Searching for unpublished data for Cochrane reviews: cross sectional study

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EDITORIAL by Loder et al
ANALYSIS, p 23

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Research: Assessment of publication bias, selection bias, and unavailable data in meta-analyses using individual participant data (*BMJ* 2012;344:d7762)
Research methods and reporting: Out of sight but not out of mind: how to search for unpublished clinical trial evidence (*BMJ* 2012;344:d8013)

STUDY QUESTION

How do Cochrane authors search for and use unpublished data in systematic reviews?

SUMMARY ANSWER

Most authors of Cochrane reviews searched for unpublished data and around half of those obtained the data. Trialists were the typical source.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Selective reporting of trials is common, and unpublished trials tend to be less positive than published ones. If unpublished data are not included in a review this can lead to bias. Cochrane authors generally search for data and around half get access to unpublished data. Drug regulators and manufacturers supplied unpublished data in only a few cases.

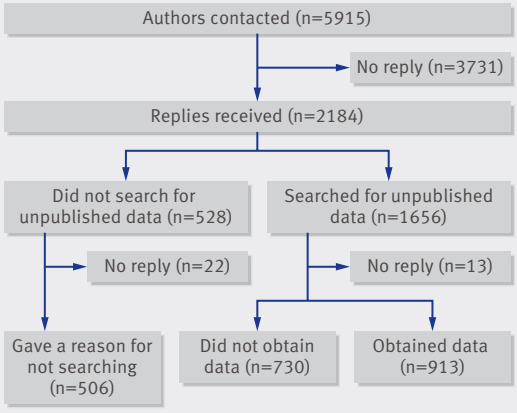
Participants and setting

Our participants were corresponding authors of Cochrane reviews as of May 2012, identified through the Cochrane Collaboration's content management system. They were invited by email to participate in an online survey.

Design

We carried out a cross sectional survey study. The questionnaire contained open ended and closed questions about Cochrane authors' experiences of searching for unpublished data for a systematic review. Authors who did not search for or obtain unpublished data were asked to give a reason. The remaining authors were asked to give details about the different sources that provided unpublished data. We sent three reminders to authors who had not completed the survey. Unpublished data could be either unpublished trials or unpublished information from already published trials, such as additional analyses or outcomes and harms.

Flowchart of replies through survey



Primary outcome

Percentage of authors who searched for and obtained unpublished data.

Main results and the role of chance

Of 5915 authors contacted by email, 2184 replied (36.9% response rate). Of those, 1656 (75.8%) had searched for unpublished data. In 913 cases (55.1% of 1656), new data were obtained and we received details about these data for 794 data sources. The most common data source was "trialists/investigators," accounting for 73.9% (n=587) of the 794 data sources. Most of the data were used in the review (82.0%, 651/794) and in 53.4% (424/794) of cases data were provided in less than a month. Summary data were most common, provided by 50.8% (403/794) of the data sources, whereas 20.5% (163/794) provided individual patient data. In only 6.3% (50/794) of cases were data reported to have been obtained from the manufacturers, and this group waited longer and had to make more contacts to get the data. The data from manufacturers were less likely to be for individual patients and less likely to be used in the review. Data from regulatory agencies accounted for 3.0% (24/794) of the obtained data.

Bias, confounding, and other reasons for caution

The response rate was low. Those authors who did not respond were probably less likely to have searched for unpublished data. The difference between manufacturers and non-manufacturers should be interpreted with caution owing to the low response rate.

Generalisability to other populations

Unpublished data should always be searched for and used in systematic reviews. Regulatory agencies should be used more often as sources of unpublished data.

Study funding/potential competing interests

This study was funded by the Cochrane Collaboration Methods Innovation Fund. We have no competing interests.

Telemonitoring based service redesign for the management of uncontrolled hypertension: multicentre randomised controlled trial

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Trial registration number
Current Controlled Trials
ISRCTN72614272.

bmj.com

- Research: Telemonitoring-based service redesign for the management of uncontrolled hypertension (*BMJ Open* 2013;3:e002681)
- Research: Experiences of patients and professionals participating in the HITS home blood pressure telemonitoring trial (*BMJ Open* 2013;3:e002671)
- Research: Cost effectiveness of telehealth for patients with long term conditions (*BMJ* 2013;346:f1035)

STUDY QUESTION

Does the use of primary care based telemonitoring for people with uncontrolled hypertension reduce daytime ambulatory blood pressure when compared with usual care?

SUMMARY ANSWER

Telemonitoring reduced mean daytime ambulatory systolic blood pressure by 4.3 mm Hg and diastolic ambulatory blood pressure by 2.3 mm Hg; however, it was also associated with a small increase in doctor and nurse consultations.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Research has suggested that telemonitoring may be effective for reducing blood pressure, but few studies were carried out in routine primary care or used the more rigorous ambulatory blood pressure as an outcome. In this study, telemonitoring in primary care resulted in rigorously measured clinically meaningful reductions in blood pressure, although clinician workload increased.

Design

Multicentre randomised controlled trial of an intervention of telemonitoring of self monitored blood pressure with optional patient decision support compared with usual care. Patients were randomised to intervention or usual care on a 1:1 basis by remote computer. Minimisation was undertaken on the basis of age, sex, general practice, use of three or more antihypertensive drugs, and current use of blood pressure self monitoring. Analysis was by intention to treat. Clinicians and patients could not be blinded to the intervention, but final data collection was done by a research nurse blind to allocation.

Participants and setting

401 adults aged 29-95 with uncontrolled blood pressure—that is, daytime ambulatory blood pressure ≥135/85 mm Hg but ≤210/135 mm Hg.

Primary outcome

Mean daytime systolic ambulatory blood pressure at six months.

Main results and the role of chance

200 participants were randomised to the intervention and 201 to usual care; primary outcome data were available for 90% of participants (182 and 177, respectively). The mean difference in daytime systolic ambulatory blood pressure adjusted for baseline and minimisation factors between intervention and usual care was 4.3 mm Hg (95% confidence interval 2.0 to 6.5; P=0.0002) and for daytime diastolic ambulatory blood pressure was 2.3 mm Hg (0.9 to 3.6; P=0.001), with higher values in the usual care group.

Harms

Three patients in the intervention group described anxiety as a result of self monitoring. Other adverse events possibly related to blood pressure control were equally distributed between the groups.

Bias, confounding, and other reasons for caution

It was not possible to blind participants or clinicians to allocation. However, outcome measures were measured by a nurse blind to allocation using ambulatory blood pressure monitoring, a technique that was not open to bias.

Generalisability to other populations

The study was conducted in a socioeconomically diverse general practice. It is, however, possible that the 26% of people approached who agreed to take part may reflect a group more interested in technology than the general population.

Study funding/potential competing interests

This study was funded by the BUPA Foundation (grant No 748/G24). Additionally, BMcK and JH were supported by the Scottish Chief Scientist Office, and ASt by the Edinburgh Health Service Research Unit.

Daytime ambulatory systolic and diastolic blood pressures over course of study in 359 participants with complete primary outcome data

Blood pressure measurement	Mean (SD) blood pressure (mm Hg)		Adjusted difference* (usual care–monitored) (95% CI)	P value	Adjusted only for baseline difference (usual care–monitored) (95% CI)	P value
	Baseline	6 months				
Systolic:						
Monitored	146.0 (10.5)	140.0 (11.3)	4.3 (2.0 to 6.5)	0.0002	4.1 (1.8 to 6.4)	0.0006
Usual care	146.5 (10.7)	144.3 (13.4)	—		—	
Diastolic:						
Monitored	87.4 (10.1)	83.4 (9.1)	2.3 (0.9 to 3.6)	0.001	2.2 (0.8 to 3.6)	0.0022
Usual care	85.7 (9.6)	84.3 (10.4)	—		—	

*Adjusted difference between treatment groups for baseline blood pressure and minimisation factors.

Implementation of self management support for long term conditions in routine primary care settings: cluster randomised controlled trial

Salford NIHR GI programme Grant Research Group

EDITORIAL by Sun and Guyatt

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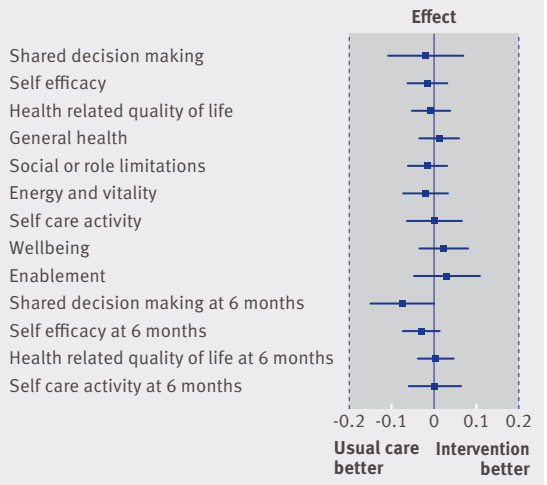
STUDY QUESTION Does the adoption of a "whole systems" model of self management support in primary care lead to improved health outcomes and cost effective management of patients with long term conditions, compared with routine primary care?

SUMMARY ANSWER The intervention had no significant effects on patient outcomes or service use so did not enhance self management support in primary care or add value to existing care for long term conditions.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Primary care practitioners reach patients from deprived communities who could benefit most from self management support. We found that short training interventions are ineffective at enhancing self management support in routine primary care even when combined with local managerial support and additional resources.

Forest plot of standardised effect sizes by outcome measures (vertical dotted bars show minimally important differences)



Design

We carried out a pragmatic, two arm, cluster randomised controlled trial, with patient outcomes at 12 months. Randomisation was at practice level. Practices were allocated 1:1 to intervention or control groups, using a minimisation procedure based on practice size, area deprivation, and contractual status (to either the National Health Service or the local primary care trust). The intervention was practice level training delivered over two sessions using a whole systems approach to self management support. Practices were trained to use a tool to assess patient support needs, guidebooks on self management, and a web based directory of local self management resources. Clinicians were given the knowledge and skills to assess patients' needs, share decisions, and ensure uptake of appropriate support. Training facilitators were employed by the health management organisation.

Participants and setting

Practices were recruited from a primary care trust in northwest England serving a socioeconomically deprived population. Patients with diabetes, chronic obstructive pulmonary disease, or irritable bowel syndrome were eligible for inclusion.

Primary outcomes

Shared decision making, self efficacy, and generic health related quality of life, all at 12 months.

Main results and the role of chance

We randomised 44 practices and recruited 5599 patients (2546 with diabetes, 1634 with chronic obstructive pulmonary disease, 1419 with irritable bowel syndrome), representing 43% of the eligible population. 4076 (72.8%) completed the 12-month follow-up. No statistically significant differences were found between patients attending trained practices and those attending control practices on any outcome. All effect size estimates were well below the prespecified threshold of clinically important difference: shared decision making: adjusted mean difference −0.47 (95% confidence interval −1.55 to 1.61), P=0.657, self efficacy −0.35 (−1.42 to 0.71), P=0.519, and health related quality of life −0.00 (−0.02 to 0.01), P=0.724. No harms were reported.

Bias, confounding, and other reasons for caution

We intended to recruit patients before allocation, but this proved logistically impractical. Recruitment was via electronic health records rather than by professional invitation, but practitioners could exclude patients after identification.

Generalisability to other populations

This was a large study with a generic intervention. The range of conditions included meant that the findings were robust and likely to be generalisable to primary care

Study funding/potential competing interests

This paper presents independent research commissioned by the National Institute for Health Research under its programme grants for applied research funding scheme (RP-PG-0407-10136). We have no competing interests.

Trial registration number

Current Controlled Trials ISRCTN90940049.

Shared care obesity management in 3-10 year old children: 12 month outcomes of HopSCOTCH randomised trial

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bmj.com
- Research: Treatment of childhood obesity by retraining eating behaviour (*BMJ* 2010;340:b5388)
- Clinical review: Obesity in children. Part 2: Prevention and management (*BMJ* 2008;337:a1848)

STUDY QUESTION Does a shared care model of obesity management, involving primary care and tertiary care obesity specialists, result in better body mass index (BMI) and related outcomes in obese children aged 3-10 years?

SUMMARY ANSWER Although the shared care model was feasible and acceptable to families and health professionals, it did not improve children's BMI or other related outcomes relative to controls after 12 months.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Shared tertiary-general practitioner care is feasible for a range of conditions and could enhance access to care for obese children, but its effectiveness has not previously been tested. A 12 month, shared care obesity management programme for 3-10 year olds was feasible, not harmful, and acceptable to healthcare providers and families but did not improve children's body mass index relative to untreated controls.

Design
This randomised controlled trial was nested within cross sectional BMI surveillance in 22 general practices in Melbourne, Australia. Each intervention family attended a single one hour consultation with the specialist obesity team at the Royal Children's Hospital and was then encouraged to see the child's general practitioner every four to eight weeks over the ensuing year. Shared care, web based software was developed to facilitate communication between healthcare providers.

Participants and setting
Practice staff weighed and measured 1195 children aged 3-10 years over a 10 month period. We enrolled 118 of the 199 obese (BMI ≥95th centile) eligible children (62 intervention; 58 control).

Primary outcome
The primary outcome was children's BMI z score measured 15 months after enrolment (12 months from first appointment for the intervention arm).

Main results and the role of chance
Retention was 90% (n=56) for intervention children and 91% (n=51) for control children at 15 months post-enrolment. All intervention families saw the obesity specialists and their general practitioner at least once (mean 3.6 (SD 2.4, range 1-11) visits). The shared care intervention was feasible and highly rated by parents and general practitioners. At outcome, the trial arms had similar BMI (adjusted mean difference −0.1 (95% confidence interval −0.7 to 0.5; P=0.7)) and BMI z score (−0.05 (-0.14 to 0.03); P=0.2), with little evidence of benefit to the secondary outcomes. BMI outcomes varied widely in both groups, with 26% of children resolving from obese to overweight and 2% to normal weight.

Harms
We identified no harms associated with the intervention.

Bias, confounding, and other reasons for caution
The general practitioners were self selected, and families were not blind to group membership. Although we recruited only 118 of the desired 172 children, findings were robust and the 95% confidence intervals did not suggest clinically meaningful benefits. All participating general practitioners were able to participate even though the shared care, web based software posed many challenges for the researchers. A more intensive shared care intervention might be more successful, but the technical and personnel support required would probably preclude wide dissemination in general practice. The improvements in BMI in both groups highlight the importance of untreated controls when determining efficacy.

Generalisability to other populations
Our results are likely to be applicable to many Western populations.

Study funding/potential competing interests
The trial and several authors were funded by the Australian National Health and Medical Research Council. Research at the Murdoch Childrens Research Institute is supported by the Victorian Government's Operational Infrastructure Support Program.

Trial registration number
Australian New Zealand Clinical Trials Registry ACTRN12608000055303.

Outcomes by trial arm

Outcome	Mean (SD) for trial arms		Adjusted difference (intervention−control)	
	Intervention	Control	Mean (95% CI)	P value
Body mass index (BMI)	23.2 (3.8)	23.6 (4.6)	−0.1 (−0.7 to 0.5)	0.7
BMI z score	2.0 (0.5)	2.0 (0.4)	−0.05 (−0.14 to 0.03)	0.2
Total body fat (%)	32.9 (7.2)	34.2 (6.2)	−0.9 (−2.6 to 0.8)	0.3
Waist circumference (cm)	75.6 (13.0)	77.9 (13.6)	−1.7 (−4.1 to 0.6)	0.1
Physical activity (counts per minute)	332 (113)	309 (106)	25.1 (−17.6 to 67.8)	0.2
Diet quality	3.8 (1.0)	3.5 (1.2)	0.3 (0.0 to 0.6)	0.05
Health related quality of life:				
Parent proxy report	77.5 (14.1)	75.8 (13.6)	−0.7 (−5.0 to 3.7)	0.8
Child self report	73.0 (15.0)	75.2 (14.5)	−1.9 (−7.8 to 4.0)	0.5
Physical appearance/self worth, %	58.7	57.0	1.0 (0.6 to 1.7)§	>0.9
Body dissatisfaction	1.3 (1.2)	1.6 (1.2)	−0.3 (−0.8 to 0.2)	0.3

Sample sizes for adjusted analyses: child, 48-56 (intervention), 44-49 (control).
*Estimated odds ratio (95% CI).