CHAPTER 4

COMPARING LIKE WITH LIKE: A SYSTEMATIC REVIEW AND META-ANALYSIS OF HOME VISITING SCHEMES AND CHILDHOOD INJURY

EXEMPLAR Roberts, I., Kramer, M.S. and Suissa, S. (1996) 'Does home visting prevent childhood injury? A systematic review of randomised controlled trials', *British Medical Journal*, 312: 29–33

What you need to understand in order to understand the exemplar study
The idea of a systematic review. *See the introduction to this chapter.*
The importance of quality criteria for including studies in the review ('inclusion criteria'). *These are explained in the exemplar, but have a look at Figure 5.2 in Chapter 5 to see why these are the quality criteria adopted.*
'agreement on methodological criteria adopted evaluated with weighted κ' and the figures given for agreement relating to Table 1 *This refers to an inter-rater reliability test.* *See Chapter 6, section 6.*
The importance of publication bias and overcoming it. *Explained in the exemplar*
The idea of a meta-analysis. *See the introduction to this chapter.*
Odds ratios, their confidence intervals and how to read an odds ratio diagram from a meta-analysis. *See Chapter 7, section 5.*
You do not have to understand the details of the statistical methods used in the study. But many of the technicalities concern data transformations. *See Chapter 6, sections 3 and 4; Chapter 7, section 6.*

Introduction

Some studies suggest that home visiting schemes reduce rates of childhood injury, while others suggest that they do not. This diversity is hardly surprising since the studies were conducted at different times, in different places, for different kinds of visiting scheme, with regard to families at different degrees and kinds of risk, and using different measures of childhood injury. In addition, each study was relatively small for a 'complex' intervention such as home visiting (see Chapter 5, section 9) and concerning rare events such as childhood injury (see Chapter 7, section 7). And some studies were much better designed than others.

The term 'systematic review' refers to reviewing a number of pieces of research on approximately the same topic, using a stringent set of quality criteria, evaluating each in relation to each other in terms of its credibility, and discerning to where the combined evidence points, if anywhere, and identifying gaps in knowledge as priorities for further research. Systematic reviews should not be confused with other publications reviewing research. These are often propagandist, with the reviewer picking and choosing between bits of research and giving them a spin in order to support some case the author is making.

From a practitioner's point of view systematic reviews enormously reduce the amount of effort needed to keep up to date with research. The Appendix to this volume is particularly useful for accessing systematic reviews. The review will give a synopsis and expert comment on perhaps ten or more studies which otherwise would all have to be found, read and understood, sometimes in several languages. All this comes at a price, of course. Practitioners who rely on systematic reviews have to accept the quality standards adopted by systematic reviewers. These usually exclude all research except experimental research, and commonly all research except randomised controlled trials, as in the exemplar reading for this chapter. If the focus is on effectiveness there is a good case for doing this (see Chapter 5, Introduction and section 1). But such a narrowing is not to everyone's taste. It is certainly true that systematic reviews side-line all research other than experimental research. This does not just follow from judgements about quality, but also from the fact that experimental research tends to take similar formats which allows for point by point comparisons to be made between studies. This is rarely possible with other kinds of research, thereby raising puzzles as to whether differences in findings derive from real differences in what was studied, or merely from using different methods to study the same thing.

Some systematic reviews include a *meta-analysis*, as does the exemplar. Put simply, this involves pooling the results of several studies as if each were just part of a much larger study including them all. Meta-

analysis can be controversial in three different ways. First, studies in the review are likely to have some differences, perhaps with different kinds of subjects entering the trial, somewhat different interventions, using different instruments and generating different kinds of baseline and outcome data. Hence like may not be being pooled with like. Second, different studies may have involved diverse kinds of statistical calculation to produce their results, hence there are good mathematical reservations about adding them together. When they are pooled this may involve complicated statistical manoeuvres to bring them all into the same scheme of measurement which may be controversial and often make it difficult to give a common-sense meaning to the results. In the exemplar Roberts et al. express the pooled results as the 'inverse variance weighted average of the study specific odds ratios'. This may be statistically appropriate, but it is difficult to understand in everyday terms (but see Chapter 7, section 6). Third, there is a possibility that a large, but badly conducted trial will over-influence the pooled results, despite reviewers' attempts to eliminate poorly conducted trials from the review using quality or 'inclusion' criteria.

While pooling may be problematic, doing something like it is unavoidable if conclusions are to be drawn from the quantitative data produced by a number of different pieces of research. It is probably appropriate to think of pooling as being quasi-mathematics rather than mathematics: rather more precise than saying 'most', but less precise than saying '73.24%'.

DOES HOME VISITING PREVENT CHILDHOOD INJURY? A SYSTEMATIC REVIEW OF RANDOMISED CONTROLLED TRIALS*

Ian Roberts, Michael S. Kramer, Samy Suissa

Abstract

Objective: To quantify the effectiveness of home visiting programmes in the prevention of child injury [. . .]

Design: Systematic review of 11 randomised controlled trials of home visiting programmes. Pooled odds ratios were estimated as an inverse variance weighted average of the study specific odds ratios.

* Editorial note: The original publication also reviewed studies of the effect of home visiting on non-accidental injury rates. These sections have been edited out of the exemplar.

Setting: Randomised trials that were available by April 1995.

Subjects: The trials comprised 3433 participants.

Results: Eight trials examined the effectiveness of home visiting in the prevention of childhood injury. The pooled odds ratio for the eight trials was 0.74 (95% confidence interval 0.60 to 0.92). Four studies examined the effect of home visiting on injury in the first year of life. The pooled odds ratio was 0.98 (0.62 to 1.53).

Conclusions: Home visiting programmes have the potential to reduce significantly the rates of childhood injury.

Introduction

Home visiting programmes have long been advocated for improving the health of disadvantaged children. In Britain home visits by health visitors are considered to have a key role in accident prevention because of the advice given during the visits on child development and home safety.[1] In the United States home visiting has been promoted primarily for the prevention of child abuse and neglect.[2] In 1991 the United States Advisory Board on Child Abuse and Neglect called for the establishment of a universal programme of home visiting in an attempt to stem the increase in numbers of child abuse reports.[3]

Over the past two decades several randomised trials have examined the effect of home visiting programmes on the occurrence of child abuse and other child health outcomes. The results of these trials, however, have been conflicting. Although several published articles have reviewed the evidence from randomised trials,[4,5] none of these satisfies the methodological criteria that have been proposed for scientific overviews.[6] To quantify the effect of home visiting programmes on the occurrence of child injury and abuse we conducted a systematic review.

Methods

Inclusion criteria We included studies in the systematic review if they met all three of the following criteria: (*a*) the assignment of the study participants to the intervention or control group had to be random or quasi-random – for example, alternate record numbers; (*b*) the study intervention had to include one or more postnatal home visits; and (*c*) the study had to address the outcomes of child injury (unintentional).

Identification of relevant trials We identified trials by a computerised literature search of Medline (January 1966 to April 1995) and Embase (January 1975 to April 1995). We also searched the social sciences citation index for articles referencing randomised trials of home visiting. Key terms used for searching included social support, family support, home (and health) visitors, home (and health) visitation, child abuse and child neglect. We reviewed the references of all relevant papers found in the searches, as well as those of review articles and textbooks. Because home visiting is often encountered in the context of the prevention of child abuse, a hand search was conducted of the *Journal of Child Abuse and Neglect* (from 1977 1(1) through to 1995 19(3)). We contacted the authors of identified papers and experts in the field and asked about any published or unpublished work that they might be aware of. To access studies not formally published, such as research reports and abstracts, we searched relevant conference proceedings. If studies met

the first two inclusion criteria but did not report outcomes of child injury or abuse we asked the authors to provide any unpublished data on child injury.

Data extraction and study appraisal We extracted the following data from each study: strategy for allocation concealment, number of randomised participants, duration of follow up, loss to follow up, blinding of outcome assessment, and the professional background of the home visitor (health or welfare professional or non-professional). We evaluated the quality of the trial using a modification of Prendiville's criteria.[7] With this approach trials are scored from 1 to 3 (1 = poorest score, 3 = best score) on three important aspects of study methodology: control of confounding at entry (adequacy of allocation concealment); control of selection bias (extent to which analyses are based on all randomised participants); and control of information bias in assessing outcome (blinding of observers). While the original criteria assigned a score of 3 for random assignment by telephone and 2 for using opaque sealed envelopes, we assigned a score of 3 for using either of these methods. Trials that assigned subjects to treatment by using methods intended to reduce the risk of foreknowledge of allocation but which were not as secure as random assignment by telephone or use of opaque sealed envelopes scored 2. Trials in which the authors did not report the method of allocation concealment (and were unable to provide further details or could not be contacted) and trials using alternate record numbers or other similar strategies scored 1. If a published report contained insufficient information for us to assess the quality of the trial, we asked the authors to provide further details. Two assessors performed the data extraction independently, with agreement on methodological criteria evaluated with weighted κ.[8] Each point of disagreement was settled by collaborative review.

Statistical methods The measure of association, the odds ratio, was calculated directly for studies in which injury was expressed in binary (yes/no) form, with the variance estimated by Wolf's method.[9] For studies in which injury occurrence was allowed to be multiple and expressed as an incidence density, the odds ratio was estimated on the assumption of a Poisson distribution, with the probability of a participant having at least one event being given by $1 - e^{-ID}$, where ID is the incidence density. Pooled odds ratios were then calculated as an inverse variance weighted average of the study specific odds ratios.

Results

The combined search strategies identified 33 trials meeting the first two inclusion criteria (randomised trials of postnatal home visiting).[10–42] Eleven of these trials (with 3433 participants) reported outcome data on injury or abuse, or on both.[10–19,42] One of the eleven trials was published as an abstract only,[42] the author of this report was contacted, but the relevant outcome data were not available for inclusion in the review. Of the remaining 10 trials, one reported no differences in the occurrence of accidents,[13] and in another injury outcome data had been collected but not reported.[19] In both of these trials the authors gave us the relevant data. The authors of 13 of the 22 trials meeting the first two inclusion criteria but not reporting outcome data on injury or abuse responded to our request for information on unpublished injury outcomes. As a result of this process one further

Table 1 Scores* for quality of methodology and study characteristics for randomised trials of home visiting

Trial (year, country)	Allocation concealment	Analysed as randomised†	Blinding†	No. of participants randomised	Follow up (years)
IHDP (1995, USA)[43]	3	2	1	985	1
Marcenko et al. (1994, USA)[10]	2	2	1	225	0.8
Johnson et al. (1993, Republic of Ireland)[11]	3	2	1	262	1
Barth (1991, USA)[12]	1	2	1	313	3
Dawson et al. (1989, USA)[13]	1	1	1	145	1
Hardy et al. (1989, USA)[14]	1	2	2	290	1.9
Olds et al. (1986, USA)[15]	3	1	2	400	4
Lealman et al. (1983, England)[16]	3	2	3	312	1.5
Larson (1980, Canada)[17]	3	2	2	80	1.5
Siegel et al. (1980, USA)[18]	3	3	1	321	1
Gray et al. (1979, USA)[19]	3	2	1	100	1.4

IHDP = infant health and development program.
* On scale of 1 to 3 (1 = poorest score, 3 = best score).
† Judged for injury outcome measures whenever possible.

trial was identified that met all three inclusion criteria.[43] Eleven trials were therefore identified that had outcome data on injury or abuse, or both.

Table 1 shows the scores for the quality of methodology for the trials included in the systematic review. The weighted κ for agreement between the two assessors was 0.94 for adequacy of allocation concealment, 0.51 for the extent to which analyses were based on all randomised participants, and 0.78 for blinding. The mean scores for the unintentional injury outcomes were: adequacy of allocation concealment, 2.4; extent to which analyses were based on all randomised participants, 1.9; blinding, 1.5.

Table 2 shows the data for the eight trials that examined the effect of home visiting on the occurrence of childhood injury. Six of the eight trials reported a lower incidence of injury in the group that received home visits. One study reported three injury outcome measures, representing three different time periods of follow up. For this study, the overall injury rates and odds ratios were calculated for the entire (four year) follow up period (odds ratio 0.74 (95% confidence interval 0.55 to 0.99)). The pooled odds ratio for injury for the eight trials (figure) was 0.74 (0.60 to 0.92). Four studies examined the effect of home visiting on injury occurrence in the first year of life only. The pooled odds ratio was 0.98 (0.62 to 1.53).

Discussion

Although home visiting is unlikely to be associated with adverse effects, the widespread implementation or intensification of home visiting programmes may have important resource implications. Our meta-analysis of the results from eight randomised trials shows a significant preventive effect of home visiting on the occurrence of childhood injury.

Table 2 Home visiting and childhood injury

Trial (year, country)	Study population	Intervention	Outcome	Participants visited	Controls	Odds ratio (95% confidence interval)
IHDP (1995, USA)[43]	Parents of low birthweight premature infants	Postnatal, non-professional, emotional, social, practial, and informational support	'Non-hospitalised injuries by maternal report'	17/345	26/551	1.05 (0.56–1.96)
Johnson et al. (1993, Republic of Ireland)[11]	Disadvantaged first time mothers	Postnatal, non-professional support and encouragement in child rearing using the child development programme	'Suffered an accident'	3/127	8/105	0.29 (0.08–1.14)
Hardy et al. (1989, USA)[14]	Inner city mothers of poor infants	Postnatal, non-professional parenting and childcare education	'Outpatient diagnosis of closed head trauma'	8/131	15/132	0.51 (0.21–1.24)
Dawson et al. (1989, USA)[13]	Pregnant women attending for maternity care not selected for psychosocial risk	Antenatal and postnatal, non-professional emotional support; information and help in using community resources	'Accidents or ingestion requiring medical attention'	5/67	6/44	0.51 (0.15–1.79)
Olds et al. (1986, USA)[15]	Primiparas who were teenagers, unmarried, or of low socioeconomic status	Antenatal and postnatal parenting education in infant development from nurse; involvement of family members and friends in child care; linkage of family members with health and human services	'Emergency visit for accidents and poisoning (1st year of life)'	0.12*	0.06*	2.06 (0.83–5.15)
			'Emergency visit for accidents and poisoning (2nd year of life)'	0.15*	0.34*	0.40 (0.21–0.77)
			'Emergency department visits for injuries/ingestion (25 to 50 months)'	0.47*	0.61*	0.71 (0.49–1.04)
Lealman et al. (1983, England)[16]	Families predicted to be at risk of child abuse	Postnatal intervention and support from social worker	'Admissions with trauma'	1/103	4/209	0.50 (0.06–4.55)
Larson (1980, Canada)[17]	Working class families	Postnatal, non-professional emotional and informational support	'Significant falls, cuts, burns, poisonings or other injuries'	1.26**	1.55**	0.73 (0.46–1.16)
Gray et al. (1979, USA)[19]	Families most likely to exhibit abnormal parenting practices	Postnatal emotional support from physician/ nurse/lay visitor	'Accidents by maternal report'	16/26	13/25	1.48 (0.49–4.5)
Pooled results						0.74 (0.60–0.92)

IHDP = infant health and development program.
* Adjusted mean.
** Cumulative accident rate per child.

Methodological issues

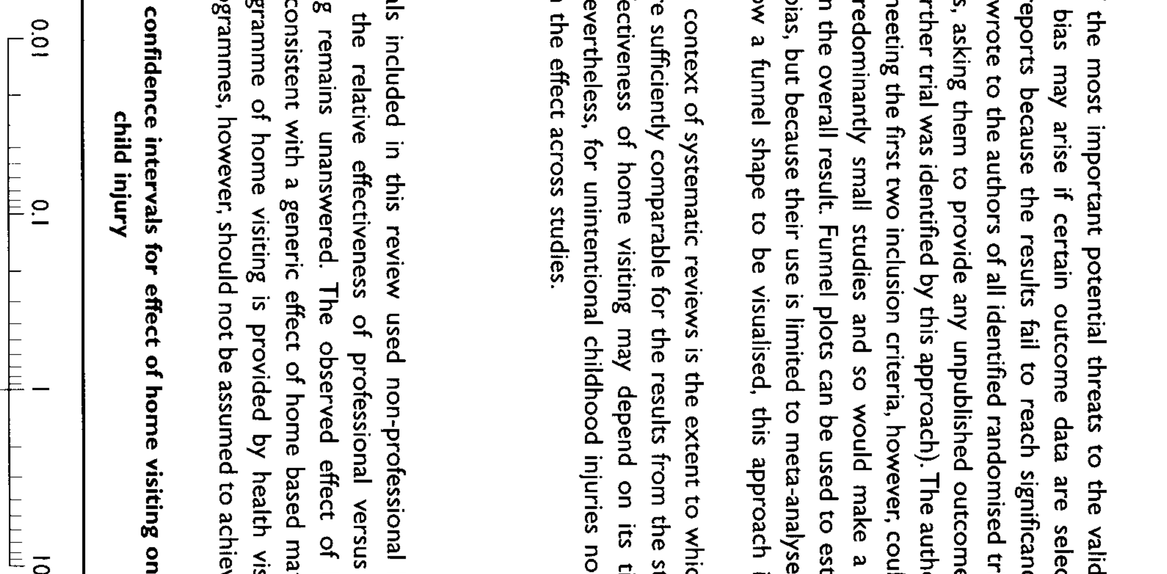
Publication bias is one of the most important potential threats to the validity of systematic reviews. Such bias may arise if certain outcome data are selectively omitted from published reports because the results fail to reach significance. To avoid this type of bias we wrote to the authors of all identified randomised trials of home visiting programmes, asking them to provide any unpublished outcome data on injury or abuse (one further trial was identified by this approach). The authors of nearly half of the studies meeting the first two inclusion criteria, however, could not be traced. These were predominantly small studies and so would make a comparatively minor impact on the overall result. Funnel plots can be used to estimate the extent of publication bias, but because their use is limited to meta-analyses that have enough trials to allow a funnel shape to be visualised, this approach is not helpful in this review.[44]

A recurring issue in the context of systematic reviews is the extent to which the interventions examined are sufficiently comparable for the results from the studies to be combined. The effectiveness of home visiting may depend on its timing, duration, and intensity. Nevertheless, for unintentional childhood injuries no clear heterogeneity was seen in the effect across studies.

Implications

Because most of the trials included in this review used non-professional home visitors, the question of the relative effectiveness of professional versus non-professional home visiting remains unanswered. The observed effect of home visiting on child injury is consistent with a generic effect of home based maternal support. In Britain a programme of home visiting is provided by health visitors. Current health visiting programmes, however, should not be assumed to achieve the

Odds ratio and 95% confidence intervals for effect of home visiting on child injury



effects on childhood injury that are implied by the results of this systematic review. Firstly, the experimental home visiting may have been more intense than that which is typically provided by health visitors. Secondly, in all but one of the trials the intervention was targeted at groups considered to be at increased risk for adverse child health outcomes. This may restrict the extent to which the results are generalisable to programmes of universal health visiting.

The Health of the Nation strategy established child accident prevention as a national priority. Few injury prevention interventions, however, have been shown to reduce injury rates in randomised controlled trials. Given the results of this systematic review, the effectiveness of home visiting by health visitors and non-professional support agencies in preventing childhood injury deserves further examination.

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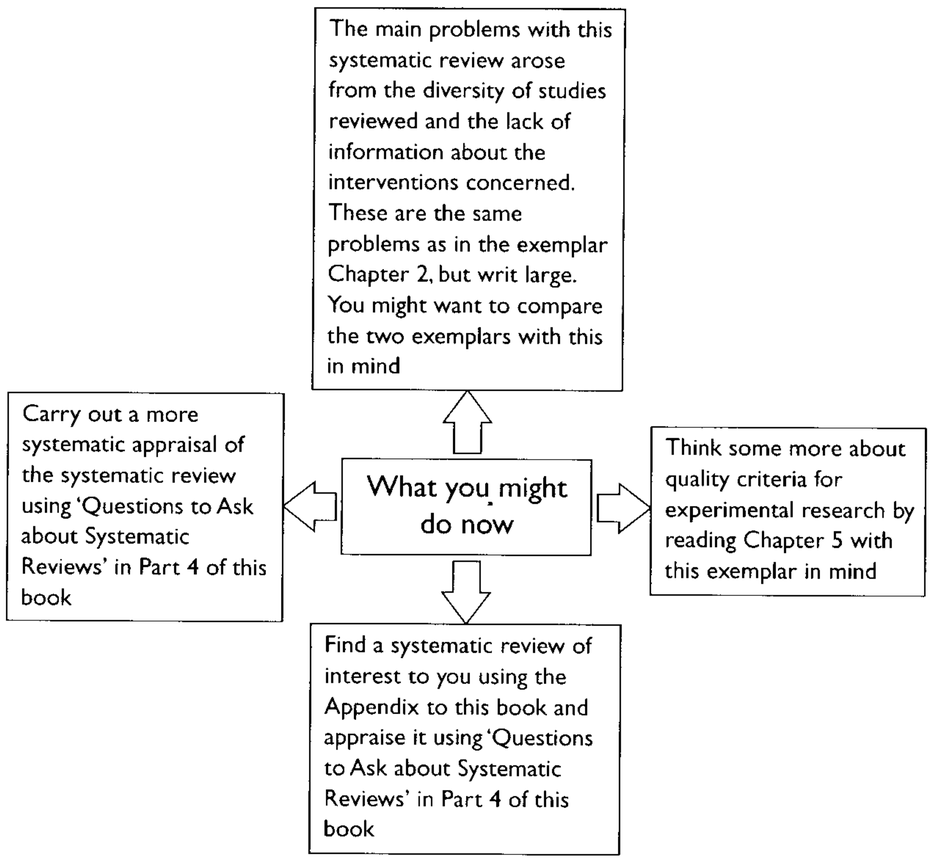
What you might do now



CHAPTER 5

THE BASICS OF EXPERIMENTAL DESIGN

Introduction

Experiments are particularly important in health care research. It has been argued that they should be more important in social care research too (Oakley and Fullerton, 1996). Some people claim that experimental methods are the only methods capable of investigating causality. They are certainly superior to all other methods in this regard. It is not possible to decide whether some health or social care intervention is effective if it is not clear what causes what effects. Thus the most telling evidence about effective practice is evidence that comes from experimental work.

The major problem in investigating causality is that everything that happens has multiple causes. A controlled experiment is an artificial situation established so that the multiple causes of phenomena can be controlled, by excluding some influences, standardising others, while allowing others to vary. This is described as *controlling variables to prevent confounding*, where 'confounding' means muddling the picture so that it is difficult to discern what is causing what to happen. The principle is much the same as that used by an electrician in isolating a circuit in a complex electrical system and then running various charges between different points at known amplitudes and seeing what happens. This chapter describes the way in which experiments are designed. Chapter 6 looks at the instruments which are used for collecting data in experimental research and Chapter 7 at the more common ways in which the results of experiments are expressed.