



Description and examples of Controlled before-and-after (CBA) study design

March 2007

This document supports Evaluating effectiveness of participation (EEP) projects and contains:

- a description of Controlled before-and-after studies (CBAs)
- a small selection of studies indicative of three DHS policy levels (p.3)
- a large selection of CBA studies from Cochrane systematic reviews (from p.6)

Introduction

To promote the use of the participation 'evaluation and monitoring cycle' and to increase the body of evidence on the effectiveness of participation in improving the quality and safety of health care, a series of demonstration projects - *Evaluating the Effectiveness of Participation (EEP) projects* - are proposed, funded by the Quality and Safety Branch of the Department of Human Services.

Hospitals and health services submitting for EEP funding must outline their study design/plan. The Department has stipulated that EEP projects should be conducted using the principles of at least a Controlled Before-and-After study (CBAs), or study designs or greater rigour (ie quasi randomised controlled trials or randomised controlled trials). This will mean that the EEP Projects may meet the inclusion criteria for some Cochrane systematic reviews (subject to the inclusion criteria set by the author).

This document outlines some information on CBA study design. Readers are also referred to more detailed information on study design issues for randomised studies, which is contained in the Cochrane Consumers and Communication Review Group Study Design Guide for Review Authors, available at <http://www.latrobe.edu.au/cochrane/resources.html>

Controlled before-and-after studies (CBAs)

A CBA study is a type of non-randomised study. Two groups are identified: the intervention group which receives the intervention and the control group which does not. The control group can be an appropriate site or activity or ward. The control group should be comparable with the intervention group on key characteristics, eg size, socio-demographic features, patient or professional type. Any systematic differences between groups should be identified at the outset, as this may influence the effects of the intervention, or the outcomes over time.

The effects of an intervention are tested by collecting data both **before** and **after** the intervention is introduced, and the results for the control and intervention groups are then compared (see *Figure 1*). Outcomes have to be measured at the same time for comparable time periods for both the before and after measurements, and for both groups.

These studies may be prone to bias, as there may be unidentified differences between the control and intervention groups that can influence or contribute to the measured results.

Some 'before-and-after studies' do not contain a separate control group. Such studies rely on the participants acting as their own controls; that is, they are compared to themselves before and after the intervention (for example, their blood pressure might be measured prior to the intervention, then following the intervention, and the two measurements

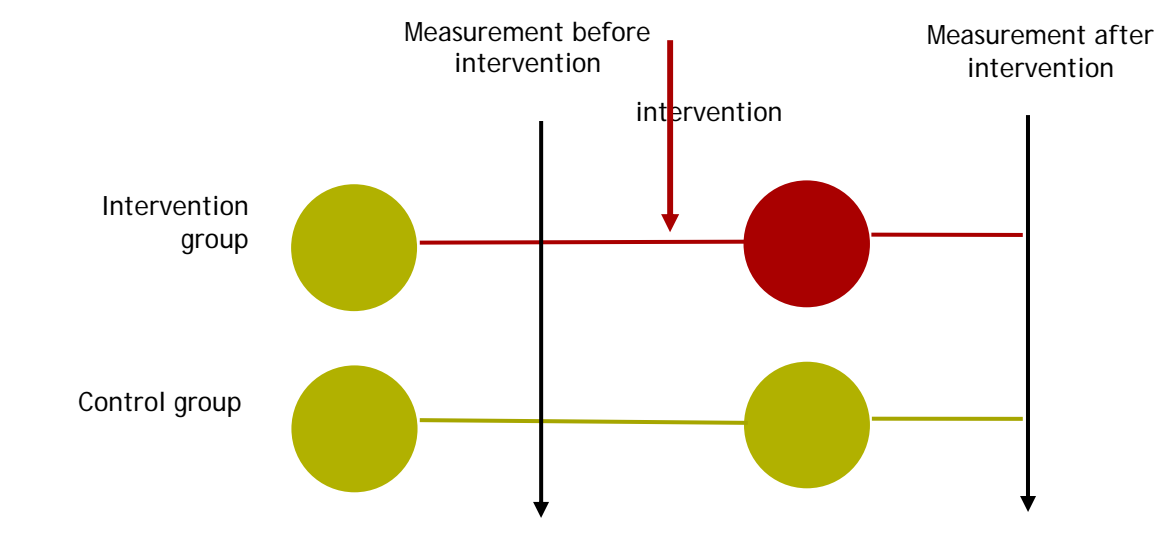
compared). However, if there is no control group, this does not allow for, or control for, the effects of time. Any changes or effects that are measured at the end of the study may have occurred anyway, without the intervention, and so cannot be dissociated from those effects due to the intervention itself. The inclusion of a separate control group in a before-and-after study avoids this problem, and means that the effect of the intervention can be determined separately from those effects which occur over time anyway (that is, those that are not related to the intervention under investigation).

In preparing this document, we have drawn on the advice of the Cochrane Effective Practice and Organization of Care Review Group, who specify that to be included in a systematic review, a CBA study must meet the following criteria:

- The timing of the periods for study for the control and intervention groups should be comparable (that is, the pre- and post- intervention periods of measurement for the control and intervention groups should be the same); and
- The intervention and control groups should be comparable on key characteristics.

CBA studies that do not meet these criteria should be excluded from a Cochrane review. These criteria therefore provide some measure of quality of study design.

Figure 1: The controlled before-and-after study



Studies from Cochrane systematic reviews indicative of three DHS policy levels

Individual studies have been selected from Cochrane systematic reviews (available at www.thecochranelibrary.com) and included in this document as examples of controlled before-and-after study design. They are presented here as tables and are in their original review table format. The study table selection process took into account dimensions of quality and safety; and consumer/patient/carer participation in line with EEP project aims.

The six study tables near the beginning of this document have been placed within the three Department of Human Services (DHS) policy levels, or priority actions, that are to be addressed by EEP projects; these studies/tables are considered to be indicative of the three levels (they also appear later in the document). The studies' interventions, outcomes and/or participants detail their relevance to DHS levels to a certain extent and include: patient education and counselling, process of care, safety and quality in care, and physician education interventions; knowledge, length and cost of treatment, patient satisfaction and guideline consistent care outcomes; and patients, carers, doctors, clinics, municipalities and hospitals as the participant groups.

The three DHS policy levels relevant the EEP projects are:

- *Individual level of care*: about the consumer and where appropriate the carer(s) participation
- *Program or department level*: about staff working in wards, programs and departments of hospitals, rehabilitation, community health, primary care, mental health and aged care services
- *Health service organisational level*: targets decision makers in health services, hospitals, community health, mental health and primary health services

The following 6 tables are edited/brief versions of review study tables that are also included later in this document. **Red highlighting** denotes specific interventions, outcomes or participants of interest to EEP projects. The citation refers to the Cochrane review title. Full references to individual studies are contained in the Cochrane reviews.

*Individual level
(DHS policy level)*

Review title: Physician advice for smoking cessation
T Lancaster and LF Stead

Study Ockene 1991

Methods Setting: American primary care residency program (physicians in training)
Recruitment: unselected
Randomization: Each physician delivered one of the three interventions according to instructions in a packet for each patient.

Participants 1286 smoking patients not selected for motivation to quit
Therapist: 196 primary care physicians in training.

Interventions 1. Advice only
2. **Patient-centred counselling, written materials, asked to schedule follow-up visit, follow-up letter**
3. Patient-centred counselling and offer of prescription for nicotine gum (not used in review).

Outcomes PP abstinence at 6 months (self-reported)

Notes All physicians received training in minimal vs intensive interventions and delivered them according to random allocation of patient.

Review title: Interventions for improving adherence to treatment recommendations in people with type 2 diabetes mellitus
E Vermeire, J Wens, P Van Royen, Y Biot, H Hearnshaw, A Lindenmeyer

Study Bradshaw 1999

Methods - **Controlled before and after study**
- Groups clearly defined
- Selection bias can be excluded
- Losses to follow-up: not described
- Duration of follow-up: clearly defined

- No correction for confounders
- Overall judgement of quality: medium

Participants - 230 type 2 diabetes patients
 - United Kingdom
 - Urban
 - Recruitment in primary care services

Interventions **To assess the effectiveness of three structured educational programmes (traditional, video and educator) on foot care, management and natural history of diabetes.**

Outcomes Change in levels of knowledge, HbA1c, blood glucose, reported smoking cessation.

*Program or department level
(DHS policy level)*

Review title: **In-hospital care pathways for stroke**
 J Kwan and P Sandercock

Study Bowen 1994

Methods Before-and-after study with one concurrent control group. Retrospective data collection.

Participants 346 patients with "cerebrovascular disease" (with DRG code 014) - CP group 54, concurrent control group 71, 'before' group 221. 392 were considered but 6 were non-strokes and 40 required intensive care (i.e. excluded).

Interventions **TREATMENT GROUP: multidisciplinary stroke protocol with critical path for nursing care, emergency room management algorithm, and hospital unit physician's order sheet.** Pre-defined tests, treatments and time projections.
CONTROL GROUP: undefined patient care for 'before' or concurrent control groups.

Outcomes Mean LOS (days): CP=5.5 vs Before=8.8 vs CC=6.7 (no CI). Carotid Doppler performed: CP=37/54 vs Before=104/221 vs CC=36/71. DVT prophylaxis: CP=14/54 vs 9/71 vs CC=30/221. UTI: CP=1/54 vs Before=32/221 vs CC=4/71. No difference in discharge destination, mortality, complications (DVT, pneumonia, infections), length or cost of rehabilitation, neuroimaging, EEG, LP, catheter angiography, 24-hour ECG, echocardiography, therapy input, or heparin use. Median hospital cost (\$): CP=4756 vs HC=7072 vs CC=7044.

Review title: **Community-based interventions for the prevention of burns and scalds in children**
 C Turner, A Spinks, R McClure, J Nixon

Study Ytterstad 1995

Methods	Controlled before-and-after study evaluating a community-based intervention
Participants	Intervention: Harstad, Norway (pop 22,000) Control 1: Six municipalities surrounding Harstad Control 2: Trondheim, Norway (pop 134, 000), located 1000 km from Harstad
Interventions	"Harstad Injury Prevention Study" - WHO Safe Communities Specific activities related to burn and scald injury included: - promotion of child safety through local private and public organisations - awareness raising through local media - promotion of tap water thermostat setting at 55°C - promotion of cooker safeguards - public health counselling to increase parent vigilance - promotion of parent skills in first aid
Outcomes	Burns and scalds incidence measured by hospital-based injury recording system for: a) baseline - 19.5 months pre-intervention) b) for seven-year period during the intervention (reported in 1995) c) for 10 year period during the intervention (reported in 1998)

*Health service organisational level
(DHS policy level)*

Review title: Interventions for providers to promote a patient-centred approach in clinical consultations

SA Lewin, ZC Skea, V Entwistle, M Zwarenstein, J Dick

Study	Roter 1998
Methods	Study design: CBA
Participants	Speciality: Primary care physicians (trained in internal medicine or family practice) Clinical setting: Ministry of Health (MOH) clinics, Trinidad and Tobago Types of patients: Adults with a chronic disease
Interventions	Content of intervention: The first day was divided into three parts: 1) An overview of the literature and rationale for the CME describing basic research regarding links between interpersonal communication and patient and doctor outcomes; 2) Presentation of the results of the baseline study conducted in the 15 MOH clinics prior to training; 3) The last two hours of the first session and all of the second day's session

were devoted to role play and practice of specific communication skills. Skills emphasised were informativeness, emotional responsiveness, and partnership building., empathy, and reassurance, as well as positive exchanges.
Control group received no training

Outcomes Consultation/practice process measures: Provider talk and emotional tone during visits; patient talk and emotional tone during visits; verbal dominance: ratio of all doctor to patient statements; (for full list see Additional Table 1)
Patient satisfaction with care: Pre/post satisfaction change scores

Review title: Specialist outreach clinics in primary care and rural hospital settings
RL Gruen, TS Weeramanthri, SE Knight, RS Bailie

Study Howe

Methods Controlled Before-After Study (communities).

Participants USA, 9 rural hospitals & clinics, all female Caucasian patients diagnosed with breast cancer 1986-1991.

Interventions Regular oncologist visits to rural hospitals to consult and administer treatment protocols commencing 1988. Prior to this it had been identified that too few patients were receiving bilateral mammography or adequate tumour staging.
Purpose: To improve rates of bilateral mammography, tumour staging, and 'state of the art' stage and type-specific cancer care.
Comparison: A program of audit and intervention feedback to family doctors and rural-based specialists, without outreach.

Outcomes Quality of care: Guideline-consistent care, including diagnostic and prognostic assessment, oncology consultation and appropriate treatment.
Access: Proportion receiving oncology consult.

CBA studies from Cochrane systematic reviews

This section of the document contains a large selection of tables from systematic reviews, unedited. Refer to The Cochrane Library website (www.thecochranelibrary.com) to contextualise the tables/ studies. Red highlighting denotes specific interventions, outcomes or participants of interest to EEP projects.

Review title: Interventions to improve antibiotic prescribing practices for hospital inpatients

P Davey, E Brown, L Fenelon, R Finch, I Gould, G Hartman, A Holmes, C Ramsay, E Taylor, M Wilcox, P Wiffen

Study Chu 2003

Methods STUDY DESIGN: CBA
QUALITY: Baseline measurement: DONE but based on 50% sample of eligible patients at Study hospitals for 1 year pre-intervention but only a 10% sample of patients at Control hospitals for 1 year pre-intervention.
Characteristics of control sites: DONE

Blinded assessment of primary outcome: DONE
Protection against contamination: DONE
Reliable primary outcome measure: DONE
Follow-up of professionals: NOT CLEAR
Follow-up of patients: DONE
Risk of Bias: MEDIUM

Participants	NUMBER & CHARACTERISTICS: 20 intervention hospitals , 16 control. Number, level of training, clinical specialty, age and time since graduation of physicians NOT CLEAR. PARTICIPANTS: 2,154 episodes in 2,087 patients. Mean age about 74, (range 27 to 106), 94% white, 41% to 49% male, CLINICAL PROBLEM: Community acquired pneumonia SETTING: 36 small (<200 beds) rural, non-University community hospitals
Interventions	Persuasive: assistance with development of individual hospital quality improvement plan; audit & feedback with benchmarking results from other hospitals. COMPARISON: 16 control hospitals. DESIRED CHANGE: increase in established management. TIMING: the intervention was implemented at Study hospitals over 3 months. Post-intervention data were collected from 100% of patients at Study and Control hospitals for 7 months after the end of the intervention phase.
Outcomes	PRIMARY: Process measures sputum and blood cultures within 4h, antibiotics within 4h, 1st antibiotic in emergency room. SECONDARY: mortality and length of stay. KEY RESULTS: Significant improvement in all process measures for Study but not Control hospitals (only blood culture was close, $p = 0.08$, rest $p > 0.50$). Improvement in proportion of patients getting ABs within 4 hours of admission. Mortality decreased in the post-intervention phase at Study and Control, no significant difference between them ($p = 0.39$). Similarly LOS decreased at Study and Control ($p = 0.47$).
Notes	EVIDENCE BASE: Evidence from 11 previous studies about effect of external feedback on quality of care for pneumonia. OTHER: No power calculation done re-study so may have been underpowered. Also improvements in outcome -mortality, duration of stay but not significant difference from control hospital and not designed to look at this e.g. there were also changes in antibiotics used. Only blood cultures and 1st antibiotics in emergency room in "by-hospital analysis" (CI includes 1 for sputum and 1st dose <4). Also no control of outside feedback from QIO. Data was cross sectional so not able to assess improvement with time. The intervention was implemented at the control hospitals at the end of the study and was associated with similar process changes.
Allocation concealment	D - Not used
Study	Cordova 1986
Methods	STUDY DESIGN: CBA comparing different surgical units on the same site. QUALITY: Baseline measurement: DONE. Characteristics of control site: NOT APPLICABLE. Characteristics of baseline and control patients: NOT CLEAR.

Blinded assessment of primary outcome: DONE.
 Protection against contamination: NOT CLEAR.
 Reliable primary outcome measure: DONE.
 Follow-up of professionals: NOT CLEAR.
 Follow-up of patients: NOT CLEAR
 Risk of Bias: HIGH

Participants NUMBER & CHARACTERISTICS:PROVIDERS: **All surgical units in a single hospital**. Number of providers, level of training, age & time since graduation NOT CLEAR.
 PARTICIPANTS: 248 are reported but there are only 164 in the analysable CBA section of the study. Adults (age >18), sex and ethnicity NOT CLEAR.
 CLINICAL PROBLEM: requiring cefazolin for surgical prophylaxis.
 SETTING: a 541-bed teaching hospital in the USA.

Interventions FORMAT & DELIVERER: Persuasive: pharmacists on the 4 Study units received a seminar and written information. They identified patients dosed inappropriately and consulted the physician to suggest a change in dosing.
 COMPARISON: 3 surgical units (same hospital) with no pharmacist Study. Baseline data were "a randomly selected sample of more than 50 patients from both groups of surgical units."
 DESIRED CHANGE: reduction in inappropriate dosing.
 TIMING: Single Study per patient. Data collected for 2 months post Study.

Outcomes PRIMARY: % of patients receiving cefazolin prophylaxis 6 hourly or less.
 SECONDARY: None
 KEY RESULTS: The pharmacist study was associated with a reduction in inappropriate cefazolin dosing from 53% to 36% on the Study units whereas inappropriate dosing increased from 77% to 81% on the control units. The paper also presents additional results after the introduction of a newsletter on all 7 units, but this is an uncontrolled before and after study therefore not eligible.

Notes EVIDENCE BASE: Criteria for appropriate dosing of cefazolin for surgical prophylaxis were approved by the Pharmacy and Therapeutics Committee and the Medical Audit Committee.
 OTHER: Cost of Study NOT DONE.

Allocation concealment D - Not used

Study Herfindal 1983

Methods STUDY DESIGN: **CBA with crossover; second site as control**.
 QUALITY: Baseline measurement: DONE.
 Characteristics of control site: DONE.
 Blinded assessment of primary outcome: DONE.
 Protection against contamination: DONE.
 Reliable primary outcome measure: DONE.
 Follow-up of professionals: NOT CLEAR.
 Follow-up of patients: NOT CLEAR
 Risk of Bias: MEDIUM

Participants NUMBER & CHARACTERISTICS:PROVIDERS: **One of four teams** each of which had an intern and senior resident who rotated between teams (six weekly

for interns, three monthly for residents). Nine full time and seven part time attending physicians were permanently assigned to one private and staff team.

PARTICIPANTS: 535 adults of whom 428 received antibiotics. Mean age 45 years, 40% male, similar between groups. Ethnicity NOT CLEAR.

CLINICAL PROBLEM: Requiring orthopaedic surgery.

SETTING: Study: 500-bed university teaching hospital in the USA. Control: 440-bed university teaching hospital in another city in the same state.

Interventions FORMAT & DELIVERER: Persuasive: clinical pharmacist assigned for 12 months to one of four teams on an orthopaedic service where clinical pharmacy services had not previously existed. The pharmacist also answered questions from members of the other three teams.
COMPARISON: Similar university teaching hospital with no clinical pharmacist assigned to the orthopaedic surgical service.
DESIRED CHANGE: Reduction in established management.
TIMING: Number of Studies per patient NOT CLEAR. Follow up until discharge.

Outcomes PRIMARY: Mean antibiotic cost per patient day in all 535 patients.
SECONDARY: Duration of postoperative prophylactic antibiotic therapy. Length of hospital stay.
KEY RESULTS: Mean antibiotic cost per patient day fell by \$0.35 at the Study site but increased by \$1.05 at the control site in the 12 months during which clinical pharmacy services were provided in comparison with the 9 month baseline period. In the 6 months after withdrawal of clinical pharmacy services antibiotic costs returned to pre-Study levels.

Notes EVIDENCE BASE: Review of literature: observational studies showing frequently prolonged post-operative prophylaxis unsupported by evidence of benefit from RCTs.
OTHER: The Study was not associated with any evidence of change in length of stay. The reduction in mean antibiotic cost per patient day was \$0.72 in the patients who received antibiotics. Compliance with prescribing guidelines increased from 68% pre-Study to 88% during the Study and then fell back to 75% after clinical pharmacy services were withdrawn (no data for control site).

Allocation concealment D - Not used

Study Landgren 1988

Methods STUDY DESIGN: CBA
QUALITY: Baseline measurement: DONE
Characteristics of control site: DONE
Blinded assessment of primary outcome: Protection against contamination: DONE
Reliable primary outcome measure: DONE
Follow-up of professionals: NOT CLEAR
Follow-up of patients: DONE
Risk of Bias: MEDIUM

Participants NUMBER & CHARACTERISTICS: PROVIDERS: All surgeons at **12 hospitals**. Number, age, sex and time since qualification NOT CLEAR.
PARTICIPANTS: 9417 patients of whom 2613 received antibiotic prophylaxis.

CLINICAL PROBLEM: patients receiving surgical antibiotic prophylaxis.
 SETTING: 12 hospitals, 4 University, 2 Suburban General and 6 Rural, in Australia.

Interventions FORMAT & DELIVERER: Persuasive: campaign with five elements: 1:reminder (message pad); 2:wall poster; 3:lecture; 4:videotape shown at meetings or in lounges and 5:academic visit from the project pharmacist.
 COMPARISON: six hospitals were used as control in Year 1, then Study and Control hospitals were crossed over in Year 2.
 DESIRED CHANGE: Reduction of established management.
 TIMING: Baseline data collected at all 12 hospitals, follow up at 6 months after first intervention, then after a further 12 months, after the second intervention.

Outcomes PRIMARY: Appropriate duration and timing of prophylaxis. SECONDARY: Cost-effectiveness.
 KEY RESULTS: No differences between Study and Control pre-intervention. The first intervention was associated with significant increase in the proportion of patients who received appropriate duration (Study - Control +0.20, p = 0.04) but not in appropriate timing (Study - Control +0.13, p = 0.12). In the second phase the Intervention had a similar impact in hospitals that crossed over from Control to Study, but removal of the intervention was associated with return to baseline practice in hospitals that crossed over from Study to Control.

Notes EVIDENCE BASE: Recommendations for duration and timing were based on Melbourne Antibiotic Guidelines (5th Edition, 1988).
 OTHER: The first Intervention was associated with a \$43,474 decrease in cost of prophylactic antibiotics in Study hospitals but a \$25,960 increase in Control, a total estimated annual saving of \$69,434. The second intervention was also associated with an estimated annual saving of \$55,636. These savings (total \$125,070) from the two interventions were considerably greater than their combined cost (\$71,950).

Allocation concealment D - Not used

Study Przybylski 1997

Methods STUDY DESIGN: CBA
 QUALITY: Baseline measurement: NOT DONE
 Characteristics of control site: NOT RELEVANT
 Reliable primary outcome measure: DONE
 Follow-up of professionals: NOT CLEAR
 Follow-up of patients: DONE
 Blinded assessment of primary outcome: NOT DONE
 Protection against contamination: NOT DONE
 Other risk of bias: the "control group" comprised patients whose physicians chose not to follow the recommended change in treatment.
 Risk of Bias: FATALLY FLAWED

Participants NUMBER & CHARACTERISTICS: PROVIDERS: **all physicians in the hospital**, number, age, sex and time since qualification NOT CLEAR
 PARTICIPANTS: 242 adult patients, mean age 51 years, 35% women, ethnicity NOT CLEAR
 CLINICAL PROBLEM: receiving parenteral antibiotics and met criteria for

switching to oral treatment
SETTING: single University Hospital in the USA

Interventions FORMAT: physicians were contacted regarding patients who could potentially be switched from parenteral to oral treatment.
DELIVERER: pharmacists
COMPARISON: the 200 patients whose physicians accepted the recommendation were compared with the 42 patients whose physicians did not
DESIRED CHANGE: reduction in established management
TIMING: immediate, concurrent, patient specific intervention. Patients enrolled over one year.

Outcomes PRIMARY: antibiotic costs. SECONDARY: length of stay.
KEY RESULTS: fatally flawed because of unacceptable allocation bias.

Notes EVIDENCE BASE: NOT CLEAR

Allocation concealment D - Not used

Review title: Interventions to improve antibiotic prescribing practices in ambulatory care

SR Arnold and SE Straus

Study **Belongia 2001**

Methods CBA
unit of allocation: **community**
unit of analysis: episode of care (for antibiotic prescribing); childcare center (for antibiotic resistance)
power calculation: not done
baseline measurement: not done
characteristics for studies using second site as control: not done
blinded assessment of primary outcome: done
protection against contamination: done
reliable primary outcome measure: done
follow up of professionals: done (for antibiotic prescribing)
follow up of patients: not done (for antibiotic resistance)
analysis appropriate: no

Participants 185 family practitioners, internists and pediatricians in two communities in Wisconsin, USA and all community residents (particularly parents of young children) being treated for respiratory tract infection

Interventions 1. **Multi-faceted including large and small group educational meetings + printed educational materials for physicians and educational meetings and printed educational materials for childcare providers and parents**
2. no intervention control

Outcomes Professional practice:
change in rate of prescribing of oral antibiotics

Patient:
change in proportion of Streptococcus pneumoniae isolates from children

resistant to penicillin

Notes	Campaign message based upon evidence based guidelines: Principles of Judicious Antibiotic Use
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Allocation concealment	D - Not used
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Study	Gonzales 1999
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Methods	CBA unit of allocation: practice unit of analysis: practice power calculation: not done baseline measurement: done characteristics for studies using second site as control: not done blinded assessment of primary outcome: done protection against contamination: done reliable primary outcome measure: done follow up of professionals: done analysis appropriate: yes
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Participants	93 general practitioners and internists in 4 practices in Colorado, USA treating adult patients with acute bronchitis
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Interventions	1. Educational meetings + including audit and feedback + patient educational materials 2. Patient educational materials + including audit and feedback 3. No intervention control
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Outcomes	Professional practice: Change in rate of prescribing of oral antibiotics for acute bronchitis Patient: None
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Notes	
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Allocation concealment	D - Not used
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Study	McNulty 2000
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Methods	CBA unit of allocation: community unit of analysis: episodes of care power calculation: not done baseline measurement: not done characteristics for studies using second site as control: done blinded assessment of primary outcome: done protection against contamination: done
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reliable primary outcome measure: done
follow up of professionals: not clear

Participants 339 general practitioners from 84 practices in Great Britain treating patient of all ages for any community acquired infection

Interventions **1. Educational meetings (small group)+ printed educational materials + audit and feedback**
2. Educational meetings (microbiology tutorial)

Outcomes Professional practice:
Change in number of antibiotics prescribed per 1000 prescribing units

Change in cost of antibiotics prescribed per 1000 prescribing units

Patient:
None

Notes Gloucestershire antibiotic prescribing guidelines created and reviewed annually by local pharmacy advisors, specialist consultants and GPs and are approved by the local Drug and Therapeutics Committees and Local Medical Committees. They are based upon local antimicrobial sensitivity patterns and trials on antibiotic use in general practice.

Allocation concealment D - Not used

Study Perez-Cuevas 1996

Methods CBA
unit of allocation: **family medicine clinics and health centers**
unit of analysis: **episodes of care**
power calculation: not done
baseline measurement: not clear
characteristics for studies using second site as control: done
blinded assessment of primary outcome: not clear
protection against contamination: done
reliable primary outcome measure: not clear
follow up of professionals: not clear
analysis appropriate: no

Participants 119 physicians in 18 primary healthcare clinics in Mexico City, Mexico treating patients of all ages with rhinopharyngitis

Interventions **1. Educational meetings + audit and feedback + participation in peer review**

2. No intervention control

Outcomes Professional practice:
Change in rate of prescribing antibiotics

Change in rate of prescribing symptomatic medications

Notes	Content of workshop derived from review of current bibliography on rhinopharyngitis
Allocation concealment	D - Not used
Study	Perz 2002
Methods	CBA unit of allocation: county unit of analysis: episode of care (? account for clustering by having a variable for county in the binomial regression model) power calculation: not done baseline measurement: not done characteristics for studies using second site as control: done blinded assessment of primary outcome: done protection against contamination: done reliable primary outcome measure: done follow up of professionals: not clear analysis appropriate: no (yes?)
Participants	Family practitioners and pediatricians (250 in intervention region, unknown in control regions) in 4 counties in Tennessee, United States treating children under 15 years of age for respiratory tract infection
Interventions	1. Multi-faceted including educational meetings + printed educational materials for physicians, printed educational materials for parents and patients. 2. No intervention control
Outcomes	Professional practice: Change in rate of prescribing of oral antibiotics Patient: Change in proportion of invasive Streptococcus pneumoniae isolates that are antibiotic resistant
Notes	Campaign message determined by East Tennessee Drug Resistance Task Force and based upon evidence based guidelines: Principles of Judicious Antibiotic Use
Allocation concealment	D - Not used
Study	Peterson 1997
Methods	CBA unit of allocation: region unit of analysis: episodes of care power calculation: not done baseline measurement: done characteristics for studies using second site as control: not clear

blinded assessment of primary outcome: done
 protection against contamination: done
 reliable primary outcome measure: done
 follow up of professionals: done
 analysis appropriate: no

Participants **250 general practitioners** in 2 regions of Tasmania, Australia prescribing treating adult women for urinary tract infection

Interventions **1. Printed educational materials + academic detailing**
2. Printed educational materials

Outcomes Professional practice:
 Change in rate of prescribing recommended antibiotics

 Opinions of general practitioners regarding program

Notes **Rational prescribing guidelines written in consultation with member of the Management Committee, Division of General Practice (Tasmania - Southern region) and a clinical microbiologist emphasizing the recommendations of the Antibiotic Guidelines Sub-Committee, Victorian Drug Usage Advisory Committee.**

Allocation concealment D - Not used

Study **Stewart 2000**

Methods CBA
 unit of allocation: community
 unit of analysis: episode of care
 power calculation: not done
 baseline measurement: not clear
 characteristics for studies using second site as control: not done
 blinded assessment of primary outcome: done
 protection against contamination: done
 reliable primary outcome measure: done
 follow up of professionals: not clear
 analysis appropriate: no

Participants Physicians in Ontario, Canada treating patients of all ages for any community acquired infections

Interventions **1. Multifaceted including educational meetings + printed educational materials for physicians and nurses and the community (different meetings and materials)**
 2. No intervention control

Outcomes Primary outcome
 Change in rate of prescribing of oral antibiotics

 Change in rate of prescribing first- and second-line antibiotics

Notes	Recommendations for first and second line therapy based on the Ontario Anti-infective Guidelines for Community-Acquired Infections, 1997 (2nd Edition), produced by a provincially funded panel
Allocation concealment	D - Not used
Review title: In-hospital care pathways for stroke	
J Kwan and P Sandercock	
Study	Bowen 1994
Methods	Before-and-after study with one concurrent control group. Retrospective data collection.
Participants	346 patients with "cerebrovascular disease" (with DRG code 014) - CP group 54, concurrent control group 71, 'before' group 221. 392 were considered but 6 were non-strokes and 40 required intensive care (i.e. excluded).
Interventions	TREATMENT GROUP: multidisciplinary stroke protocol with critical path for nursing care, emergency room management algorithm, and hospital unit physician's order sheet . Pre-defined tests, treatments and time projections. CONTROL GROUP: undefined patient care for 'before' or concurrent control groups.
Outcomes	Mean LOS (days): CP=5.5 vs Before=8.8 vs CC=6.7 (no CI). Carotid Doppler performed: CP=37/54 vs Before=104/221 vs CC=36/71. DVT prophylaxis: CP=14/54 vs 9/71 vs CC=30/221. UTI: CP=1/54 vs Before=32/221 vs CC=4/71. No difference in discharge destination, mortality, complications (DVT, pneumonia, infections), length or cost of rehabilitation, neuroimaging, EEG, LP, catheter angiography, 24-hour ECG, echocardiography, therapy input, or heparin use. Median hospital cost (\$): CP=4756 vs HC=7072 vs CC=7044.
Notes	Acute stroke. All 3 groups were similar except concurrent control group had more haemorrhagic strokes (CC=14.7% vs CP=5.7% and Before=8.3%).
Allocation concealment	D - Not used
Study	Kwan 2004
Methods	Before-and-after study with one concurrent control group (patients admitted to general medical wards). Mixed prospective and retrospective data collection.
Participants	439 patients with stroke and TIA - CP group 197, 'before' group 154, and GMW group 88.
Interventions	TREATMENT GROUP: integrated care pathway for use in an acute stroke unit

from July 2000 to April 2001. CP document was a multidisciplinary patient record developed by stroke team to guide patient care during first five days of admission. CP consisted of check-lists and comprised three sections - doctors', nurses', and therapists' sections. On admission, initial assessments were guided by doctor's clerking proforma, nursing and therapy assessment forms, and various assessment tools. Staff followed treatment algorithms to guide acute stroke care including management of common medical problems (e.g. fever, hypoxia). Patients' goals and progress discussed at weekly MDT meeting.

CONTROL GROUP: usual care within the same acute stroke unit was identical to CP group except the use of the CP. One extra physiotherapist was employed between the two study periods. GMW GROUP: stroke care provided by medical consultants and nursing staff in general medical wards. Same therapists worked in acute stroke unit. No CP, stroke protocol, or multidisciplinary record. Access to rehabilitation and neuroimaging same as CP group.

Outcomes Mean LOS (days): CP=13.4+/-15.1 vs Before=13.8+/-19.7 vs GMW=13.6+/-23.4. Death by day 5: CP=11/197 vs Before=9/154 vs GMW=7/88. Death in hospital: CP=25/197 vs Before=20/154 vs GMW=9/88. Discharge to institution: CP=69/197 vs Before=56/154 vs GMW=25/88. Discharge to home: CP=103/197 vs Before=78/154 vs GMW=54/88. Dependency (mRS>2) on day 5: CP=108/123 vs GMW=35/42.

COMPLICATIONS IN FIRST 5 DAYS: Pneumonia: CP=21/197 vs Before=16/154 vs GMW=8/88. UTI: CP=10/197 vs Before=15/154 vs GMW=5/88. Pressure sore: CP=5/197 vs Before=4/154 vs GMW=2/88. DVT: CP=2/197 vs Before=0/154 vs GMW=0/88. Falls: CP=19/197 vs Before=12/154 vs GMW=5/88. Fever: CP=46/197 vs Before=42/154 vs GMW=26/88. Constipation: CP=24/197 vs Before=25/154 vs GMW=9/88. Seizures: CP=7/197 vs Before=5/154 vs GMW=4/88. Any complication: CP=102/197 vs Before=92/154 vs GMW=44/88. TESTS: Total CT scan: CP=189/197 vs Before=143/154 vs GMW=82/88. CT <24hr: CP=163/197 vs Before=111/154 vs GMW=66/88. Carotid duplex: CP=96/197 vs Before=80/154 vs GMW=45/88. ECG: CP=192/197 vs Before=152/154 vs GMW=78/88. Echo: CP=55/197 vs Before=32/154 vs GMW=34/88. Cerebral angiogram/MRA: CP=2/197 vs Before=2/154 vs GMW=1/88. CXR: CP=95/197 vs Before=104/154 vs GMW=42/88. DRUGS: Aspirin <48hr: CP=133/175 vs Before=101/133 vs GMW=55/78. Subcutaneous heparin: CP=6/197 vs Before=5/154 vs GMW=5/88. IV heparin: CP=1/197 vs Before=5/154 vs GMW=0/88. Oral antibiotics: CP=17/197 vs Before=16/154 vs GMW=10/88. IV antibiotics: CP=24/197 vs Before=9/154 vs GMW=13/88. IV fluids: CP=81/197 vs Before=65/154 vs GMW=26/88. Acute antihypertensive therapy: CP=6/197 vs Before=8/154 vs GMW=8/88. OTHERS: Urine catheters (for incontinent patients): CP=37/91 vs Before=30/64 vs GMW=21/29. TEDS: CP=9/197 vs Before=10/154 vs GMW=11/88. Compared to the 'before' and GMW groups, documentation was better in CP group for: 1) certain aspects of neurological assessment; and 2) anatomical site of the brain lesion and its pathological type.

Notes Acute stroke. Both groups similar except . CP group had more total anterior circulation strokes (29% vs 18%, p=0.005). No data on costs. Compliance generally good in terms of use of CP document and level of completeness.

Allocation concealment D - Not used

Review title: Nursing record systems: effects on nursing practice and health care outcomes

Study **Scharf 1997**

Methods A controlled before and after study. Power calculation: NOT DONE
Unit of Allocation: Wards. Unit of analysis: Patients (quota samples).
Baseline measurements: NOT CLEAR. Characteristics of second site: NOT
DONE
Reliable primary outcome measures: NOT CLEAR. Follow up of
professionals: NOT DONE. Follow up of patients: DONE.
Consumer involvement and ethical approval: NOT CLEAR

Participants Nurses on two coronary care units. Quota samples of 100 patients.
Country: USA

Interventions Introduction of a nursing flow sheet with standard care plans available for
reference only, compared with system of separate nursing diagnosis form,
individual care plans, and nursing progress notes.

Outcomes Adherence to documentation standards, **patient satisfaction**. Nurse time
spent charting (recorded on intervention unit only).

Notes

Allocation D - Not used
concealment

**Review title: Interventions for providers to promote a patient-centred approach in
clinical consultations**

SA Lewin, ZC Skea, V Entwistle, M Zwarenstein, J Dick

Study **Roter 1998**

Methods Study design: CBA

Allocation procedure: Doctors were not randomised (those who did not
attend the training were allocated to control)

Protection against contamination: Not done (some doctors drawn from the
same clinics)

Outcome assessors blind?: Yes

Intention to treat analysis: Not done

Potential for unit of analysis error for some outcomes?: Yes, but
adjustments made

Participants Speciality: Primary care physicians (trained in internal medicine or family
practice)

Clinical setting: Ministry of Health (MOH) clinics, Trinidad and Tobago

Types of patients: Adults with a chronic disease

Interventions Content of intervention:

The first day was divided into three parts:

- 1) An overview of the literature and rationale for the CME describing basic research regarding links between interpersonal communication and patient and doctor outcomes;
- 2) Presentation of the results of the baseline study conducted in the 15 MOH clinics prior to training;
- 3) The last two hours of the first session and all of the second day's session were devoted to role play and practice of specific communication skills.

Skills emphasised were informativeness, emotional responsiveness, and partnership building.

Informative elements emphasised in the training were increased information giving in both the biomedical and psychosocial realms. Also included in this domain was an emphasis on increasing providers' use of open-ended questions.

In the affective domain, emotional responsiveness was emphasised, including statements of concern, empathy, and reassurance, as well as positive exchanges.

As a method of enhancing patient involvement in the process of care, and thereby building a stronger therapeutic partnership, providers were encouraged to use facilitations, which include paraphrase, interpretations, and signals of interest.

Participants were provided with a detailed and annotated manual defining the target skills, transcripts of sample MOH medical visits, an overview of patient and doctor questionnaire results, and selected readings and bibliography.

Duration and timing: 2x 4hr sessions given over two day period

Numbers of providers receiving intervention: 10 (3 for one day of training only)

Numbers patients followed up in IG:43

Reviewers' score for intensity of the patient centredness of the intervention: 6/10

Reviewers' score for intensity of the teaching strategies used: 6/10

Control group received no training

Numbers of providers in CG: 8

Numbers of patients followed up in CG: 28

Outcomes Consultation/practice process measures: Provider talk and emotional tone during visits; patient talk and emotional tone during visits; verbal dominance: ratio of all doctor to patient statements; (for full list see Additional Table 1)

Patient satisfaction with care: Pre/post satisfaction change scores

Health care behaviours: N/A

Health status and well being: N/A

Notes Measures used:

For all consultation process outcomes:
 Type: Analysis of audiotapes
 Index: Roter Interactional Analysis System (RIAS) (Roter 1997)

For patient satisfaction:
 Type: patient questionnaire
 Index: 9 item on a 2 point scale (no reference given)

Allocation concealment D - Not used

Review title: Specialist outreach clinics in primary care and rural hospital settings

RL Gruen, TS Weeramanthri, SE Knight, RS Bailie

Study Howe

Methods Controlled Before-After Study (communities).
 Baseline: DONE
 Comparable control: NOT DONE
 Blinded assessment: NOT CLEAR
 Protection against contamination: DONE
 Reliable outcomes: NOT CLEAR
 Follow up: providers: DONE patients: DONE

Participants USA, 9 rural hospitals & clinics, all female Caucasian patients diagnosed with breast cancer 1986-1991.

Interventions Regular oncologist visits to rural hospitals to consult and administer treatment protocols commencing 1988. Prior to this it had been identified that too few patients were receiving bilateral mammography or adequate tumour staging.
 Purpose: To improve rates of bilateral mammography, tumour staging, and 'state of the art' stage and type-specific cancer care.
 Comparison: A program of audit and intervention feedback to family doctors and rural-based specialists, without outreach.

Outcomes **Quality of care: Guideline-consistent care, including diagnostic and prognostic assessment, oncology consultation and appropriate treatment.**
Access: Proportion receiving oncology consult.

Notes

Allocation concealment D - Not used

Study Tyrer

Methods Controlled Before-After Study (regions).
 Baseline: DONE
 Comparable control: NOT DONE
 Blinded assessment: DONE
 Protection against contamination: DONE
 Reliable outcomes: DONE

Follow up: providers: DONE patients: DONE

Participants	East Nottingham, UK, general practice clinics in urban area of 130 km ² , patients 15-64 years old contacting specialist psychiatric services 1978-1985.
Interventions	Specialist psychiatric clinics based in general practice clinics. Increased in number after sectorization 1981. Purpose: To improve liaison and collaboration between general practice and psychiatry. Comparison: Rest of Nottingham where outreach clinics less prevalent.
Outcomes	Service utilisation: Admissions to hospital, proportion receiving inpatient care.
Notes	
Allocation concealment	D - Not used

Review title: Diethylcarbamazine (DEC)-medicated salt for community-based control of lymphatic filariasis

S Adinarayanan, J Critchley, PK Das, H Gelband

Study	Kaul 1992
Methods	Design: DEC-medicated salt versus control study of communities Follow up: 10 yr
Participants	Malayan filariasis 4 communities (3 receiving DEC-medicated salt and one receiving no salt) each with an average population of 430 individuals
Interventions	1. DEC-medicated salt (0.23%) for 1 yr: 3 communities 2. No intervention: 1 community
Outcomes	1. Pretreatment and post-treatment mf prevalence for the communities 2. Mf density 3. Disease rates (measure not specified) 4. Vector infection and infectivity rates in the DEC-medicated salt villages only
Notes	Location: remote hill settlements in Karala, India
Allocation concealment	D - Not used

Study	Krishna Rao 1976
Methods	Design: DEC-medicated salt versus control study of communities Follow up: 2 to 5 yr
Participants	Bancroftian filariasis 3 communities with population of 24,094, 2489, and 4557 individuals
Interventions	1. DEC-medicated salt (0.1%) for 45 wk (1 community) 2. DEC-medicated salt (0.1%) for 12 wk (1 community) 3. No salt (1 community)
Outcomes	1. Community mf prevalence before and after treatment 2. Mf density 3. Disease prevalence 2. Vector infection and infectivity 3. Adverse events
Notes	Location: Andhra Pradesh, India
Allocation concealment	D - Not used

Review title: Strategies for integrating primary health services in middle- and low-income countries at the point of delivery

CJ Briggs and P Garner

Study	Schellenberg 2004
Methods	Controlled before and after study in two selected districts
Participants	Health facilities in the districts
Interventions	Aim: to improve curative care in children through guidelines for common illnesses (WHO/UNICEF IMCI) Groups 1. WHO/UNICEF Integrated management of childhood illness package including training of health workers. 2. Routine services
Outcomes	Infant mortality. Intermediate outcomes:
Notes	quality of care,
Allocation	D - Not used

concealment

Study Tuladhar 1982

Methods Controlled before and after study in four selected districts, 2 with vertical programme and 2 with integrated programme.

Participants Districts.

Interventions Aim: to increase family planning use, reduce fertility and reduce infant mortality. Groups: 1. Integrated family planning/maternal and child health programme: 48 district offices, 298 health posts, which included family planning, nutrition monitoring, health education, immunisation, TB and leprosy case finding and treatment, referral, treatment of common illnesses, and training of traditional birth attendants. Some included antenatal, delivery and postnatal care, and malaria surveillance. 2. Vertical family planning/maternal and child health programme: dedicated staff at 40 district offices and 492 service centres, providing family planning, antenatal care and immunization vaccination for children under five years.

Outcomes 1. Family planning knowledge, use and intention to use. 2. Family size preferences. 3. Infant mortality.

Notes Nepal.

Allocation C - Inadequate concealment

Review title: Patient education for adults with rheumatoid arthritis

RP Riemsma, JR Kirwan, E Taal, JJ Rasker

Study Balmer 1989

Methods A 6 months counselling intervention. Assessments were done at baseline and after 6 months. Quality: 0/0/1/0

Participants 30 RA-patients randomised (20 couns/10 contr) 1 drop-out (couns) before start of sessions. No inclusion criteria mentioned. Mean age: 56 yr, 73% female.

Interventions **Counselling: 2 groups (10 persons) received weekly (1 hr) counselling sessions over 6 months by different counselors.**
Controls: no-intervention

Outcomes Included: None.
Not reported: McGill Pain Questionnaire, VAS-pain, AIMS, Ritchie Articular

Index, Beck Depression Inventory, ESR.
Others: Arthritis Helplessness Index, Multidimensional Health Locus of Control.

Notes	VAS = Visual Analogue Scale AIMS = Arthritis Impact Measurement Scale ESR = Erythrocyte Sedimentation Rate
Allocation concealment	D - Not used
Study	Barlow 1997
Methods	A 3 weeks, cross-over design. Assessments were done at baseline, after 3 weeks and after 6 months. Quality: 0/0/0/0
Participants	Consecutive patients with definite RA were asked to participate, 142 agreed, 34 were lost to follow-up (no reasons stated), 108 RA-patients were used for T1-T2 analysis. Mean age was 59.3 yr and 81% were female.
Interventions	Experimental group: Mailed RA-leaflets from the ARC, to be read at home during a three week period. Control group: no intervention.
Outcomes	Included: VAS-pain, HADS (Anxiety and Depression). Others: HAQ (only at baseline), VAS-fatigue, ASE (pain and other symptoms).
Notes	ARC = Arthritis and Rheumatism Council (UK) VAS = Visual Analogue Scale HADS = Hospital Anxiety and Depression Scale HAQ = Health Assessment Questionnaire ASE = Arthritis Self-Efficacy
Allocation concealment	D - Not used

Review title: Interventions for improving communication with children and adolescents about a family member's cancer

JT Scott, MJ Pricor, M Harmsen, A Broom, V Entwistle, A Sowden, I Watt

Study	Heiney 1990
Methods	Objectives: To evaluate the effects of a support group on the social adjustment of siblings of paediatric oncology patients. Study design: non-randomised geographical (non-equivalent) control, pretest-posttest. Recruitment: convenience sample.

Allocation: siblings living more than 60 miles from their sibling's treatment centre were allocated to the control group.

Informed consent: yes (from parents).

Total number approached: not stated.

Number recruited: 14.

Method of analysis: An independent t-test was used to compare between group results.

Follow-up: not stated, probably 100%.

Participants	<p>Country: USA.</p> <p>Clinical setting: paediatric oncology centre.</p> <p>Inclusions: siblings aged 9 to 15 years whose brothers or sisters were treated at a paediatric oncology clinic; and (1) who lived within a 60-mile radius of the treatment centre, and (2) whose parents agreed to participate in a concurrent parent group.</p> <p>Exclusions: siblings living beyond a 60-mile radius of the treatment centre were excluded from the experimental group but were eligible for inclusion in the control group.</p> <p>Healthy siblings of patients with common childhood cancers.</p> <p>Age: not stated.</p> <p>Gender: male n=6, female n=8.</p> <p>Ethnicity: not stated.</p>
Interventions	<p>Aims: not stated.</p> <p>I (n=7): participated in a closed support group. Each of 7 sessions focused on a specific topic selected by the researchers from those identified as common concerns of siblings of children with cancer. The therapists used techniques to enhance the group processes described by Yalom (1983). Cotherapists included specialists in child psychiatry and a paediatric nurse practitioner.</p> <p>C (n=7): Participants had no structured contact with the treatment centre staff.</p> <p>N = (baseline) 14.</p> <p>Theoretical basis: group psychotherapy (Yalom 1983).</p>
Outcomes	<p>Timing of outcome assessment: baseline assessment before the beginning of the group; follow-up assessment at the end of the 7, 1-hour sessions (timing of control group not stated).</p> <p>Coping, adjustment and wellbeing: social adjustment was measured using the Social Adjustment Scale - Self Report (Weissman and Bothwell 1976). Only 2 areas (peer relations and</p>

family) were used out of 6 covered by the scale.

Notes Power calculation: N/A

In view of the discrepancy between the experimental and descriptive data, the study authors suggest that "the quantitative measurement tool used may not have tapped the therapeutic benefits of participating in a support group. The benefits may have been delayed".

Allocation concealment A - Adequate

Review title: Interventions for improving adherence to treatment recommendations in people with type 2 diabetes mellitus

E Vermeire, J Wens, P Van Royen, Y Biot, H Hearnshaw, A Lindenmeyer

Study Bradshaw 1999

Methods

- Controlled before and after study
- Groups clearly defined
- Selection bias can be excluded
- Losses to follow-up: not described
- Duration of follow-up: clearly defined
- No correction for confounders
- Overall judgement of quality: medium

Participants

- 230 type 2 diabetes patients
- United Kingdom
- Urban
- Recruitment in primary care services
- Traditional (87), Video (86), Educator (57)
- Sex: M 52.2 %
- Age: mean 66.4, traditional (M: 66.7%), video (M: 46.8%), educator (M: 58.5%)
- Smoking: 22.2 %, traditional 28.7 %, video 23.3 %, educator 10.5%
- Weight: mean 77.9 kg
- HbA1c: mean 7.35, traditional 7.63, video 7.35, educator 6.91

Interventions To assess the effectiveness of three **structured educational programmes (traditional, video and educator)** on foot care, management and natural history of diabetes.

Outcomes Change in levels of knowledge, HbA1c, blood glucose, reported smoking cessation.

Notes

Allocation concealment D - Not used

Study Clarke 2002

Methods	<ul style="list-style-type: none"> - Controlled before and after study - Blinding (patients, outcome assessors): no - Losses to follow-up: clear - Duration of follow-up: clear - Overall judgement of quality: poor
Participants	<ul style="list-style-type: none"> - 748 type 2 diabetes patients - Multicentre study, patients recruited in primary care services - Sex: F: 386, M: 362 - Age: mean 59
Interventions	To evaluate the effect of a Diabetes Healthways management programme. Behaviour and metabolic outcomes of patients enrolled are compared before and after. Nurse call system aimed at formulating health care goals and reinforcing behavioural changes.
Outcomes	Change in medication taking, change in use of preventive services, HbA1c, LDL, diabetic retinopathy (DRE), microalbuminuria
Notes	Of the 2982 patients enrolled , 748 were assessed in the survey. No baseline characteristics are shown for the enrolled population, though the survey sample is claimed to be representative.
Allocation concealment	D - Not used

Study **Jiang 1999**

Methods	<ul style="list-style-type: none"> - Controlled before and after study - Patient , administrator of treatment, and outcome assessment blinding: data missing. - Description of losses to follow-up are missing - No intention to treat analysis - Similarity of groups at the start of the study: not mentioned - Groups equally provided of care: data missing - Overall judgement of quality: poor
Participants	<ul style="list-style-type: none"> - Multicenter study in urban areas in Taiwan. - 217 type 2 diabetes patients in an outpatient setting. - Inclusion criteria: aged between 35 and 70 years old, able to read, HbA1c level $\geq 8.0\%$ and with stable metabolic control. - Sex: intervention (F 61, M 69), control (F 49, M 38) - Age: intervention (52.3 +- 6.7), control (52.9 +- 7.4) - Body Mass Index: intervention (25.2 +- 3.5), control (25.6 +- 3.2) - Duration of disease since diagnosis: intervention (8.0 years +- 8.0), control 6.7 yrs +- 5.3) - Treatment: Diet and oral hypoglycaemic agents: intervention 121, control 87
Interventions	A 5 section education program was offered to type 2 diabetes patients.

Diabetes self-care was assessed before and 4 months after attending a diabetes education programme including basic knowledge, dietary control, blood glucose monitoring, management of hypoglycemia, medication compliance, foot care and exercise. A total of 121 attended four to five sections and were called the intervention group, and the 87 who only received the basic section were called the control group.

Outcomes Fasting plasma glucose, HbA1c, total cholesterol, triglycerides, systolic and diastolic blood pressure, body weight, and waist-hip ratio.

Notes

Allocation concealment D - Not used

Review title: Community-based interventions for the prevention of burns and scalds in children

C Turner, A Spinks, R McClure, J Nixon

Study	Ytterstad 1995
Methods	Controlled before-and-after study evaluating a community-based intervention
Participants	Intervention: Harstad, Norway (pop 22,000) Control 1: Six municipalities surrounding Harstad Control 2: Trondheim, Norway (pop 134, 000), located 1000 km from Harstad
Interventions	"Harstad Injury Prevention Study" - WHO Safe Communities Specific activities related to burn and scald injury included: - promotion of child safety through local private and public organisations - awareness raising through local media - promotion of tap water thermostat setting at 55°C - promotion of cooker safeguards - public health counselling to increase parent vigilance - promotion of parent skills in first aid
Outcomes	Burns and scalds incidence measured by hospital-based injury recording system for: a) baseline - 19.5 months pre-intervention) b) for seven-year period during the intervention (reported in 1995) c) for 10 year period during the intervention (reported in 1998)

Notes

Allocation concealment D - Not used

Review title: Home safety education and provision of safety equipment for injury prevention

D Kendrick, C Coupland, C Mulvaney, J Simpson, SJ Smith, A Sutton, M Watson, A Woods

Study	Bentzen 1997
Methods	CBA (C) Allocated at level of municipality
Participants	Population of children aged 0-15 years in 2 municipalities, Odense (intervention) and Randers (control)
Interventions	I = community injury prevention programme including advice in well child clinics and group based health programmes, pamphlets, puppet theatre, posters, exhibitions C = no community injury prevention programme
Outcomes	Injury outcomes ascertained from injury surveillance system Incidence of cut injuries - I = 468/10000 boys; 343/10000 girls at baseline and 361/10000 boys; 280/10000 girls at follow up C = 7.7/10000 boys; 5.8/10000 girls at baseline and 54.9/10000 boys; 40.9/10000 girls at follow up No P values reported Medically attended injuries (ED attendances)
Notes	Blinding - u Outcomes 80% - y Balance - y
Allocation concealment	D - Not used
Study	Blake 1993
Methods	Non RCT/CBA
Participants	Parents in two inner city health clinics
Interventions	I = educational video C = no video
Outcomes	Functional smoke alarm Significant increase in

purchase and installation of smoke alarms in
intervention group
No figures or P values reported

Notes Blinding - u
 Outcomes 80% - n
 Balance - u
 Allocation of participants not described

Allocation B - Unclear
concealment

Study Coggan 2000

Methods CBA (C)
 Allocation at level of communities

Participants Population of two communities, Waitakere (intervention) and a control
 community matched on demographic variables, new housing developments,
 road safety and safer community coordinator positions

Interventions I = community based injury prevention programme focussing on child safety
 including multi-agency collaboration, education & training, advocacy and
 action for hazard reduction
 C = no community based injury prevention program

Outcomes Fitted fire guard - Intervention community significantly more likely to have
 a fitted fire guard P = 0.0002. No figures reported.
 Acquisition of stair gate - Intervention group significantly more likely to
 acquire a stair gate P < 0.0001. No figures reported.
 Acquisition of appropriate fencing for swimming pools - Intervention group
 more likely to acquire pool fencing, P = 0.0001.
 No figures reported
 Injury outcomes ascertained from injury surveillance system. Hospital
 admission rates for injury - Significant reduction in injury hospitalisation
 rates during intervention and post intervention phase in intervention as
 compared to control community P < 0.05. Figures not reported

Notes Blinding - u
 Outcomes 80% - y
 Balance - n
 Intervention community had higher child injury rates at baseline

Allocation D - Not used
concealment

Study Franklin 2002

Methods CBA

Participants Children and young people, aged 4-17 years, referred
 from the county court system, fire departments, schools
 and parents with firesetting incident

Interventions	I = trauma burn outreach prevention program (TBOPP) - a 1 day multidisciplinary program with interactive content focusing on the impact of firesetting behaviour including a peer counselling approach C = No TBOPP
Outcomes	Firesetting behaviour Recidivism rate - I = 1/132 C = 37/102, OR 0.01 (0.002 to 0.1)
Notes	Blinding - u Outcomes 80% - u Balance - n Control group were children who were not referred to the prevention programme Control group were marginally younger and less likely to have a history of arson
Allocation concealment	D - Not used
Study	Gaffney 1996
Methods	CBA (C) Allocation level not reported
Participants	Populations of unspecified control and intervention areas
Interventions	I = multi-faceted campaign to reduce risk factors and the rate of hot water scalds in children aged 0-4 years C = no campaign
Outcomes	Awareness and use of scald limiting products - no changes in awareness or use of scald limiting products. No figures or P values reported
Notes	Blinding - u Outcomes 80% - u Balance - u
Allocation concealment	D - Not used

Review title: On-site mental health workers in primary care: effects on professional practice

P Bower and B Sibbald

Study Basler 1990

Methods	Design: CBA Base measurement: Done Base control (patient): Done Blind assessment: Done Contamination protection: Not done Reliable: Not clear Follow up: Professionals: Not clear Patients: Not done
Participants	60 patients Pain problems 3 PCPs Germany
Interventions	1. Replacement model Psychologist Group cognitive-behaviour therapy 2. Usual PCP care
Outcomes	Direct effects: GP consultations
Notes	
	Allocation concealment D - Not used

Review title: Effectiveness of intermediate care in nursing-led in-patient units

PD Griffiths, MH Edwards, A Forbes, RL Harris, G Ritchie

Study **Davies 1994**

Methods	Controlled before and after study comparing NL pre / post implementation with 2 control wards Baseline Comparability: Not clear - length of stay and quality of care reported for 2 (1) control wards. Lengths of stay differs markedly Blinded assessment: done for length of stay, not done for quality. Reliable assessment: done for length of stay unclear for quality, satisfaction Contamination: Unclear Follow up: sample size and follow up are unclear.
Participants	Elderly care 'rehabilitation'. Patients over 75 with a range of diagnoses (examples given CVA, MI, pneumonia and hip fracture). Sample size not specified but pre and post length of stay data presented from 6 month periods. Data is presented from 53 nurses relating to job satisfaction.
Interventions	Unit / setting: 18 bed unit in a satellite (non acute) hospital linked to (2 miles) a District General Hospital (UK). Care management: Care managed in a single weekly interdisciplinary meeting chaired by a senior nurse. No routine medical assessment with primary nurse planning care and initiating medical involvement / referring

to other disciplines.

Nursing Team: No detail given.

MD team: Included 'therapists' (Occupational Therapy and Physio) Social work and medics. No registrar / senior registrar input onto ward.

Education / preparation for staff: None described although the process of implementation is described as developing from within the unit (i.e. bottom up)

Other: Attempts to create less formal atmosphere (e.g. nurses did not wear uniforms).

Control: . Two 'similar' wards with routine medical care management.

Outcomes	Length of stay quality of care nurse job satisfaction Process of interdisciplinary care
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Notes	Quality score: N/A
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Allocation concealment	D - Not used
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Review title: Improving health professionals' management and the organisation of care for overweight and obese people

EL Harvey, A-M Glenny, SFL Kirk, CD Summerbell

Study	Richman 1996
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Methods	CBA Follow up: providers: NA patients: NOT DONE Baseline: DONE for weight, BMI, fat mass, blood pressure, NOT DONE for marital and occupational status. Characteristics of study groups: DONE Blinded assessment: NOT DONE Reliable outcomes: NOT CLEAR Protection against contamination: NOT CLEAR Follow-up duration: NOT DONE Unit of allocation: Patients Unit of analysis: Patients
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Participants	N (providers): Shared care (SC) = 24 GPs, hospital based service - Metabolism and Obesity Service (MOS) NOT CLEAR. N (total patients): 138, BMI 30-40 (approx 29 kg overweight, approx 46 years) 110 F, 28 M. The SC patients were the first 37 referred to MOS in the study period. These were each matched with 1-4 MOS patients, on gender, age and BMI. Country: Australia Proportion of eligible providers who participated: NA
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Interventions	1. SC = professional intervention: conferences (group meeting, plus observation of MOS procedures), Plus:
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Organisational intervention: professional, integration of services and continuity of care (**patient held records**). SC aimed to encourage consistent messages from primary and secondary care (MOS) professionals and to encourage treatment of obesity by GPs. N (patients) = 37
 2. MOS usual care control group (established hospital programme: weekly sessions by allied health professionals, with negotiated level of follow-up). N (patients) = 101.

Outcomes	Process: NOT DONE Patient: Weight loss, measured by electronic scales with accuracy to 0.1 kg, % excess weight lost (change in weight/kg overweight x 100), BMI. (Also Food Habits Questionnaire, cognitive restraint, disinhibition and hunger.)
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Notes

Allocation concealment D - Not used

Review title: Interventions to promote collaboration between nurses and doctors

M Zwarenstein and W Bryant

Study Jitapunkul 1995

Methods	Firm trial: patients randomised to 1 of 2 wards, 1 of which was allocated to receive the intervention.
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Participants	Academic hospital, 2 female general medical wards, all professional staff.
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Interventions	Four times weekly nurse-doctor ward rounds for decision-making.
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Outcomes	Length of stay, mortality, discharged home.
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Notes	Unit of analysis error - allocated intervention to wards but analysed patients without correction for clustering.
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Allocation concealment B - Unclear

Review title: Multisystemic Therapy for social, emotional, and behavioral problems in youth aged 10-17

JH Littell, M Popa, B Forsythe

Study Borduin 1990

Methods	Random assignment to treatment conditions
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Participants 16 male adolescents who had been arrested for sexual offenses. Mean age 14, 62% Caucasian, 38% African American

Interventions **MST (average 37 hours, range 21 to 49) vs individual therapy (average 45 hours)**

Outcomes Re-arrest for sexual offense, arrest for non-sexual offense

Notes Variable observation period (21 to 49 months; mean = 37 months)

Allocation concealment B - Unclear

Study Borduin 1995

Methods Random assignment to treatment conditions and to therapist within conditions.

Participants 210 families of youth age 12-17 who had 2+ prior arrests and no evidence of psychosis or dementia. Youth were living with at least one parent or parent figure in 2 rural counties in Missouri. Average age 15; 79% male; 68% Caucasian, 32% African American.

Interventions **MST** provided by 2nd and 3rd year doctoral students in clinical psychology. Average 23 hours of service (range 5 to 54). Interventions varied (83% received family therapy, 60% school intervention, 57% peer intervention, 28% individual therapy, 26% marital therapy).

Individual therapy provided by Master's level therapists at local social service agencies, mean of 28 hours (range 15 to 72). Brief contact with parents in 66% of cases.

Outcomes Subsequent arrest, arrest for substance-related offense, arrest for violent crime. Data from subsample (n=126) on psychiatric symptoms, behavior problems, family functioning, peer relationships.

Notes Outcomes measured after the end of probation. Variable observation periods. Conflicting reports on number of cases randomly assigned.

Allocation concealment B - Unclear

Study Henggeler 1997

Methods Random assignment to treatment conditions, using yoked

pairs.

Participants	155 cases (73 yoked pairs plus 9 MST cases). Youth ages 11 to 18 who committed a violent criminal offense or had 3 prior arrests, cases that were not yet adjudicated, youth at imminent risk of out-of-home placement. Two sites in South Carolina: one rural and urban, predominantly (78%) Caucasian; the other rural and predominantly (58%) African American.
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Interventions	MST provided by Master's level mental health professionals (with backgrounds in social work or pastoral counseling) over an average of 122.6 days (sd 32.6) in one site, and 116.6 days (sd 39.8) in the other site. Usual services in juvenile justice, including a minimum of six months on probation.
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Outcomes	Emotional and behavioral functioning, criminal activity, incarceration, family relations, peer relations.
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Notes	Yoked design was not retained. Outcome data were pooled across sites. Some correlations between adherence measures and outcomes.
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Allocation concealment	B - Unclear
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Study	Leschied 2002
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Methods	Random assignment to treatment conditions.
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Participants	409 juvenile offenders, age 10 to 18 (average 14.6), in 4 sites in Ontario. 2 sites received referrals only from probations. Overall 74% male, 13% Aboriginal. 27% of MST cases dropped out.
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Interventions	MST average of 34 sessions over 4.9 months Usual services in juvenile justice, including case management plan developed by probation officer and interventions with therapeutic components.
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Outcomes	Prosecutions, convictions, incarceration, social skills, parental supervision, family functioning.
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Notes	Unpublished data. Estimated cost of MST: \$6,000 to \$7,000 (CDN) per case under non-research conditions. Actual MST costs: \$25,000 (CDN) per case.
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Allocation concealment B - Unclear

Study Ogden 2004

Methods Random assignment to treatment conditions.

Participants 104 families of youth age 12-17 (average 15 years) with antisocial behavior problems in 4 sites in Norway. 4 families refused to participate in MST. Of 100 remaining, 63% were male.

Interventions **MST vs usual services** (placement, in-home supervision, or other)

Outcomes Internalizing and externalizing behavior problems, social competence, family functioning, out-of-home placement, treatment satisfaction.

Notes 4 MST cases were replaced. Proportion of cases in MST is higher than expected, given original 5/9 odds of assignment to MST. Collection and analysis of follow-up data are underway; intent-to-treat analysis will not be possible, since investigators can not follow drop-outs.

Allocation concealment B - Unclear

Review title: Physician advice for smoking cessation

T Lancaster and LF Stead

Study Ardron 1988

Methods Setting: Adult diabetic outpatient clinic in Liverpool, UK.
Recruitment: volunteers who responded yes to the question "Do you want to give up smoking?" (selected by motivation)
Randomization: method not stated

Participants 60 clinically stable diabetic patients <40 years, smoking >5 cpd, motivated to stop
Therapists: medical registrar supported by health visitor

Interventions **1. Routine advice (5 minute talk)**
2. Intensive advice (longer talk, leaflet, and visit from health visitor at home within 2 weeks involving family, giving further advice and written materials).
Intervention level: intensive (2) vs minimal (1)
Aids used: Yes

Follow-up visits: one

Outcomes	Point prevalence at 6 months Validation: expired CO and urinary cotinine
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Notes	Contributes data to intensive vs minimal comparison
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Allocation concealment	B - Unclear
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Study	Burt 1974
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Methods	Setting : Hospital cardiac unit and cardiac outpatient clinic in Scotland Recruitment: Consecutive survivors of acute myocardial infarction identified as smokers (unselected) Randomization: by day of admission
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Participants	210 survivors of acute myocardial infarction Ages not stated, pipe and cigarette smokers Number of cigarettes smoked not stated Therapists: Hospital consultants, reinforced by junior medical and nursing staff
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Interventions	1. Repeated emphatic advice to quit as an inpatient with follow up in a special clinic 2. Normal inpatient care followed by discharge to care of the family doctor Intervention level: intensive vs minimal Aids used: no Follow-up visits: yes, number not stated
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Outcomes	Reported PP cessation at 12 months Validation: none
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Allocation concealment	C - Inadequate
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Study	Butler 1999
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Methods	Setting: General Practices (Registrars), UK; Recruitment: All smokers attending for consultation (except those with terminal illness) Randomization: block randomization using sealed envelopes.
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Participants	536 smokers (70% female) at various stages of change
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Interventions	1. Standardized brief advice
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2. Structured motivational counselling (based on stage of readiness to change)

Outcomes	PP at six months (self-reported abstinence in the previous month). Validation: none
Notes	Contributes data to intensive vs minimal comparison only.
Allocation concealment	A - Adequate

Study	McDowell 1985
Methods	Setting: Family practices in Canada Recruitment: Volunteers for smoking cessation programme (selected) Randomization: method not stated
Participants	366 adult cigarettes smokers in 9 group family practices (153 relevant to review) mean cpd 25 Therapists: 56 family physicians
Interventions	1. Brief physician advice 2. Health education in groups for 8 weeks (not used in review) 3. Cognitive behaviour modification in 8 group sessions (not used in review) 4. Control: self-monitoring of smoking. Intervention level: Minimal Aids used: None Follow-up visits: None
Outcomes	PP cessation at 12 months Validation: none performed, although subjects threatened with salivary thiocyanate measurement.
Notes	In this review only 1 (intervention) and 4 (control) are considered.
Allocation concealment	B - Unclear
Study	Morgan 1996
Methods	Setting: outpatient medical practices, USA Recruitment: Practices volunteered. Randomization: cluster randomized by practice, no blinding at stage of recruitment of participants
Participants	659 smokers aged 50-74, unselected for motivation. Therapists: Physicians with 45-60 minutes training
Interventions	1. Physician advice, stage-based, tailored self-help guide. Follow-up letter

from physician and call from project staff. Smokers in contemplation given prescription and free 1 week supply of gum.

2. Usual care (delayed intervention)

Intervention level: intensive

Aids used: Yes

Follow-up visit: Yes (phone call)

Outcomes Abstinenence at 6 months (assume PP)
Validation: none

Notes Some practices excluded post randomization, possibility of selection bias. Results sensitive to use of a model allowing for correlation, but corrected OR not provided.

Allocation concealment C - Inadequate

Study Ockene 1991

Methods Setting: American primary care residency program (physicians in training)
Recruitment: unselected
Randomization: Each physician delivered one of the three interventions according to instructions in a packet for each patient.

Participants 1286 smoking patients not selected for motivation to quit
Therapist: 196 primary care physicians in training.

Interventions 1. Advice only
2. Patient-centred counselling, written materials, asked to schedule follow-up visit, follow-up letter
3. Patient-centred counselling and offer of prescription for nicotine gum (not used in review).
Each group was further randomized to minimal (no calls) or intensive follow up by telephone (3 calls over 6 months) from a health educator (HE).
Intervention level: Minimal (1 without follow-up counselling) vs Intensive (all other conditions)
Aids used: Yes
Follow up: with physician (2)

Outcomes PP abstinence at 6 months (self-reported)
Validation: none

Notes All physicians received training in minimal vs intensive interventions and delivered them according to random allocation of patient. Group 1 without HE follow up is considered minimal intervention and is compared to all the other arms as intensive intervention. 2 compared to 1 (both without HE follow up) for effect of physician follow up. 12 month outcomes have been reported but do not give rates by HE follow up condition; no main effects or interactions were found.

Allocation concealment A - Adequate

Review title: Substitution of doctors by nurses in primary care

M Laurant, D Reeves, R Hermens, J Braspenning, R Grol, B Sibbald

Study	Chambers 1977
Methods	CBA
Participants	2313 patients, all ages, 52% male 1 nurse Unknown number of doctors
Interventions	Intervention: two villages allocated to nurse-led care Control: neighbouring villages allocated to doctor-led care
Outcomes	Process of care: standards of care Resource utilisation: direct costs
Notes	Nurse title: practice nurse Nurse role: First contact care and ongoing primary care Study period: 12 months

Allocation concealment D - Not used

Study	Gordon 1974
Methods	CBA
Participants	169 patients, all ages, 38% female. Unknown number of nurses and doctors
Interventions	Intervention: patients allocated to nurse-led primary care Control: patients allocated to doctor-led primary care
Outcomes	Patient outcomes: health status; satisfaction; compliance with medication and follow-up attendance. Process of care: lapses in care
Notes	Nurse title: nurse clinician Nurse role: First contact and ongoing primary care Study period: 12 months

Allocation concealment D - Not used

Review title: Media-based behavioural treatments for behavioural problems in children

P Montgomery, G Bjornstad, J Dennis

Study	MarkieDadds 2005b (HD not CBA?)
Methods	Allocation: Randomised using table of random numbers Blinding of assessors: Not reported Duration of follow-up: 6 months Setting: Community Control condition: Waiting list
Participants	Children with behaviour problems aged 2-5 years. N=63
Interventions	2 groups: *1) self-directed parent training (n=32); TT=nil 2) waiting list control group (n=31); TT=nil
Outcomes	Parent reports using standardised measures.
Notes	Reported that 9 (28%) families in the self-directed condition and 7 (23%) in the waiting list condition did not complete post-treatment measures.
Allocation concealment	A - Adequate

Review title: Reminder packaging for improving adherence to self-administered long-term medications

CJ Heneghan, P Glasziou, R Perera

Study	Becker 1986
Methods	Random allocation with no statement of concealment.
Participants	The study was carried out in the Department of Family Practice and Community Health of Temple University School of Medicine. Of 180 patients recruited to the trial, 171 patients aged 20 to 80 years taking medication for previously diagnosed hypertension were included for analysis. All patients had demonstrated poor blood pressure control (diastolic > 90 mm Hg) on at least one visit during the preceding two years. Patients enrolled were primarily middle-aged black women. Less than 20% were employed, most had not completed high school and they had been taking medication for an average of 11 years. Patients who had significant visual, auditory, or mental problems were excluded. The special packaging group reported slightly better compliance and had better blood pressure control at the beginning of the study.
Interventions	The intervention group (n = 86) received their medications in a single plastic blister sealed with a foil backing on which was printed the day of the week and

the time of day at which each medication was to be taken. All medications for both groups were provided free of charge. Each package of medication had 28 blisters, each one representing 28 consecutive doses of medication, the intervention was provided as a three month supply of medication. Patients in the control group (n = 85) received all of their medications in separate vials for each pill. Vials were labelled with the drug name, the dosage, the medication instructions, and the physician's name.

Outcomes **Self-reports of adherence** (patients who admitted less than perfect adherence were considered non-adherent), and pill counts (patients were considered adherent if they had taken 80% or more of their prescribed medication). Blood pressure was taken three times during each visit. The first measure was discarded and an average of the second and third measures was used as the blood pressure measurement for that visit. Blood pressure control was defined as diastolic blood pressure less than 90 mm Hg.

Notes Physicians caring for patients were aware that adherence studies were in progress, but were blinded to the aims of the study and the group to which an individual patient was assigned.

Allocation concealment B - Unclear

Study **Binstock 1988**

Methods Random allocation with no statement of concealment.

Participants The study enrolled 112 patients with hypertension who were randomized into one of five groups. The groups were similar on age, sex, race, number of medications, and blood pressure at trial entry (one half the subjects were aged between 50 and 65 years old).

Interventions Group one (control) (n = 32) participated in a bimonthly educational program on high blood pressure conducted by a nurse. Group two (n = 23) participated in an educational program and trained to monitor blood pressure at home. Group three (n = 15) participated in an educational program and developed a compliance contract. Group four (n = 30) participated in an educational program and used calendar pill packs. Group five (n = 11) received a combination of home blood pressure monitoring, contracts, calendar pill packs and the educational program. The calendar pill packs were plastic containers marked with the days of the week from which their medications were dispensed. Comparisons were made between the control group one and group four.

Outcomes	No adherence outcomes were reported. A blood pressure check and compliance questionnaire were completed at the first session and at one year follow up. Outcomes from group one and group four were compared and were measured at three months.
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Notes	Home blood pressure was the most expensive and complex of the strategies. Duration of follow up was one year (mean 9 months), and 100% follow up was reported.
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Allocation concealment	B - Unclear
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Review title: Written action plans for asthma in children

S Bhogal, R Zemek, FM Ducharme

Study Letz 2004

Methods	STUDY DESIGN Quasi-randomized controlled trial 2 Parallel group
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ALLOCATION
Allocation not concealed.

PEDRO QUALITY RATING SCORE:
Random allocation: NO
Concealed allocation: NO
Baseline comparability: YES
Between group comparison: YES
Blinding of subject: NO
Blinding of therapist: NO
Blinding of assessor: NO
Adequacy of follow-up: NO
Intention-to-treat analysis: NO
Point estimate of variability: YES
Total PEDro Score: 3

SAMPLE SIZE CALCULATION
No sample size calculation were reported

ROLE OF TREATMENT PHYSICIANS
Treating physicians were involved in the research project

Participants	STUDY POPULATION Children aged 6 to 12 years of age, seen in an allergy and asthma clinic and having been diagnosed with mild to severe persistent asthma. Persistent asthma defined as experience of symptoms of at least 2 times per week, FEV1 equal to or less than 80% predicted and FEV1 or PEF variability of 12% or greater.
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SIZE OF STUDY POPULATION
Number of children randomized: 51; 25 symptom-based, 26 peak flow-based

Number of children completing study: 50; 25 symptom-based, 25 peak flow-based

CHARACTERISTICS OF INCLUDED STUDY PARTICIPANTS

Age, median (range): 8.9 PEF, 9.4 Symptoms
Sex, male (%): 60% PEF, 68% Symptoms
Family History: 61.54% PEF, 56% Symptoms
Race, Caucasian (%): 100% PEF; 100% Symptoms
Severity, pre-bronchodilator FEV1: 76.75% PEF, 78.75% Symptoms
Total daily dosage of inhaled steroids: 434 PEF, 561 Symptoms
Patients with use of systemic steroids in year prior to randomization (%): 76.9% PEF, 72% Symptoms

INCLUSION CRITERIA:

Newly diagnosed with persistent asthma, based on patient history, examination, and pre-post-bronchodilator-pulmonary function testing.

EXCLUSION CRITERIA:

Previous use of WAP

Interventions PEF versus Symptom-based

LENGTH OF INTERVENTION PHASE

3 months

TARGET

Self-management plans were targeted at both child and parents with the reading/language of the WAP at the 6th grade level

EXPERIMENTAL GROUP

Peak flow-based plan

Individualized action plan included peak flow measurements that were estimated from the patient's measured and predicted peak expiratory flow. Peak flow readings at or below which each step should be initiated were written into each subject's action plan.

Yellow zone: Recommended when peak flow was less than 80% but greater than 60% of predicted best

Red zone: Recommended when peak flow was at or less than 60% of the predicted best

CONTROL GROUP

Symptom based

Green zone: Baseline therapy with inhaled corticosteroid

Yellow zone: Dose of inhaled steroid was doubled and b2 agonists were used every 4 hours. Instructions listed common symptoms of asthma including persistent cough, symptoms or a common cold, and dyspnea as indicators for initiation of Yellow Zone.

Red zone: Patient and/or parent instructed to call office or present to the emergency room. Red Zone Initiated if relief following bronchodilator lasted less than 2 hours, if patient became short of breath doing normal daily activities, if there was uncontrolled coughing, or if breathing made it difficult for the patient to speak.

CO-INTERVENTION

1 educational session at enrollment for all children

CHILDREN ON DAILY ANTI-INFLAMMATORY MEDICATION DURING INTERVENTION PERIOD: 100%

Outcomes WAP USAGE
 Number of times plan was used
 Step taken

 HEALTH CARE RESOURCES UTILIZATION
 Number of acute care visits
 Number of telephone calls made to health care provider

 MEDICATION CONSUMPTION
 Number of systemic corticosteroid received

Notes

Allocation B - Unclear
concealment