



Centre-based early education interventions for improving school readiness (Protocol).

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Centre-based early education interventions for improving school readiness (Protocol)

Macdonald G, McCartan CJ



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[Intervention Protocol]

Centre-based early education interventions for improving school readiness

Geraldine Macdonald¹, Claire J McCartan¹

¹Institute of Child Care Research, School of Sociology, Social Policy and Social Work, Queen's University Belfast, Belfast, UK

Contact address: Claire J McCartan, Institute of Child Care Research, School of Sociology, Social Policy and Social Work, Queen's University Belfast, 6 College Park, Belfast, Northern Ireland, BT7 1LP, UK. c.j.mccartan@qub.ac.uk.

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To evaluate the effectiveness of centre-based interventions for improving school readiness in preschool children.

BACKGROUND

Description of the condition

In many parts of the world, children are legally obliged to attend school at a particular age. The age at which compulsory education begins can range between four and seven years, depending on location. Developmental differences between children are rarely taken into consideration when setting the age of school entry; nor are they always reflected in the teaching and learning environment within mainstream education. Children who start school without being ready to cope with the requirements of formal education may be significantly disadvantaged (Duncan 2007; Duncan 2010; Sawhill 2012). There is some evidence that delaying formal schooling until six or seven years of age (as in Finland, for example) may confer benefits (Fleischman 2010; McEwan 2008; OFSTED 2003; Prais 1997; Russell 1986) and early introduction to formal learning can have negative consequences for a child's emotional well-being (Elkind 2001). Datar 2006 found that delaying school starting age by one year significantly boosted test scores when chil-

dren started formal education. Analysis of the National Child Development Study found that test scores at age seven were significant predictors of adult outcomes in educational attainment and the labour market at age 23 (Connolly 1992) and 33 (Harmon 1988; Robertson 1996); those scoring in the lowest quartile at age seven earned on average 20% less than the rest of the sample (Currie 2001). Analysis of the Terman Life Cycle Study found that starting school early was associated with lower educational attainment, worse midlife adjustment and increased mortality risk (Kern 2009).

The benefits of delaying kindergarten entrance are significantly larger for 'at-risk' children, for example: children living in poverty; children with a disability; children of mothers with low educational attainment; children in lone parent families; or children who have English as a second language (Datar 2006; Duncan 1997; Lee 2002; Lipina 2009; Zill 1998). This may be because starting compulsory education later maximises the likelihood that children are developmentally 'ready' for school, or be explained by exposure to other preschool activities that facilitate school readiness, or both. In low- and middle-income countries, increasing emphasis and

priority is being placed on access to quality preschool education in international development policy (UNICEF 2012); children in these economies face multiple disadvantages and increasing school enrolment, improving academic achievement and reducing school drop-out are considered key to providing a route out of poverty.

School readiness

School readiness is increasingly recognised as a composite of the readiness of an individual child and that of the environment into which s/he enters when starting school (Kagan 1997).

School readiness most often refers to a child's readiness for formal learning in a school setting. It is a multi-dimensional concept that encompasses the behavioural, emotional and cognitive aspects of a child's development, alongside his or her adaptation to the classroom environment (National Education Goals Panel 1991). Children who struggle in school include those who are academically (or cognitively) not able to cope, who have problems with communication or social skills, who are unable to follow directions, and who find it difficult to work on their own (poor concentration) or in groups (turn taking, collaboration) (see Caprara 2000; Diekstra 2008; DiPerna 1999; Durlak 2011; Pasi 2001; Zins 2004). Children who start formal education 'school ready' are much more likely to learn, stay on in school and succeed (CGECCD 2008; Nonoyama-Tarumi 2009; Save the Children 2004; Stith 2003).

There is some debate around the precise definition of school readiness and how it should be assessed (Aiona 2005). One view is that children are ready for school once they reach a certain age; others specify school readiness as a range of skills and competencies that a child is taught at home or in a childcare environment. Another view assesses readiness on multiple factors of the child's **family** (the family context and home environment), **community** (the level of resources and support made available to families with young children), **services** (extent of quality, accessibility, and affordability of programmes available locally to support families with young children), and early learning centres/**schools** (aspects such as school attainment levels and class sizes, which indicate the quality of education available).

For the purposes of this review, we will define school readiness in terms of the five domains set out by the National Education Goals Panel (National Education Goals Panel 1997):

- *Physical development and health* - this incorporates a child's health, background, status, growth, and disability. The development of motor skills is also essential to school readiness, from the gross motor skills required in physical play and development to the fine motor skills used for writing and drawing.
- *Social and emotional development* - this involves a child's ability to interact with others and their capacity for self regulation. It encompasses children's self perception and their ability to understand other people's feelings, and interpret and communicate their own feelings.

- *Approaches to learning* - this refers to a child's attributes to apply their skills and knowledge, for example, curiosity, creativity, independence, co-operativeness, and persistence.

- *Language and literacy* - this refers to a child's engagement with language in both written and oral forms.

- *Cognition and general knowledge* - conducting play-oriented, exploratory activities that stimulate knowledge. It includes thinking and problem-solving as well as developing knowledge about particular objects and how the world works. Mathematical knowledge, abstract thought, and imagination are included in this domain.

Size of the problem

Research has estimated that 10% to 20% of school-enrolled children display emotional and behavioural barriers to learning significant enough to warrant formal intervention (Sugai 2000). This figure rises to 30% to 50% in neighbourhoods with high levels of deprivation (Adelman 2008). Analysis of the Millennium Cohort Study found that UK children from low- to middle-income families were five months behind children from high-income families in terms of vocabulary skills and had more behaviour problems (Washbrook 2011). For those children living in poverty, persistent achievement gaps by social class can be identified as early as nursery stage, suggesting that the problem must be tackled before school (Brooks-Gunn 1997; Coley 2002; Grantham-McGregor 2007; Lee 2002; Walker 2007; West 2000).

Consequences for children not ready for school

Success at school can impact positively on a child's self esteem, behaviour, attitude, and future success (Lynch 1997; Pianta 1996); failure at school can impact directly on long-term outcomes such as unemployment, crime, teenage pregnancy, and psychological and physical morbidity in adulthood (Hertzman 1996), and perpetuates the cycle of disadvantage. Children who start school with problems that interfere with their ability to settle, enjoy school, and learn are therefore significantly disadvantaged. Negative and antisocial behaviour is often related to poor academic performance, and for those experiencing emotional difficulties and family disruption, school drop-out, academic failure and discipline problems at school are very much a risk (Alexander 2001; Kutash 2006; Loeber 2000).

Description of the intervention

A range of different interventions have been developed to promote school readiness in young children across the globe, in low-, middle-, and high-income economies. Most focus on preparing the child for the academic content of education, with a particular focus on literacy and numeracy, but many also concentrate

on developing the psychosocial competencies important for learning, including self regulation, sitting still, listening, following instructions, and taking turns in conversation and play. As indicated above, emphasis is also placed on the readiness of the home, the school/early education setting, the community (i.e. the resources and support available) and the services available to a family with young children. Parents and other caregivers have a profound impact on a child's learning, with diet, sleep, stress, and attachment all exerting an influence on a child's ability to develop and learn. Hence, some school readiness interventions include primary and community health care, parenting advice, and social services support to help parents with accessing benefits, job seeking, and health care advice, including nutrition and parenting skills. The US Head Start Program, for example, offers family-based interventions for at-risk children that include targeted support for their mothers, such as mental health services, substance abuse counselling, employment assistance, housing assistance and continuing education (Lacy 1997). Programmes vary in duration and intensity but often involve two or more part-time sessions per week over a 12-week or longer period in the months prior to a child starting school. Interventions are often targeted at low-income families and those who do not speak English as their first language as they tend to be less ready for school. There are also specific programmes tailored for children with special needs.

Interventions, which may be provided via nationally funded programmes for preschool children, such as Head Start, vary in the range of educational, health, nutritional, and social services they offer, and in the teaching methods and curricula they provide; they may be tailored to the individual child. Interventions may focus on one or more of the following domains.

Physical development and health: many of the programmes also place emphasis on supporting parents to help their children. These schemes endorse positive discipline, promoting learning and developing by encouraging parents to work with their children, encouraging home reading, and reinforcing what is learned in the early education setting.

Social and emotional development: developing prosocial friendship skills, emotional understanding and expression, self control, and social problem-solving skills. Play underpins many of the teaching strategies, and through the provision of appropriate indoor and outdoor play environments, children can learn about setting rules and consequences, explore and develop their sense of the world, communicate with others as they problem solve, take risks and make mistakes, and think creatively and imaginatively. Books are also used to explore difficult issues such as bullying or domestic violence.

Language and literacy: developing key pre-literacy skills is embedded in many of the interventions. These help children develop their vocabulary and communication skills, and phonological awareness, and an understanding of print conveying meaning and letters creating a code of language. Strategies can include interactive reading programmes that encourage children to ask

questions, discuss and retell stories or predict story endings, and require early education centre staff delivering the intervention to engage active listening, language expansion, and de-contextualised talk. Rhymes and songs with mime and gesture are used to support language development. Children are encouraged to practise letter shapes and early writing skills in painting and drawing to develop their fine motor skills as a precursor to independent writing. Shared or paired reading is also used to enhance language and literacy skills, and promote an appreciation of books. These strategies are all used to develop pre-reading and pre-writing skills.

Approaches to learning: children are encouraged to explore new experiences to develop their curiosity and confidence in trying new things. In Maths and Science activities, they are encouraged to ask questions, form hypotheses or make guesses. Children are encouraged to read and write stories, and change or make up their own endings. Games including 'I Spy' can be used to extend natural curiosity. These kinds of activities are used to help children develop problem-solving skills, apply persistence to achieve an outcome, and use their initiative to develop their independence. Creative play using role play and props and materials is also a method used to develop these competencies.

Cognition and general knowledge: mathematical concepts are introduced through play, with the use of mathematical vocabulary to describe everyday objects and positions. Story time and circle time is used to help relate informal mathematical knowledge to more formal mathematical concepts.

Environmental readiness: environmental factors can help support children's transition to school. This growing emphasis on the importance of environmental readiness reflects, in part, the needs of the growing number of children with working mothers and experiencing childcare outside the home and in childcare centres. Families with small children also need to have access to appropriate health care, affordable quality childcare, and to live in safe neighbourhoods. Many of the interventions reference classroom organisation and structure, which directs different types of learning through play in a variety of locations in the classroom. There is an emphasis on stimulating resources and equipment, including building blocks, art and science materials, books, and computer software.

How the intervention might work

Essentially, school readiness programmes seek to mitigate the risk factors associated with children facing poverty and disadvantage through the nurture and development of key skills and competencies required for formal learning, and by attempting to reduce the achievement gap that is already present once children start school. Using Head Start as an example (Head Start Resource Centre 2011), and taking each of the above domains in turn, school readiness interventions seek to do the following.

1. Ensure children are socially and emotionally ready, and able to:

- engage and maintain positive adult-child relationships and interactions;
 - maintain positive peer relations;
 - display attention, emotional regulation, and appropriate classroom behaviour;
 - follow rules;
 - develop a sense of self, self confidence, and identity.
2. Ensure children have or develop adequate language and literacy skills, and are able to:
 - build and use increasingly complex vocabulary;
 - use language for conversation and communication;
 - engage with literature.
 3. Promote a positive approach to learning, such that children:
 - show interest in varied topics and activities;
 - persist when working.
 4. Ensure children have or develop adequate cognitive skills and general knowledge, so that they are able to:
 - use mathematics regularly;
 - ask questions, make predictions, develop hypotheses to gain understanding of their environment.
 5. Ensure that children are physically well, and able to:
 - be healthy and safe;
 - use large muscles to control movement, balance etc.;
 - use fine motor skills.
 6. Provide a 'ready environment' such that:
 - systems of early care and education are available to families in order to secure appropriate care and support services;
 - schools recognise that each child has unique learning needs, and provide age-appropriate and developmentally relevant early education learning environments, linked to other children's services;
 - families are economically stable and parents are well informed about bringing up their children;
 - families have access to community-based health care, including harm prevention, and the promotion of safe neighbourhoods and supportive communities.

Immigrant children

It is also important to note that a number of school readiness programmes have been developed to target specific populations. Children from immigrant families often face multiple disadvantage: poverty, poorer mental and physical health, lower verbal interaction and shared literacy experiences at home, discrimination and access to poorer quality education (Brooks-Gunn 2005; Schofield 2006; Waters 2005; Yoshikawa 2011). Specifically tailored interventions have been used to meet the needs of this group, which can include multi-lingual approaches to teaching and culture-specific classroom resources; sensitivity to discrimination by peers and

educators; engaging parents in programme and curricular development; parent counselling; and gateway service provision for accessing health and social services.

Intervention programmes may differ in their emphasis or in the combination of factors they address. The focus of this review will be programmes that include literacy and numeracy skills along with a focus on social and emotional learning.

Why it is important to do this review

Failure at school can have a significant and lifelong impact on the social and physical well-being of an individual, which can impact on future generations (Woodhead 1985). Evidence suggests that school readiness is an important independent factor and predictor of future academic achievement, even controlling for variations in cognitive abilities and family resources (Grolnick 1994). Evidence from the US reported that 40% of children eligible for Head Start (low-income) are turned away because of lack of funding, with less than 5% of those eligible for Early Head Start receiving the early infant intervention (Helburn 2002). Recent moves in the UK also sought to reduce early years funding and it is therefore important to review the evidence of its effectiveness. The economic and social investment return in early childhood education programmes is greater than other governmental human capital development programmes (UNICEF 2012); however, many governments invest less than 2% in preschool education (UNESCO 2007). International evidence has estimated a 20% to 30% loss in income in countries where investment in preschool programmes is minimal (Grantham-McGregor 2007; Handa 2008). School readiness is an integral part of the work towards universal access to basic education as set out in UNESCO's Millennium Development Goals (United Nations 2000), Education for All (World Education Forum 2000) and World Fit for Children (UNICEF 2003). A recent systematic review (Petrosino 2012) found that interventions aimed at improving school enrolment in developing countries were having a positive impact; children who are 'ready to learn' are more likely to stay on in school once enrolled (UNICEF 2012).

A number of systematic reviews have been conducted in aspects of early education. Miller and colleagues completed a systematic review on home-based child development interventions for preschool children from socially disadvantaged families (Miller 2012). Another review of early childhood education programmes examined interventions targeting children experiencing poverty (Chambers 2010), and meta-analyses conducted by Camilli and colleagues (Camilli 2010) and Darrow (Darrow 2009) concentrated on literacy and cognitive-focused interventions. However, there is currently no Cochrane systematic review of early education interventions designed specifically to assess school readiness.

OBJECTIVES

To evaluate the effectiveness of centre-based interventions for improving school readiness in preschool children.

METHODS

Criteria for considering studies for this review

Types of studies

All relevant randomised and quasi-randomised trials (i.e. trials where a quasi-random method of allocation is used, such as alternation or date of birth).

Types of participants

Children aged three to seven years prior to starting compulsory education.

Types of interventions

Centre-based programmes delivering a school readiness intervention, compared with no treatment control or treatment as usual (for example, centres that do not have a school readiness programme or home-based intervention). Centres are defined as organisations that offer onsite early education provision, for example, preschool, nursery unit, kindergarten, registered childcare facility.

Programmes must provide educational services directly to the children, with or without parental involvement, lasting for at least 10 hours per week for two months.

Interventions/programmes must target cognitive, pre-reading/reading or pre-writing/writing, and/or mathematical skills development as well as the prosocial behaviours associated with school readiness, e.g. social-emotional development, approaches to learning, physical well-being, and creating a ready environment.

We will exclude:

1. educational interventions delivered only through home visits or in family childcare settings;
2. educational interventions provided solely to the parents;
3. programmes that specifically target children with special needs.

Types of outcome measures

Where data are available, outcomes will be reported as short-term (up to one year), medium-term (between one year and two years) and long-term (over two years).

Primary outcomes

1. School readiness*, as measured by scales such as the Bracken Basic Concepts Scale Revised (BBCS-R) (Bracken 1998); Brigance Diagnostic Inventory of Early Development (Brigance 1992; Glascoe 1995); Developmental Indicators for the Assessment of Learning (DIAL-R) (Mardell-Czudnowski 1998); Early Development Instrument (Janus 2007); Gesell School Readiness Test (GSRT) (Haines 1980).

2. Adverse effects* (for example, child anxiety, disengagement from education, school anxiety, lower educational attainment).

Secondary outcomes

Child outcomes

- Cognitive development* as measured by, for example, the Wechsler Intelligence Scale for Children (WISC-IV) (Wechsler 2003), Non-Reading Intelligence Tests (Young 1989), the expressive one-word picture vocabulary test (EOWPVT; Brownell 2000), Dimensional Change Card Sort (DCCS) (Zelazo 2006), parent/teacher rating of cognitive development (grade ratings, identification/placement in special needs programmes etc.).

- Academic achievement (as measured by academic achievement test scores such as pre-reading/reading, vocabulary, oral comprehension, phonological awareness, pre-writing/writing, verbal skills and mathematics (for example, the Vocabulary Subtest of the Stanford-Binet Intelligence Test-Revised (Roid 2003; Thorndike 1986), Peabody Picture Vocabulary Test (Dunn 2007), the Wechsler Individual Achievement Test (Wechsler 2002)).

- Emotional well-being and social competence* (as measured by behavioural assessments of social interaction, problem behaviours, social skills and competencies, child-parent relationship/child-teacher relationship).

- Physical development*.

- Health development* (as measured by access to health care and health status).

Adverse outcomes

- Parent stress.

Economic costs

- Cost data: unit of costs of programme, costs per child.

*All items marked with an asterisk will be used to populate a 'Summary of findings' table.

Search methods for identification of studies

Electronic searches

We will search the following electronic databases. We will apply no language restrictions to the electronic searches. We will secure translations where necessary.

- Cochrane Central Register of Controlled Trials (CENTRAL), part of *The Cochrane Library*
- Ovid MEDLINE
- EMBASE
- CINAHL Plus
- PsycINFO
- Sociological Abstracts
- ERIC
- British Education Index (BEI)
- Australian Education Index (AEI)
- Social Sciences Citation Index (SSCI)
- Conference Proceedings Citation Index - Social Science & Humanities
- Cochrane Database of Systematic Reviews
- Database of Abstracts of Reviews of Effects (DARE)
- Campbell Collaboration Library (www.campbellcollaboration.org/lib/)
- EPPI-Centre Evidence Library (<http://eppi.ioe.ac.uk>)
- EPPI-Centre Database of Education Research (<http://eppi.ioe.ac.uk>)
- WorldCat (limited to dissertations and theses)
- Networked Digital Library of Theses and Dissertations (NDLTD) (www.ndltd.org/)
- DART-Europe (www.dart-europe.eu/)
- metaRegister of Controlled Trials (www.controlled-trials.com/mrct/)
- ClinicalTrials.gov (ClinicalTrials.gov)

We will use the following search strategy to search Ovid MEDLINE and adapt it for the databases listed above. We will use a randomised trials filter where appropriate. Searches will not be limited by date or language.

1. "Early Intervention (Education)"/
2. (early intervention adj10 education\$.tw.
3. (learn\$ adj3 (prepar\$ or ready or readiness\$)).tw.
4. (academic\$ adj3 (prepar\$ or ready or readiness\$)).tw.
5. ((preschool\$ or pre-school\$) adj3 (prepar\$ or ready or readiness\$)).tw.
6. (school\$ adj3 (prepar\$ or ready or readiness\$)).tw.
7. (early adj3 education\$).tw.
8. (literac\$ adj3 (achieve\$ or acquisition or develop\$ or learn\$ or promot\$ or skill\$)).tw.
9. (literac\$ adj3 (prepar\$ or ready or readiness\$)).tw.
10. (reading adj3 (achieve\$ or acquisition or develop\$ or learn\$ or promot\$ or skill\$)).tw.
11. (reading adj3 (prepar\$ or ready or readiness\$)).tw.

12. (language\$ adj3 (achieve\$ or acquisition or develop\$ or learn\$ or promot\$ or skill\$)).tw.
13. (language adj3 (prepar\$ or ready or readiness\$)).tw.
14. (social adj3 (develop\$ or competenc\$ or learn\$)).tw.
15. (emotion\$ adj3 (competenc\$ or develop\$ or learn\$)).tw.
16. performance skill\$.tw.
17. (personal adj3 develop\$).tw.
18. (health adj3 physical develop\$).tw.
19. (math\$ adj3 (achieve\$ or acquisition or develop\$ or learn\$ or promot\$ or skill\$)).tw.
20. (math\$ adj3 (prepar\$ or ready or readiness\$)).tw.
21. (learn\$ adj3 approach\$).tw.
22. (cogni\$ adj3 (acquisition or develop\$ or promot\$ or skill\$)).tw.
23. (communica\$ adj3 (acquisition or develop\$ or promot\$ or skill\$)).tw.
24. (knowl\$ adj3 (acquisition or develop\$ or promot\$ or skill\$)).tw.
25. "Head Start".tw.
26. "California\$ Healthy Start".tw.
27. "SAIL".tw.
28. "Sure Start".tw.
29. "Incredible Years".tw.
30. "Project STAR".tw.
31. "Parents Learning Actively with Youngsters".tw.
32. "Foundations for Success".tw.
33. "Family Check up".tw.
34. "Healthy Children Ready to Learn".tw.
35. (home adj3 school\$).tw.
36. (transition adj3 school\$).tw.
37. or/1-36
38. Schools/
39. Schools, Nursery/
40. child day care centers/
41. ((early adj2 education\$) or early years or ECCE).tw.
42. (creche\$ or nurser\$ or kindergarten\$ or kinder-garten\$ or preschool\$ or pre-primary or preprimary or playgroup\$ or playgroup\$ or pre-school\$ or (child\$ adj3 centre\$) or (child\$ adj3 center\$)).tw.
43. settings based.tw.
44. ((school\$ or classroom) adj2 (based or setting\$)).tw.
45. elementary school\$.tw.
46. child care/
47. (child-care or child care or childcare).tw.
48. 46 or 47
49. (centre\$ or center\$ or facilit\$ or "out of home" or polic\$ or program\$ or scheme\$ or setting\$).tw.
50. 48 and 49
51. Day Care/
52. (daycare\$ or day-care\$ or daycentre\$ or daycenter\$ or (centre-based adj3 care\$) or (center-based adj3 care\$) or (day\$ adj3 (centre\$ or center\$))).tw.

53. or/51-52
 54. exp Infant/
 55. exp child/
 56. (infant\$ or baby or babies or toddler\$ or child\$ or boy\$ or girl\$ or pre-kindergarten\$ or prekindergarten\$ or preschool\$ or pre-school\$).tw.
 57. or/54-56
 58. 53 and 57
 59. 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 50 or 58
 60. 37 and 59
 61. randomized controlled trial.pt.
 62. controlled clinical trial.pt.
 63. randomi#ed.ab.
 64. placebo\$.ab.
 65. drug therapy.fs.
 66. randomly.ab.
 67. trial.ab.
 68. groups.ab.
 69. or/61-68
 70. exp animals/ not humans.sh.
 71. 69 not 70
 72. 60 and 71

Searching other resources

We will examine the reference lists of relevant studies and reviews to identify further studies. We will then compile a list of all these studies, send this list to experts in the field and ask them to forward any published or unpublished studies that we have missed. We will also search the websites of relevant organisations and government departments, including: the What Works Clearinghouse (WWC) (<http://ies.ed.gov/ncee/wwc/>); the Network for Policy Research, Review and Advice on Education & Training (www.norrag.org); the UNICEF Evaluation and Research Database (ERD) (<http://www.unicef.org/evaldatabase/>); and Child Family Community Australia (Research Practice and Policy Information Exchange) (<http://www.aifs.gov.au/cfca/>).

Data collection and analysis

Selection of studies

The review authors will independently screen the titles and abstracts yielded by the search against the inclusion criteria. We will obtain full reports for all titles that appear to meet the inclusion criteria or where there is any uncertainty. Review author pairs will then screen the full-text reports and decide whether these meet the inclusion criteria. We will seek additional information from study authors where necessary to resolve questions about eligibility. We will resolve disagreement through discussion. We will record the

reasons for excluding trials. Neither of the review authors will be blind to the journal titles or to the study authors or institutions.

Data extraction and management

The review authors will independently extract data from each included study using a data extraction form designed and piloted to collect information about the population (age, gender, ethnicity, location), intervention (physical well-being, emotional well-being and social competence, language and literacy, approaches to learning, cognition and general knowledge, environmental readiness), methods (blinding, sample size, outcome measures, follow-up duration, attrition and handling of missing data, and methods of analysis). When data are missing, CMcC will contact the study authors.

Assessment of risk of bias in included studies

Both authors will assess the risk of bias of included studies independently, using The Cochrane Collaboration's 'Risk of bias' tool (Higgins 2011). Any disagreements will be resolved by discussion and, if necessary, with involvement of a third party. GM will review all 'Risk of bias' judgements. We will use the tool to assess the following domains, with review authors' judgements presented as 'low risk of bias', 'high risk of bias', and 'unclear risk of bias': sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other sources of bias (for example, stopping the trial early, baseline imbalances, choice of design, evidence of carry-over in cross-over trials, comparability of groups). We will present results in a 'Risk of bias' table, together with details of the available information that led to each judgement.

Sequence generation: we will describe the method used to generate the allocation sequence in detail to assess whether it should have produced comparable groups. The authors will make a judgement on the sequence generation process.

We will judge the risk of bias as follows (see Higgins 2011):

- 'low' when participants and researchers were unaware of participants' future allocation to treatment condition until after decisions about eligibility were made and informed consent was obtained;
- 'unclear' when allocation concealment was not clearly stated or unknown;
- 'high' when allocation was not concealed from either participants before informed consent or from researchers before decisions about inclusion were made, or allocation was not used.

Allocation concealment: we will describe the method used to conceal the allocation sequence in sufficient detail to assess whether intervention schedules could have been identified in advance of, or during, recruitment. The authors will make a judgement on whether the allocation was adequately concealed.

We will judge the risk of bias as follows:

- ‘low’ when participants and researchers were unaware of participants’ allocation to treatment;
- ‘unclear’ when allocation concealment was not clearly stated or unknown;
- ‘high’ when allocation was not concealed from either participants or allocation was not used.

Blinding: we will describe any measures used to blind participants, personnel and outcome assessors so as to assess knowledge of any group as to which intervention a given participant might have received. The authors will make a judgement on whether knowledge of the allocated intervention was adequately prevented during the study.

Blinding of participants and personnel

We will judge the risk of bias as follows:

- ‘low’ when blinding of participants and personnel was ensured;
- ‘unclear’ where there was not adequate information provided in the study report or blinding of participants or personnel was not assessed;
- ‘high’ when blinding of participants or personnel was not assured.

Blinding of outcome assessors

We will judge the risk of bias as follows:

- ‘low’ when blinding of outcome assessment was ensured;
- ‘unclear’ where there was not adequate information provided in the study report or blinding of outcome assessment was not assessed;
- ‘high’ when blinding of outcome assessment was not assured.

Incomplete outcome data: we will extract and report data on attrition and exclusions, as well the numbers involved (compared with those randomised), reasons for attrition/exclusion (where reported or obtained from investigators), and any re-inclusions performed by review authors following the retrieval of missing data. The authors will make a judgement on whether incomplete outcome data have been adequately addressed.

We will judge the risk of bias as follows:

- ‘low’ when the number of participants randomised to groups is clear and data for all participants who completed the trial were included in the analyses;
- ‘unclear’ when information about which participants completed the study could not be acquired by contacting the researchers of the study;
- ‘high’ when there is clear evidence that there was attrition or exclusion from analysis in at least one participant group.

Selective outcome reporting: we will determine the likelihood that the authors of the trial omitted some of the collected data when presenting the results by comparing methods and results outcomes in identified studies, and we will judge the risk of bias as:

- ‘low’ when all collected data seem to be reported;
- ‘unclear’ when it is not clear whether other data were collected and not reported;
- ‘high’ when the data from some measures used in the trial are not reported.

Other sources of bias: we will describe any important concerns about bias not addressed in other domains in the tool. Assessment will determine whether any other bias is present in the trial, such as stopping the trial early, changing methods during the trial or other anomalies.

We will judge the risk of bias as follows:

- ‘low’ when allocation was by community, institution or school, and it is unlikely that the control group received the intervention;
- ‘unclear’ when professionals were allocated within a clinic or school, and it is possible that the communication between intervention and control professional could have occurred;
- ‘high’ when it is likely that the control group received part of the intervention.

The authors will make a judgement on whether the study is free of other problems that could put it at a high risk of bias. Some parent- or teacher-reported outcomes in behavioural change may be subject to bias and we will examine this further.

Measures of treatment effect

We will calculate the unadjusted treatment effects using The Cochrane Collaboration’s Review Manager software ([RevMan 2012](#)) where possible.

Dichotomous data

Where dichotomous data are presented, we will calculate an odds ratio with a 95% confidence interval (CI) for each outcome in each trial ([Higgins 2011](#)). For meta-analyses of dichotomous outcomes included in the ‘Summary of findings’ table, we will express the results as absolute risks, using high and low observed risks amongst the control groups as our reference point.

Continuous data

We will calculate mean differences (if all studies use the same measurement scale) or standardised mean differences (SMDs) (if studies use different measurement scales) and 95% CIs for continuous outcome measures. If necessary, we will compute effect estimates from P values, t statistics, ANOVA tables or other statistics as appropriate. We will calculate SMDs using Hedges g.

Economic issues

We will summarise available data on the costs of programmes within the studies under review.

Unit of analysis issues

Cluster-randomised trials

If cluster-randomised trials are included in this review, we will follow the guidance on statistical methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011, Section 16.3). We will seek direct estimates of the effect from an analysis that accounts for the cluster design; alternatively, we will extract or calculate effect estimates and their standard errors (SEs) as for a parallel-group trial, and adjust the standard errors to account for the effect of clustering (Donner 1980). This will be done using an intracluster correlation co-efficient (ICC), which describes the relative variability in outcomes within and between clusters. We will extract information on the ICC from the articles if available. If the ICC is not available, we will contact the authors or obtain external estimates from similar studies. We will use existing databases of ICCs to identify an ICC that matches on outcome measures and cluster types. In the event that we are unable to identify an appropriate ICC, we will perform sensitivity analyses at ICC = 0.5, 0.4, 0.3, 0.2, and 0.05 to cover a broader range of plausible values, while still allowing for strong design effects for small cluster studies. We will combine these estimates and their adjusted SE with those from parallel designs using the generic inverse variance method in RevMan.

Studies with multiple treatment groups

In the primary analysis we will combine results across all eligible intervention groups (centre-based school readiness programmes) and compare them with the combined results across all eligible groups, making single pair-wise comparisons. We will investigate heterogeneity by disaggregating these groups and making multiple comparisons, although we will use the approach of combined groups to determine summary estimates (Higgins 2011).

Dealing with missing data

Where necessary, we will contact study authors to obtain any data not available in the published report (for example, group means, standard deviations, details of drop-outs or descriptive data regarding the interventions). For studies in which the missing data are not available, we will conduct analyses using only the available data (missing data will not be imputed). We will describe all missing data and drop-outs in the 'Risk of bias' tables, and discuss the extent to which these missing data could alter the results or conclusions of the review. We will assess the sensitivity of any primary meta-analyses to missing data using meta-regression to test for any effect of missingness on the summary estimates (Higgins 2011).

Assessment of heterogeneity

We will assess clinical variation across studies by comparing the distribution of important participant factors among trials (for example, age, gender, socioeconomic status), study factors (for example, randomised versus quasi-randomised trial, allocation concealment, blinding of outcome assessors, loss to follow-up, intervention type). We will describe statistical heterogeneity by calculating the I^2 statistic (Higgins 2011), a quantity that describes the approximate proportion of variation in point estimates that is attributable to heterogeneity rather than sampling error. We will use the Chi^2 test to assess the strength of evidence that heterogeneity is genuine. We will discuss the possible reasons for any heterogeneity and conduct sensitivity analyses accordingly, where data permit.

Assessment of reporting biases

If we identify 10 or more studies, we will draw funnel plots (estimated differences in treatment effects against their standard error). Asymmetry could be due to publication bias, but can reveal a real relation between trial and effect size, such as when larger trials have lower compliance and compliance is positively related to effect size (Sterne 2011). When such a relation is found, we will first examine clinical variation between the studies (Sterne 2011, 10.4). As a direct test for publication bias, we will conduct sensitivity analyses to compare the results from published data with data from other sources.

Data synthesis

Where the interventions are similar in i) age of children starting programme, ii) content of programme delivered, iii) intensity and duration of programme, we plan to synthesise the results in a meta-analysis. We will use a random-effects model to assess the impact of statistical heterogeneity. Unless the model is contraindicated (by funnel plot asymmetry), we plan to present the results from the random-effects model. In the event of severe funnel plot asymmetry, we will present both fixed-effect and random-effects analyses, under the assumption that asymmetry suggests that neither model is appropriate. If both indicate a presence (or absence) of effect, we will report this. We will calculate all overall effects using inverse variance methods. If some primary studies report an outcome as a dichotomous measure and others use a continuous measure of the same construct, we will convert results for the former from an odds ratio to a SMD, provided that we can assume the underlying continuous measure has approximately a normal or logistic distribution (otherwise we will carry out two separate analyses).

Subgroup analysis and investigation of heterogeneity

We will conduct further exploratory investigations of the causes of heterogeneity using subgroup analyses. If sufficient studies are found, we will conduct exploratory subgroup analyses according

to the following categories: intervention intensity and duration; socioeconomic status; English language learners.

Sensitivity analysis

In order to explore the impact of studies with high risk of bias on the robustness of the results of the review, we will conduct sensitivity analyses by removing studies with a high risk of bias on baseline measurements and blinding of outcome assessment, and re-analysing the remaining studies to determine whether these

factors affect the results. We will also re-analyse the data using different statistical approaches (for example, using a fixed-effect instead of a random-effects model) (Higgins 2011) to explore the impact of our decision to use a random-effects model.

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* Indicates the major publication for the study

CONTRIBUTIONS OF AUTHORS

Geraldine Macdonald developed the concept of the review and with Claire McCartan, designed the review. Geraldine will be responsible for co-ordinating the review. Data collection will be conducted by Geraldine Macdonald and Claire McCartan.

DECLARATIONS OF INTEREST

Geraldine Macdonald is Principal Investigator of and grant holder for a randomised controlled trial evaluation of a home-based intervention (Lifestart) aimed at improving developmental outcomes of preschool children, and a randomised controlled trial of a school readiness programme (Ready to Learn). Potential conflicts of interest will be minimised by the assessment of eligibility and risk of bias by the authors.

Geraldine Macdonald is the Co-ordinating Editor of the Cochrane Developmental, Psychosocial and Learning Problems Group.

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