing definitions and describing the techniques that the intervention protocols were employing.

Despite these complementary factors, developing new codes presented some challenges. Several codes that were created refer to overlapping processes, such as for instance 'Attachment building' and 'Responsive care'. I explored this with my supervisor, and made the decision to differentiate between these two processes – with the former relating to socio-emotional aspects of parental care that lies at the core of attachment building; and the latter being reflective of responsive and sensitive care that facilitates a child's

learning experience. In practice, these two codes were often used in describing similar categories of information provided in some of the protocols. In other protocols the distinction was clearer, with only 'Responsive care' being covered in the protocol, with lesser emphasis on emotional attachment building. This underscored the importance of keeping these two code definitions separate, rather than merging them into one code category. Fortunately, in cases of overlap, or techniques falling under several categories, the PracticeWise framework allows for coding of two or more codes at the same time.

The strength of my analysis is further increased by the fact that the coding was done by two assessors: myself and a Master student research volunteer which increased the inter-rater reliability of the analysis. Furthermore, to the best of my knowledge no other studies using the same methodology in relation to early years psychosocial stimulation interventions currently exist, which makes this an original piece of research. Replication studies of early years interventions using the same or a similar coding system would be valuable future research to consolidate the strength of the findings gained from conducting the current review.

Some of the administrative challenges of conducting the common elements analysis included the time demands of contacting intervention study authors and requesting the original protocols; not always having the up to date contact information for these researchers; and not always receiving responses. Occasionally, the protocols themselves were no longer available to study authors. Several protocols were written in a language other than English. Translation services were too expensive to employ for the purpose of a small study like this, but would be a useful and necessary addition to future research,

considering that interventions such as these are conducted in different countries across the world, with various different languages spoken in local communities in which interventions are delivered.

A key limitation of the current review lies in the fact that it did not specify or record information about supervision and training of facilitators, although some of the intervention provided guidance on this in their manuals. There was also a great variety in the quality of the protocols: some provided a lot of information to facilitators for how the intervention should be 'set up' and delivered while other provided a very limited set of instructions about the delivery of intervention.

Despite the limitations, the results of the review offer useful insights into what constitutes effective early years psychosocial stimulation interventions conducted in trials in LMIC. This can inform future efforts to understand which elements are most effective for disseminating psychosocial programmes in new contexts or with new delivery methods. This can be helpful for future development of interventions aimed at promoting early child development, as well as implementing existing effective interventions at larger scale.

4 Empirical paper

Conducting a secondary data analysis, or 'secondary analysis of existing data' (Cheng & Phillips, 2014), offers both advantages and constraints for the researcher. One of the biggest advantages of engaging in secondary research is the low cost and the ease of access to a large data sample with enough information to be able to formulate a research question and answer it with the existing data. Recruitment, data collection, and ethical approval - all processes

required for primary analysis research - are bypassed, which means that there are fewer variables 'outside of one's control' to contend with during the time of research. On the other hand, some issues of 'access and control' do remain, in my case it was mainly in relation to communication with research teams in an international context, with whom I did not have – at least initially - a direct professional relationship.

The dataset that I used was derived from a study conducted in South Africa, and the data was held by researchers in the United States. This inevitably involved some delays in accessing and understanding the data, as well as in communications regarding clarification of the variables. The data analyst responsible for data management of this trial was on long term leave when I got access to the data, which meant that there was a delay in clarification of the structure of the data. 'Getting to know the data', of hundreds of different variables in relation to mothers and children's outcomes was a complex and time-consuming process. Not having been involved in the study and data collection meant that I was not familiar with the variables and was initially not always able to 'decipher' the meanings of the levels of the data. This constitutes a challenge in secondary analysis of existing data – it is time consuming to familiarise oneself with the data, the documentation, and the structure of data files, that the researcher did not personally collect (Hofferth, 2005). Fortunately, some support around this was available, but as discussed this involved delays.

Reflecting on the project retrospectively, I found that it is important to think about the research process as promoted by the positivist tradition in quantitative research methods (Barker, Pistrang, & Elliott, 2002). The ideal positivistic research process does not begin with the data, it usually begins with

a question (Barker et al., 2002; Neuman, 2003). The question then develops into testable hypotheses, and the researcher designs a study to test them, collecting and analysing data, and reporting the results in the final stages (Hofferth, 2005). In practice, however, even experimental studies starting out with data collection do not always follow this trajectory, and this linear path is even less reflective of the process of secondary data analysis research, where the data is already collected. In this case, the process of conducting the research is not driven purely by the research question; it can be said that research is both hypothesis- and data-driven (Cheng & Phillips, 2014). The questions one is asking are reliant on the ability of the data to answer them, as well as what has already been investigated by other researchers using the data. Within this, one must also consider the fit between the research question and the dataset. For instance, in using a large longitudinal study - there were hundreds of variables which were not directly relevant for answering the questions that I was asking. A lot of thought therefore had to be put in to filter out non-relevant data from relevant data. Furthermore, one must be cautious in not letting these vast amount data determine the study direction completely, as in the process of *data mining,* without prior expectations being set (Hofferth, 2005). Exploratory use of the data is permissible of course, however in such cases it is not recommended that the same data be used to test subsequent hypotheses (Hofferth, 2005). A balance must be struck between studying what is possible within constraints of the dataset and yet being able to think about what the researcher is testing prior to conducting the analysis.

I have found the process of formulating a research question based on the available data challenging at times, with a number of adaptions to research

questions necessary in light of what was possible to test with the data available. Ultimately, the decision was made to look at children's outcomes only, as quite a lot of primary research has already been done on maternal outcomes, and following on from the overall theme of my thesis project, it made sense to focus on early childhood development. In addition, as we expected the intervention to have an effect at 5 year follow up, my initial thoughts were around testing mediational effects of cumulative risk and intervention on children's outcomes, in addition to moderation effects which were in the end examined. This however was not possible due to the null results of intervention.

Furthermore, at the start of the research project there were no published papers to answer the question of 5 year outcomes and communication with the original research team did not indicate that somebody was in the process of analysing the 5 year outcome data. However, towards the end of the research process, this changed and an early draft of a paper was shared with me, investigating the 5 year follow up data. The paper had been drafted by the original study group while I was writing my own study, apparently having started after I originally enquired. This is not problematic in itself, especially as it provided a confirmatory view of our results, but it is a testament to the lively research community, particularly as it relates to a valuable, semi-private and not fully explored dataset. This naturally is another challenge of conducting secondary data research and can impact on the originality of one's research questions.

5 Conclusions

My involvement with the different stages of this research project afforded me some invaluable insights into the difficulties and rewards of delving into a new and previously unfamiliar research topic. It has given me an understanding of the state of early childhood development initiatives globally and offered insights into the challenge of bridging the gap between what developmental psychologists know about healthy early child development and governments' and health care systems' limited capacity to implement interventions that are built on these insights – particularly for communities in low resource settings. The null findings of the 5 year follow-up data of the current study was a noteworthy example of such a challenge: developing and implementing interventions that are effective and efficient while delivering long-term improvements to children's life chances is an issue of pressing importance, particularly in the context of limited resources governments and communities have at their disposal. It is the task of researchers and clinicians to ensure these resources are spent on highly effective interventions and this study seeks to contribute in this regard.

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Appendices

Appendix A – AMSTAR 2

AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

1. Did the research questions and inclusion criteria for the review include the components of PICO?

For Yes:
- ☐ Population
- ☐ Intervention
- ☐ Comparator group
- ☐ Outcome

Optional (recommended)
- ☐ Timeframe for follow-up

☐ Yes
☐ No

2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?

For Partial Yes:
The authors state that they had a written protocol or guide that included ALL the following:
- ☐ review question(s)
- ☐ a search strategy
- ☐ inclusion/exclusion criteria
- ☐ a risk of bias assessment

For Yes:
As for partial yes, plus the protocol should be registered and should also have specified:
- ☐ a meta-analysis/synthesis plan, if appropriate, *and*
- ☐ a plan for investigating causes of heterogeneity
- ☐ justification for any deviations from the protocol

☐ Yes
☐ Partial Yes
☐ No

3. Did the review authors explain their selection of the study designs for inclusion in the review?

For Yes, the review should satisfy ONE of the following:
- ☐ *Explanation for* including only RCTs
- ☐ OR *Explanation for* including only NRSI
- ☐ OR *Explanation for* including both RCTs and NRSI

☐ Yes
☐ No

4. Did the review authors use a comprehensive literature search strategy?

For Partial Yes (all the following):
- ☐ searched at least 2 databases (relevant to research question)
- ☐ provided key word and/or search strategy
- ☐ justified publication restrictions (e.g. language)

For Yes, should also have (all the following):
- ☐ searched the reference lists / bibliographies of included studies
- ☐ searched trial/study registries
- ☐ included/consulted content experts in the field
- ☐ where relevant, searched for grey literature
- ☐ conducted search within 24 months of completion of the review

☐ Yes
☐ Partial Yes
☐ No

5. Did the review authors perform study selection in duplicate?

For Yes, either ONE of the following:
- ☐ at least two reviewers independently agreed on selection of eligible studies and achieved consensus on which studies to include
- ☐ OR two reviewers selected a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder selected by one reviewer.

☐ Yes
☐ No

AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

6. Did the review authors perform data extraction in duplicate?

For Yes, either ONE of the following:

- ☐ at least two reviewers achieved consensus on which data to extract from included studies
- ☐ OR two reviewers extracted data from a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder extracted by one reviewer.

☐ Yes
☐ No

7. Did the review authors provide a list of excluded studies and justify the exclusions?

For Partial Yes:	For Yes, must also have:	
☐ provided a list of all potentially relevant studies that were read in full-text form but excluded from the review	☐ Justified the exclusion from the review of each potentially relevant study	☐ Yes ☐ Partial Yes ☐ No

8. Did the review authors describe the included studies in adequate detail?

For Partial Yes (ALL the following):	For Yes, should also have ALL the following:	
☐ described populations ☐ described interventions ☐ described comparators ☐ described outcomes ☐ described research designs	☐ described population in detail ☐ described intervention in detail (including doses where relevant) ☐ described comparator in detail (including doses where relevant) ☐ described study's setting ☐ timeframe for follow-up	☐ Yes ☐ Partial Yes ☐ No

9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?

RCTs

For Partial Yes, must have assessed RoB from	For Yes, must also have assessed RoB from:	
☐ unconcealed allocation, *and* ☐ lack of blinding of patients and assessors when assessing outcomes (unnecessary for objective outcomes such as all-cause mortality)	☐ allocation sequence that was not truly random, *and* ☐ selection of the reported result from among multiple measurements or analyses of a specified outcome	☐ Yes ☐ Partial Yes ☐ No ☐ Includes only NRSI

NRSI

For Partial Yes, must have assessed RoB:	For Yes, must also have assessed RoB:	
☐ from confounding, *and* ☐ from selection bias	☐ methods used to ascertain exposures and outcomes, *and* ☐ selection of the reported result from among multiple measurements or analyses of a specified outcome	☐ Yes ☐ Partial Yes ☐ No ☐ Includes only RCTs

10. Did the review authors report on the sources of funding for the studies included in the review?

For Yes

- ☐ Must have reported on the sources of funding for individual studies included in the review. Note: Reporting that the reviewers looked for this information but it was not reported by study authors also qualifies

☐ Yes
☐ No

11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?

RCTs

For Yes:

- ☐ The authors justified combining the data in a meta-analysis
  - ☐ AND they used an appropriate weighted technique to combine study results and adjusted for heterogeneity if present.
  - ☐ AND investigated the causes of any heterogeneity

☐ Yes
☐ No
☐ No meta-analysis conducted

For NRSI

For Yes:

- ☐ The authors justified combining the data in a meta-analysis
  - ☐ AND they used an appropriate weighted technique to combine study results, adjusting for heterogeneity if present
  - ☐ AND they statistically combined effect estimates from NRSI that were adjusted for confounding, rather than combining raw data, or justified combining raw data when adjusted effect estimates were not available
  - ☐ AND they reported separate summary estimates for RCTs and NRSI separately when both were included in the review

☐ Yes
☐ No
☐ No meta-analysis conducted

12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?

For Yes:

- ☐ included only low risk of bias RCTs
- ☐ OR, if the pooled estimate was based on RCTs and/or NRSI at variable RoB, the authors performed analyses to investigate possible impact of RoB on summary estimates of effect.

☐ Yes
☐ No
☐ No meta-analysis conducted

13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?

For Yes:

- ☐ included only low risk of bias RCTs
- ☐ OR, if RCTs with moderate or high RoB, or NRSI were included the review provided a discussion of the likely impact of RoB on the results

☐ Yes
☐ No

14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?

For Yes:

- ☐ There was no significant heterogeneity in the results
- ☐ OR if heterogeneity was present the authors performed an investigation of sources of any heterogeneity in the results and discussed the impact of this on the results of the review

☐ Yes
☐ No

15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?

For Yes:

- ☐ performed graphical or statistical tests for publication bias and discussed the likelihood and magnitude of impact of publication bias

☐ Yes
☐ No
☐ No meta-analysis conducted

AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both

16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?

For Yes:

- ☐ The authors reported no competing interests OR
- ☐ The authors described their funding sources and how they managed potential conflicts of interest

☐ Yes
☐ No

To cite this tool: Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J, Moher D, Tugwell P, Welch V, Kristjansson E, Henry DA. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ. 2017 Sep 21;358:j4008.

Appendix B – Adapted Protocol Coding Sheet

Protocol Coding Sheet

Coding is based on: Description in article ☐ Primary Protocol Source ☐

Title of what you coded:

Authors:

Year:

Practice Element Codes (check all that apply)

Accessibility Promotion		Mindfulness - Caregiver	
Activity Scheduling/Homework-Caregiver		Modelling - Caregiver	
Anger Management - Caregiver		Monitoring	
Assertiveness Training - Caregiver		Motivational Enhancement	
Attending		Performance Feedback	
Behavioural Contracting – Caregiver		Praise	
Caregiver Coping		Psychoeducation - Caregiver	
Caregiver-Directed Nutrition		Problem solving - Caregiver	
Nutritional Care or Recommendation		Relationship/Rapport Building	
Cognitive – Caregiver		Relaxation	
Commands		Stimulus/Antecedent Control	
Communication Skills		Support Networking	
Differential Reinforcement		Supportive Listening - Caregiver	
Discrete Trial Training		Tangible Rewards	
Emotion Regulation Skills		Therapist Praise - Caregiver	
Family Engagement		Parental Self-monitoring	
Family Therapy		Parental Self-care	
Goal Setting		Attachment building/Bonding	
Guided Imagery		Responsive care/parenting	
Individual therapy for caregiver		Coaching	
Maintenance/Relapse Prevention		Parenting Skills	
Marital Therapy		Role-play	
Medical Care or Recommendation		Use of toys	

Mentoring - Caregiver		Talking to baby	
Play/pretend		Physically comforting baby	
Story-telling		Session aids	
Reducing harsh discipline		Community peers	
Mentalising		Peer support	
Live/video demonstrations		Sleep hygiene/training	
Hygiene practices			

Appendix C – Practice elements descriptions

Practice Elements descriptions

1. *Accessibility Promotion*

Any strategy used to make services convenient and accessible or to proactively enhance treatment participation. This might include "appointment reminders" (e.g., telephone confirmations, reminder letters, web-based treatment reminders (incl. email contacts), text messages), availability of on-site child care ("child care"), after-hours scheduling, drop-in appointments ("flexible scheduling"), holding treatment sessions at a local school, the family's home, or other convenient site ("location"), and transportation to appointments, bus tokens, gas money ("transportation").

2. *Other: Activity Scheduling/Homework - Caregiver*

The assignment or request that a child/caregiver participate in specific positive activities outside of sessions, with the goal of promoting or maintaining involvement in rewarding and enriching experiences.

3. *Other: Anger Management - Caregiver*

Exercises or techniques designed to promote caregiver's ability to regulate or prevent anger or aggressive expressions and seek productive resolutions to conflict.

4. *Other: Assertiveness Training - Caregiver*

Exercises or techniques designed to promote the caregiver's ability to assert his or her needs appropriately with others, usually involving rehearsal of assertive interactions.

5. *Attending*

Exercises involving the youth and caretaker playing together in a specific manner to facilitate their improved verbal communication and nonverbal interaction. Typically the caretaker is instructed to provide a running commentary or description on the youth's activities, and is instructed not to give commands, criticize, or question the youth. Attending can be done with the therapist observing, or assigned as homework.

6. *Other: Behavioral Contracting - Caregiver*

The commitment to a particular course of action as denoted by a contract or agreement. This is inclusive of suicide-safety contracts.

7. *Caregiver Coping*

Exercises or strategies designed to enhance caretakers' ability to deal with stressful situations, exclusive of formal interventions targeting one or more caretaker (which are coded as individual therapy for caregiver, marital therapy, and/or communications skills as appropriate).

8. *Caregiver-Directed Nutrition*

Setting an expectation for parents or caregivers to take charge of eating and weight management for a child. This may include aspects of diet, exercise, and feeding environment or behaviour. This practice refers to the clear establishment of responsibility and authority. A variety of practices may be used to implement this responsibility or authority and those should be coded separately, such as stimulus or antecedent control, praise, response cost, etc. *This may also include advice about breastfeeding, weaning and portion sizes for children.*

9. *Nutritional Care Or Recommendation*

Provision of counselling, education, professional services or recommendations for dietary or nutritional modification or supplementation. If the provided services or recommendations cover physical health or well-being beyond the areas of diet and nutrition, then Medical Care Or Recommendation should also be coded.

10. *Other: Cognitive - Caregiver*

Any techniques designed to alter interpretation of events through examination of the caregiver's reported thoughts, typically through the generation and rehearsal of more realistic, alternative counter-statements. This can sometimes be accompanied by exercises designed to comparatively test the validity of the original thoughts and the alternative thoughts by gathering and reviewing real life evidence.

11. *Commands*

Training for caretakers in how to give instructions or commands in such a manner as to increase the likelihood of child compliance.

12. *Communication Skills*

Training for youth or caretakers in how to communicate more effectively with others to increase positive functioning, increase consistency, or minimize stress. In some contexts, this can include a variety of specific communication strategies (e.g., active listening, "I" statements, constructive criticism). *This may also involve learning to communicate and express emotions more effectively.*

13. *Differential Reinforcement*

The training of caretakers, teachers, or others involved in the social milieu of the child to selectively ignore target behaviours and selectively attend to competing behaviours.

14. *Discrete Trial Training*

A method of teaching involving breaking a task into many small steps and rehearsing these steps repeatedly with prompts and a rich schedule of reinforcement.

15. Other: Emotion Regulation Skills

Techniques that are designed to promote learning to recognise and manage/control emotions and understanding emotion-behaviour-thoughts links (cognitive behavioural perspective). This may also involve psychoeducation about emotions (Code alongside Psychoeducation), and learning to differentiate between feelings and behaviours, and awareness of the choices to act or not to act on feelings constructively. Also instructions focused on identifying/labelling (e.g., I am happy, I am mad, I am sad) or regulating emotions.

16. *Family Engagement*

The use of skills and strategies to facilitate the family's positive interest in participation in an intervention. This may involve instructions in the protocols for the facilitator to invite family members to take part in the session, or encouraging the mothers to share responsibility for childcare and actively seeking support from families/partner. It may also involve the family members receiving the intervention alongside the mother (in early childhood development interventions)

17. *Family Therapy*

A set of approaches designed to shift patterns of relationships and interactions within a family, typically involving interaction and exercises with the youth, the caretakers, and sometimes siblings. Sometimes family therapy is performed with a single client, but uses the same approaches to shifting patterns of family interactions that are part of more traditional, multi- client family therapy. May also be used to capture family interventions aimed at *relational restructuring* between the parent and child as well as any other family member.

18. *Goal Setting*

The explicit selection of a therapeutic goal for the purpose of working toward achieving that goal. This often involves repeated assessment of the successful approximation of the goal.

19. *Guided Imagery*

Visualization or techniques of guided imagination used for the purpose of mental rehearsal of successful performance (e.g., picturing one's self passing a test). Guided imagery for the purpose of physical relaxation (e.g., picturing calm scenery, or a special place) is not coded here, but rather coded as relaxation.

20. Individual therapy for caregiver

Any therapy designed directly to target individual (non-dyadic) psychopathology in one or more of the youth's caretakers. If the therapy for caretakers involves marital therapy or communication skills (both of which are dyadic), those are not coded here, unless there are additional services for individual caretaker psychopathology, in which case all that apply should be coded.

21. *Maintenance/Relapse Prevention*

Exercises and training designed to consolidate skills already developed and to anticipate future challenges that might arise after termination or reduction of services, with the overall goal to minimize the chance that gains will be lost in the future

22. *Marital Therapy*

Techniques used to improve the quality of the relationship between caregivers.

23. *Medical Care Or Recommendation*

Provision of professional services, consultation, education, medications, or advice regarding adaptations to address physical health or well-being. If the provided services or recommendations specifically address physical fitness or exercise than Physical Exercise or Education should be coded. If the provided services or recommendations specifically address diet and nutrition, then Nutritional Care Or Recommendation should be coded.

24. *Other: Mentoring - Caregiver*

Pairing of participant with a more senior and experienced individual who serves as a positive role model.

25. *Other: Mindfulness - Caregiver*

Exercises designed to facilitate present-focused, non-evaluative observation of experiences as they occur, with a strong emphasis on being "in the moment." This can involve the participant's conscious observation of feelings, thoughts, or situations.

26. *Other: Modelling - Caregiver*

Demonstration to the caregiver of a desired behaviour, typically performed by a therapist, confederates, peers, or other actors to promote the imitation and subsequent performance of that behaviour in parents.

27. *Monitoring*

Training a caretaker, teacher, or other member of the child's social ecology in the repeated measurement or observation of some target mood or behaviour.

28. Motivational Enhancement

Exercises designed to increase readiness to participate in additional therapeutic activity or programs. These can involve cost-benefit analysis, persuasion, or Socratic questioning or a variety of other approaches, but the goal is to increase motivation for engagement in a therapeutic change process.

29. *Performance Feedback*

Providing information about one's own or another's performance to the youth, parent, or others based on assessment or observation. This includes such things as information about change in treatment, comparison of quality or rate of performance relative to norms, benchmarks or risks, or review of recorded interactions

30. *Praise*

The training of parents, teachers, or others involved in the social ecology of the child in the administration of social rewards to promote desired behaviors. This can involve praise, encouragement, affection, physical proximity, or "social reinforcement" (e.g., training peers in a group to administer praise to one another). If only "positive reinforcement" is specified as being trained to parents, teachers, or others, code as both "Praise" and "Tangible Rewards" (see below). This does not get coded for when only the therapist provides praise or reinforcement to the child.

31. *Other: Problem Solving - Caregiver*

Training in the use of techniques, discussions, or activities designed to bring about solutions to targeted problems, usually with the intention of imparting a skill for how to approach and solve future problems in a similar manner. Includes components such as brainstorming, choosing a solution, and evaluating the results.

32. Psychoeducation-Caregiver

The formal review of information with the caretaker(s) (Socratic or otherwise) about the development of the child's problem and its relation to a proposed intervention. This often involves an emphasis on the caretaker's role in either or both. This can include multiple media (e.g., videotape about mental health problem) and statements such as, "parents met with therapists to get information on therapy."

33. *Other: Relationship/Rapport Building - Caregiver*

Strategies in which the primary aim is to increase the quality of the relationship between the caregiver and the therapist/facilitator.

34. *Relaxation*

Techniques or exercises designed to induce physiological calming, including muscle relaxation, breathing exercises, meditation, and similar activities. Imagery exclusively for the purpose of physical relaxation is also coded here.

35. *Stimulus/Antecedent Control*

Strategies to identify specific triggers for problem behaviours and to alter or eliminate those triggers in order to reduce or eliminate the behaviour. This includes both the manipulation of the environment to remove specific triggers (e.g., no TV in the bedroom

to improve sleep) as well as the development of plans to cope with situations known to be challenging (e.g., shopping at the grocery store with a disruptive youth).

36. *Support Networking*

Strategies to explicitly identify, engage, develop, or otherwise increase the involvement or effectiveness of individuals in the client's social ecology to provide instrumental or emotional support for the client or assist in the performance of therapeutic tasks or activities (e.g., homework). This may include building the individual or collaborative skills of the client and/or the support persons. Support networking is more specific and active than just working together or receiving treatment in a group or social environment. If skills training is limited to the client's social behaviour without explicit reference or targeting to elicit support from others, than the Social Skills Training code should be used.

37. *Other: Supportive Listening - Caregiver*

Reflective discussion with the participant designed to demonstrate warmth, empathy, and positive regard, without suggesting solutions, actions, or alternative interpretations.

38. *Tangible Rewards*

The training of parents, teachers, or others involved in the social ecology of the child in the contingent administration of tangible rewards to promote desired behaviours. This can involve tokens, points, charts, or record keeping, in addition to direct (i.e., first order) reinforcers. The mention of a "Contingency System" may also be coded as "Tangible Rewards;" do not code "Contingency System" as "Response Cost" if no further information is given, as a contingency system does not necessarily involve response cost.

39. *Other: Therapist Praise/Rewards - Caregiver*

The administration of tangible (i.e. rewards) or social (e.g., praise) reinforcers by the therapist to promote a desired behaviour in the caregiver.

40. Other: Parental self-monitoring

Conducted by parents of their own behaviours, including mood charts, behaviour diaries etc.

41. Other: Parental Self-care

Any strategies that promote parental awareness of importance of their own wellbeing in caring for children, along with techniques aimed to increase parental psychological/physical wellbeing.

42. Other: Attachment building/Bonding

Provision of broader training in attachment building/bonding with the child. This may include psychoeducation/demonstrations/discussions about providing **consistent loving care** to the child, being accessible to the child as a parent, being responsive to the child's emotional needs. The facilitator may be pointing to the difference between feeding/physical care and emotional/psychological care – and highlighting importance to provide both, in order for the child to optimally grow and develop. Making the link clear between providing 'love' and - child's potential to 'learn and be happy'. (Code alongside with Psychoeducation-Caregiver if information about attachment building is provided).

43. Other: Responsive care/parenting

Promotion of awareness of importance of responsive/sensitive parenting and care. This may include responding to the child's words, actions, communications, interests. It may also involve 'myth-busting' around comforting or picking the child up when crying/in distress, such as ideas about 'spoiling' the child. May also include instructions for following the child's lead – paying attention to child's wishes for exploration (within boundaries), rather than being pushed into activities by others. Any strategies to promote 'mediated learning experience/scaffolding' – guiding the child's process of learning by the parent. May also be coded to include responsive physical care (e.g. not force feeding when child is not hungry, or feeding when child is sleepy). (Code alongside with Psychoeducation-Caregiver if information is provided by facilitator).

44. Other: Coaching

Facilitator is encouraged to provide feedback to parents when they try new techniques out, praising where necessary and providing gentle suggestions when they need improvement – as the activity is being carried out.

45. Other: Parenting Skills

Provision of broader training in parenting skills not captured by specific PracticeWise coding system, such as parenting psychoeducation, child rights education (e.g. Boys and girls, or children with disabilities, requiring same care, attention and opportunities), strategies for improving interactions with the child (if not already captured by Attachment Building or Responsive Parenting), attention to positive qualities of the child, parental supervision/monitoring of the child. *(Based on Brown et al 2017 code category)*

46. Other: Role-play

Caregivers encouraged to act out (with facilitator or each other) either their routine practices (with the aim of understanding what behaviour currently looks like), or trying out new strategies/behaviours through role play with the aim to provide rehearsal for novel practices.

47. Other: Use of toys

Strategies (including psychoeducation around why it is important to provide toys for children) to promote the use of toys in parenting practices. This may involve provision of toys by facilitators, or DIY activities to make simple toys from low-cost materials. May also involve parents being encouraged to use the toys with their children, or facilitators demonstrating the use of toys during the sessions.

48. Other: Talking to baby

Any strategies to promote parental involvement in talking with baby, also in the pre-verbal stages. This may include imitating babble, singing to baby, expanding on what infant said, paying attention to what infant is looking at and labelling objects, pointing and verbalising. This could also be coded if facilitator provides psychoeducation about developmental benefits for child of this activity (Code along with Psychoeducation-Caregiver).

49. Other: Play/Pretend

Parent-child activities using play that provide a rich learning experience for the child (specific code Use of Toys if toys implemented along with Play/Pretend). May include information giving about children learning through play (e.g. some protocols call play children's 'work').

50. Other: Story-telling

Any strategy that promotes the use and caregivers' ability to use story-telling with their children. May involve demonstration by facilitator, provision of books or pictures to support story telling.

51. Other: Reducing harsh discipline

Any instructions/strategies provided to caregivers aimed at reducing harsh/physical/aggressive discipline. Recommendations around more positive ways of dealing with children, reinforcing good behaviours. Information provision about negative effects of harsh discipline on child.

52. Other: Mentalising

Active discussions/questions that are aimed to facilitate/promote caregiver's capacity to mentalise (think and feel what the child thinks and feels) their child (Example: asking parents "What is your child feeling/thinking when you praise him/her?')

53. Other: Live/Video demonstrations

Code if protocol includes live/video demonstrations.

54. Other: Hygiene practices

Information and instructions regarding safe, hygienic practices in the child's environment

55. Physically comforting baby

Instructions/encouragement to provide physical comfort/soothing baby through touch (swaddling, picking up at distress, gentle touch). May also be coded if intervention includes baby massage as a strategy.

56. Session aids

Facilitation of intervention involves session aids, calendars for participants, or other objects or materials provided (if it is toys code as Use of Toys, not Session tools)

57. Community peers

Intervention delivered by community peers, community health workers from the local population, or trained peer tutors.

58. Peer support

If intervention involves a peer support element or group.

59. *Sleep hygiene/training*

May include psychoeducation about sleep in young children. Can include sleep hygiene for parents.