

Content and outcome of usual primary care for back pain: a systematic review

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ABSTRACT

Background

Most patients seeking help for back pain are managed in primary care.

Aim

To describe the content and outcome of 'usual care' for low back pain in primary care trials.

Design of study

A systematic review of randomised controlled trials published since 1998.

Setting

Primary care.

Method

Randomised controlled trials of back pain in adults were scrutinised to obtain data on treatment and outcome measures in groups receiving usual primary care. A narrative review of the resulting heterogeneous data was undertaken.

Results

Thirty-three papers were identified for analysis. Overall the exact nature of the treatment received in the 'usual' primary care group was poorly recorded. Medication was frequently used, and there were suggestions that levels of opioid prescription were higher than might be expected from clinical guidelines. Requesting of plain-film X-rays occurred more often than recommended. There was very little information to suggest that doctors were promoting physical activity for patients with back pain. Disability scores (Roland–Morris Disability Questionnaire) and pain scores improved over time for patients with acute or subacute back pain, but not for those with chronic pain.

Conclusion

Treatment received by patients with back pain was varied and often not in line with back-pain guidelines, particularly with respect to opioid prescription and X-ray investigation. The content of the 'usual care' arm in trials is crucial to interpreting the outcome of studies, but was poorly described in the papers reviewed. Future trials should more fully describe the 'usual care' arm.

Keywords

back pain; family practice; general practice; primary health care.

INTRODUCTION

Low back pain is a common condition that is frequently seen in primary care. In the UK there are between 3 and 7 million GP consultations for back pain in a year. Fifty-two million working days are lost each year and, at any one time, 6% of the working population will have had at least one day off work in the last 4 weeks due to back pain.¹ The annual cumulative consultation rate of patients presenting to their GP with back pain is 6.4%.²

Despite evidence-based guidelines for the management of low back pain,^{3,4} chronic or recurrent back pain is common and it continues to pose considerable challenges and frustrations for patients and practitioners. Attempts have been made to address this situation using educational programmes for GPs to promote the adoption of guidelines, but these have failed to show significant changes in everyday clinical practice.^{3,4} One reason for this may be that the nature of routine clinical practice in primary care has not been adequately considered when producing guidelines.

'Usual care' is often used as the control or comparator group in randomised controlled trials. It

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is important to know the content of these control treatments in order to interpret the effect sizes published in trials. The current study is a systematic review with the following specific objectives:

- to describe the treatments contained within 'usual care' approaches to low back pain, as reported in primary care-based randomised controlled trials published between 1994 and 1997 (a period when many clinical guidelines were published); and
- to describe the clinical course of patients randomised to the 'usual care' approaches outlined in the first objective.

METHOD

Inclusion criteria for studies to review

Types of studies. Randomised controlled trials published in any language from 1998 only were included. This date range was chosen as it follows the publication date of many national guidelines on the care of low back pain in primary care worldwide,⁵⁻⁷ and hence reflects current clinical practice.

Types of participants. Participants aged 18 years or over with non-specific low back pain of any duration, who had been treated in primary care, were included. Low back pain was defined as pain in the back located below the scapulae and above the natal cleft of the buttocks, with or without pain radiating to the leg.⁸ Studies involving specific pathological processes or surgical techniques were excluded.

Types of treatments. A randomised controlled trial was included for review if at least one treatment group involved usual care of low back pain in primary care. Any interventions used to provide this usual care were recorded.

Types of outcome measures. For the study's first objective of describing usual care approaches to treat low back pain, relevant outcome measures were consultation rates, advice, medication usage (prescribed to the patient or purchased by the patient without prescription), investigations, and referrals. For the second objective of describing the clinical course of low back pain in those receiving usual care, information was gathered on pain scores (Visual Analogue Scale, modified Von Korff Pain Scale, Aberdeen Back Pain Scale, and the Extended Aberdeen Spine Pain Scale), overall satisfaction, back-specific functional scores (Roland-Morris Disability Questionnaire [RMDQ]), and work absence.

Search strategy for identification of studies

Relevant studies meeting the inclusion criteria were identified by a computer search of the electronic

How this fits in

Despite back pain being a common problem in primary care, it is poorly described and its treatment appears at odds with guideline recommendations. A better understanding of primary care is needed to facilitate the incorporation of evidence-based medicine into routine consultations.

databases MEDLINE (1966–2007), EMBASE (1966–2007), CINAHL (1982–2007), AMED, DARE, and ISI Web of Science. The search strategy looked for terms within the subject heading, title, and abstract, and included the following terms: random, clinical trials, low back pain, back pain, backache, physicians-family, family practice, general practice, family medicine, primary care, and primary medical care (Appendix 1). The search was augmented by examination of the Cochrane Central Register of Controlled Trials and references given in the identified randomised controlled trials and appropriate reviews.

Methods of review

Study selection. The principal researcher performed the initial database search using the search strategy. The number of potential studies was reduced by the removal of duplicates. Studies were excluded if it was immediately apparent from their abstract that they did not meet the inclusion criteria. Trials in the remaining group were then assessed by examining the full paper.

Methodological quality assessment. One researcher scored all papers; each paper was also independently assessed by other researchers. Disagreements about the methodological score were resolved by discussion.

The Cochrane Collaboration Back Review Group publishes guidelines on systematic reviews. It recommended an 11-point scoring system for assessing methodological quality, including items relating to internal and external validity. Studies with a score of ≥ 6 out of 11 are judged to be of high quality, as they are above the arbitrary cut-off point of 50%.^{9,10}

Subsequently, it has been suggested that the list of assessment criteria can be reduced to just the five points relating to internal validity,¹¹ which are: (1) concealment of treatment allocation; (2) blinding of patients; (3) blinding of outcome assessor; (4) intention-to-treat analysis; (5) and an acceptable drop-out rate. In this review a study was judged to be of high quality if it achieved a score of ≥ 3 out of 5.

There was disagreement between reviewers about quality scores of six out of 33 papers. In every case disagreements were resolved by the two researchers involved, without the need to call on a third reviewer to adjudicate.

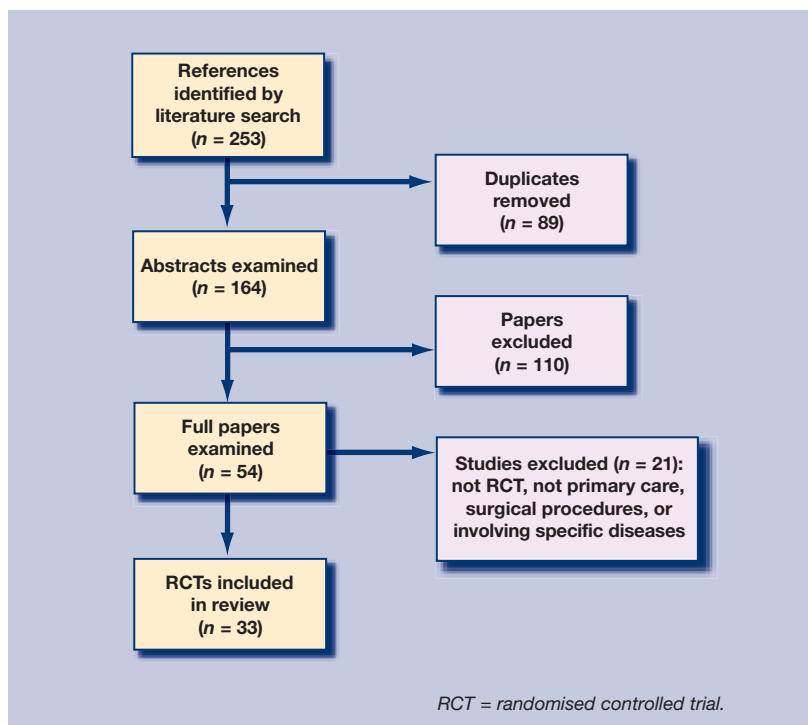


Figure 1. Systematic review flowchart.

Data extraction. This was performed by the lead researcher and other independent reviewers. One key aspect of the review was to determine whether usual care had been adequately described in terms of types of treatments that health professionals had at their discretion to use ('allowed'), and what treatments actually took place ('actual'). Each reviewer was instructed to make their own judgement as to whether allowed and actual usual care had been adequately described. Disagreements were resolved by discussion.

A standardised form was used by each reviewer to record their findings. Information gathered was collated using a Microsoft Office Access database.

Data analysis. Due to the sparseness and heterogeneity of the data, it was appropriate to perform a qualitative assessment rather than a meta-analysis. Also, the purpose of this study was to describe and statistically summarise treatment and outcome measures relating to the usual care arm of trials, rather than to compare effect sizes.

Frequencies were presented of specific elements of care, for example, consultation rates, medication usage (prescribed or purchased over the counter), and referrals. Mean scores with standard deviations (SDs) were extracted from each paper (if stated) and presented for pain (Visual Analogue Scale, modified Von Korff Pain Scale, Aberdeen Back Pain Scale) and RMDQ score. Measures of pain and satisfaction were all converted to a 0–10-point scale (a higher score indicated greater pain or greater satisfaction

respectively) to facilitate interpretation and comparison across studies.

Duration of back pain in each study was classified pragmatically as acute (0–6 weeks), subacute (6–12 weeks), chronic (more than 12 weeks), or mixed (any duration included in study). It should be acknowledged that such classification may not reflect clinical practice, where back pain often fluctuates with time and recurrent acute attacks may be indistinguishable from relapses of a chronic problem.

RESULTS

Study selection

The initial search yielded 164 potentially relevant studies. After examining the full text of 54 papers, 33 were included in the review.^{3,12–43} This process is detailed in Figure 1.

Study characteristics

Study characteristics are presented in detail in Appendix 2. Type of care given or intended to be given in the usual care control group is described, in addition to the outcome of the experimental intervention compared with usual care.

Of the 33 studies identified, eight investigated patients with acute back pain,^{13–15,32,34–36,39} 11 with patients who had subacute pain,^{16,18–21,23,27,33,38,41,42} six examined patients with chronic pain,^{17,24–26,31,37} and eight studies investigated patients with mixed-duration pain.^{3,12,22,28–30,40,43}

Baseline RMDQ score, where appropriate, is given to describe the severity of back pain in participants entering the trials. The studies were conducted in Australia, Canada, Finland, Mallorca, the Netherlands, Norway, Sweden, UK, and US. Thirty out of 33 studies assessed were deemed to be of good quality (that is, they achieved a quality score of ≥ 3 out of 5).

Methodological quality

In the 33 studies, one study scored 1,³⁴ two scored 2,^{27,30} 13 scored 3,^{12,17,19–22,26,29,32,37,40–42} 16 scored 4,^{3,14–16,18,23–25,28,31,33,35,36,38,39,43} and one scored 5 out of a maximum score of 5.¹³ In 16 out of 33 studies it was not possible to tell if the outcome assessor was blinded,^{3,12,17–22,26,27,29,30,34,37,41,42} and in only three of 33 studies were the patients blinded to the nature of the treatment group.^{3,13,18} In two studies it was not stated if the treatment allocation was concealed,^{30,40} and in three it was not possible to tell if the analysis was by intention to treat.^{27,32,34} All papers reported the drop-out rates.

Content of usual care approaches

Adequacy of description of usual care. Of 33 studies, 11 had no description of either the allowed or actual treatment in the control group,^{14,17,18,22,24,27,28,30,32,40,42} seven had a description of both,^{15,23,26,29,35,38,41} six

described just the actual treatment,^{3,22,25,33,34,43} and nine just the allowed treatment.^{12,13,16,19,20,31,36,37,39}

The 10 most commonly recorded aspects of usual care are presented in Table 1. Of these 10 common aspects, a mean of 3.1 items (SD 2.2) were reported in the studies included in the review. Appendix 3 gives more information about aspects of consultations and demonstrates the wide variation in the detail of recording of usual care.

Consultation rates with GP. Due to the heterogeneous ways in which data about consultations were collected, it was not possible to perform a comprehensive quantitative analysis. Overall, 17 of 33 papers reported data on consultation rates. The following qualitative data were found:

- **Acute back pain.** Four of eight studies described consultation rates per patient, one found a rate of 3.9 (no SD stated) consultations in 1 year,³⁶ and another 3.3 (SD 1.6) in 8 weeks.¹⁵ Another found that 60% of patients presented to their GP once, 31% twice, and 9% more than twice in the course of a year.¹³ A fourth states that consultation rates were similar for patients in the experimental and control arms, although figures are not given.³⁹
- **Subacute back pain.** Four of 11 studies provide data on consultations for subacute back pain. One found 62.5% of patients presented to their GP in the first 3 months of the trial, and 51.1% in the second 3 months.³³ A second study reported that 21% consulted once, 3% twice, and 5% three or more times in the first 6 months, and 16%, 3%, and 5% respectively at 9 months.²¹ Mean number of visits to the GP in 1 year was six in a further study.²⁰ Jellema *et al* found that 24% of patients were seeking additional help from their GP in the first 6 weeks, and 28% in the remainder of the year of the study.¹⁸
- **Chronic back pain.** Two of six studies reported data on consultations for chronic back pain. One reported a mean of 13.2 (SD: 5) visits in one year,³¹ and another reported a mean of 1.2 at baseline for the previous year and 1.7 in the year of the study.²⁵
- **Mixed-duration back pain.** Of eight papers, one found the mean number of visits to be 3.6,²⁹ and one found 4.8 visits for mixed-duration back pain.²² Thomas *et al* reported that 40% of patients presented to the GP in the first 12 weeks of their study.⁴³

Medication

Only 12 out of 33 studies gave information about medication taken by patients for their back pain.^{3,15,21,24-26,31,33,38,39,41,43}

Table 1. Ten most commonly recorded aspects of usual care.

Consultation activity record	Number of studies recorded	Percentage of studies recorded
Radiology used	11	33
Other investigation ordered	2	6
Medication used (prescribed or over the counter)	11	33
Sick note issued	22	67
Written advice given	9	27
Activity level recorded	3	9
Exercise advice recorded	4	12
Seen by physiotherapist	15	45
Hospital referral made	8	24
Consultation rate details	17	52

See Appendix 3 for reference details.

Many patients were taking medication at baseline, with figures reported of 69%,³⁹ 80%,²⁴ 90%,⁴³ and 69% (prescribed) and 73% (over the counter).²¹

Two papers gave information about opioid prescription: 34% of patients in a US study,¹⁵ and 18.7% in the UK³ were prescribed them. Unfortunately, there was no information about the strength of the opiates or whether combination drugs were prescribed.

Work absence

Information about absence from work was quite heterogeneous due to the way in which authors recorded this information and differences in the type of usual care; some studies only recruited patients who were absent from work because of back pain.^{33,35} It is important to remember this when comparing data about sick notes from different countries. The different procedures for obtaining a sick notes in different countries may give a false interpretation of the data. As mentioned in the paper Dutch GPs do not give sick notes, British GPs do.

Acute back pain. One study reported that 81% of patients had no certified sick leave, fewer than 9% had 10 or more days of certified sick leave in a year, and overall there was a mean of 3 days' sick leave.¹³ Another reported a mean 2.2 days (SD: 3.4) of sick leave since randomisation at 8 weeks' follow-up.¹⁵

Subacute back pain. Patients reported a mean of 14 days of sick leave at baseline,²¹ and 15 in the 3 months before commencement of the study.¹⁹

Chronic back pain. Varied information was found related to work absence for chronic back pain. Two studies reported that 50%,³¹ and 57.3%¹⁷ of patients were off sick at baseline, whereas in another study the patients only had 3 days off sick at baseline.²⁵

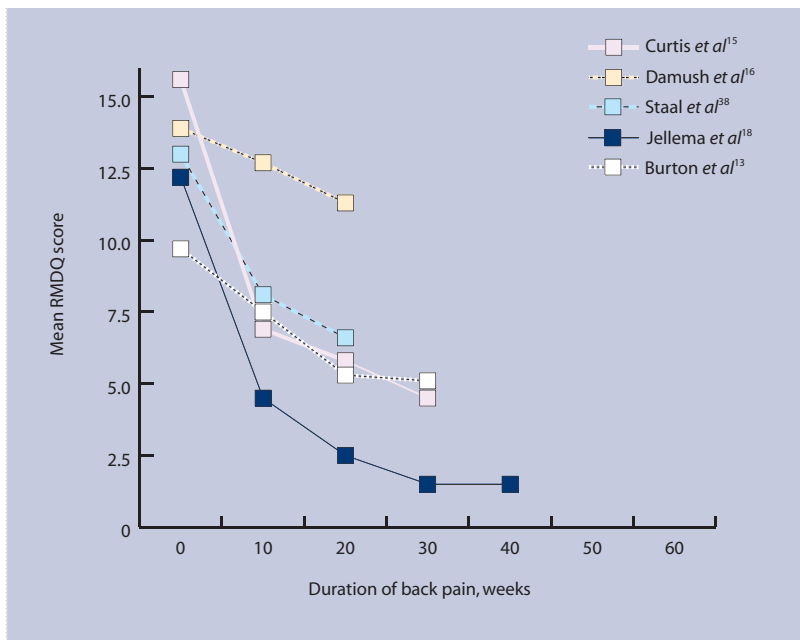


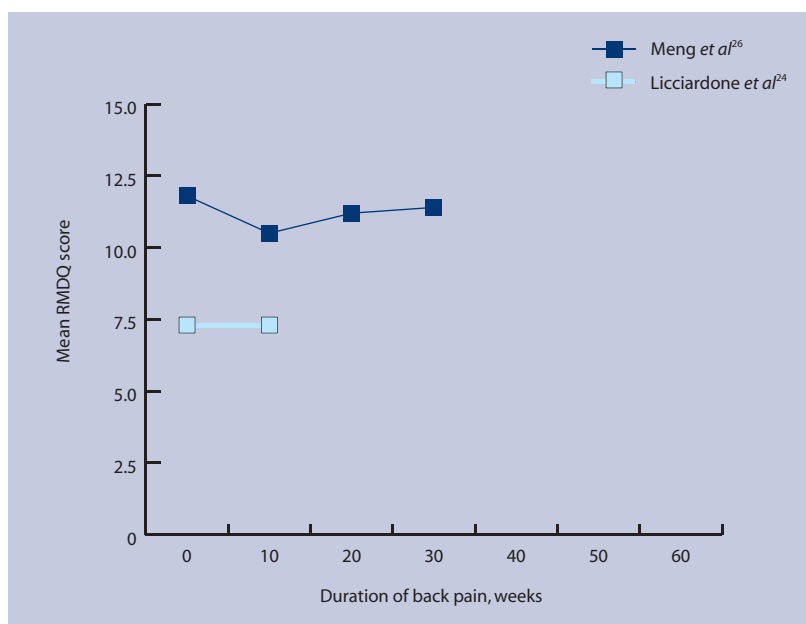
Figure 2a. Change in Roland–Morris Disability Questionnaire (RMDQ) scores over time according to duration of acute/subacute back pain.

Figure 2b. Change in Roland–Morris Disability Questionnaire (RMDQ) scores over time according to duration of chronic back pain.

Activity levels and exercise advice

Three studies gave details on the activity levels of patients before they presented to their GP^{19,32,33} and three reported the advice given to patients about exercise during the trial.^{15,31,33}

Physiotherapy. For acute back pain, 7%¹⁵ and 8.6%³⁹ of patients were referred to physiotherapy. For subacute back pain, 18%,¹⁸ 31%,²¹ and 92.9%³³ of patients receiving usual care were referred to physiotherapy at baseline or in the first 6 weeks. For mixed-duration back pain 49% were referred within the first 12 weeks.⁴³ In the case of chronic back pain



it was not possible to compare data in a meaningful way, due to heterogeneity as discussed in relation to work absence.

Radiology. Use of plain film X-rays in the management of back pain varied, particularly between countries. The percentages of patients having this investigation were 19% (US),¹⁵ 53.6% (Canada),³³ 7% (UK),²¹ and 4% (UK).²⁹

Clinical course of patients randomised to usual care

Functional disability (RMDQ score). The data shown in Figures 2a and 2b suggest that the speed at which RMDQ scores improve is inversely related to the duration of back pain: that is, the longer the duration of pain, the slower the rate of improvement. In acute and subacute pain there was a definite trend for improvement. The single study that did not follow this trend¹⁶ involved usual care provided by university-affiliated clinics and the emergency department of a hospital in an inner-city setting in the US; as such, these patients may not be representative of patients normally managed in primary care.

Pain score. For acute and subacute pain there was a general trend for pain scores to improve with time, as observed on the 0–10-point pain scale used to rate the studies. In two studies acute pain mean pain scores improved by 5.8 and 2.0 between baseline and their endpoints respectively.^{13,35} For subacute pain, mean pain scores improved by 1.2, 5.0, 2.0, 1.0, and 3.9 respectively.^{16,18,19,21,33}

For patients with chronic pain, the pain score changed little over the course of the study, with changes in mean pain scores of 0.9, –0.8, 0.6 and –1.8 respectively (a negative value meaning reduction of pain).^{24–26,31}

Satisfaction. For acute pain, mean satisfaction scores at study endpoint were 7.2 (treatment),³⁵ 7.0 (explanation),³⁵ and 4.1 (overall), according to the 0–10-point satisfaction scale used to rate the studies.¹⁵ In subacute pain, endpoint satisfaction scores were 4.7,³³ and 4.1.¹⁹ In one study on chronic back pain the mean endpoint satisfaction score was 4.4.²⁴ A study on mixed-duration back pain expressed this differently, with the number of patients who were very satisfied or satisfied at 85% following their initial consultation, and at 70% after 6 weeks (Figure 2c).²²

DISCUSSION

Methodological quality

That many studies did not have blinding of patients or outcome assessors is not unusual. Often blinding

is not possible, or even sensible, due to the pragmatic nature of the trial design, the interventions used, or ethical constraints.

Studies were presented in different ways, which made quality assessment and data extraction difficult to carry out. Future randomised controlled trials on back pain should be presented in line with Consolidated Standards of Reporting Trials (CONSORT) recommendations.⁴⁴

Overall, most papers reviewed were of an acceptable quality according to the study's quality scale. A small number of trials failed to describe concealment of allocation to treatment,^{30,40} or intention-to-treat analysis.^{27,32,34}

Direct comparison between studies was difficult due to the differing ways in which data were recorded. For example, pain experienced by patients was assessed using Visual Analogue Scale, modified Von Korff Pain Scale, Aberdeen Back Pain Scale, and the Extended Aberdeen Spine Pain Scale. Nevertheless, the patterns of changes in pain were similar to those for disability, with patients with acute and subacute back pain showing larger improvements than participants with chronic back pain.

Description of usual care

Overall, usual care was poorly described in these studies. Historically, there has been a tendency to allow care in the control group to be according to the normal practice of the care provider, with little or no recording of what actually took place. This contrasts with the intervention treatment, against which usual care is compared, which is often described in great detail.

It is clear that healthcare providers vary widely in their preferred practices, due to many factors including their experience and the expectations of the population in which the studies are set. As such, control groups in separate studies reviewed here may receive a range of different treatments. This makes comparison between studies difficult.

Although the practice of comparing a new treatment with the prevailing current practice is well accepted, interpretation of such studies is problematic when the usual care groups vary so widely and are not adequately described. This is particularly pertinent given that a healthcare provider may act differently purely by knowing their practice is under scrutiny.

Attempts to standardise usual care have shown little effect in changing clinician behaviour.³ It is important to accept that usual care is heterogeneous, and this needs to be taken into account when interpreting the results of studies. The present authors suggest that a minimum dataset about usual care is recorded to improve understanding of the treatments received in the usual care group (Table 1

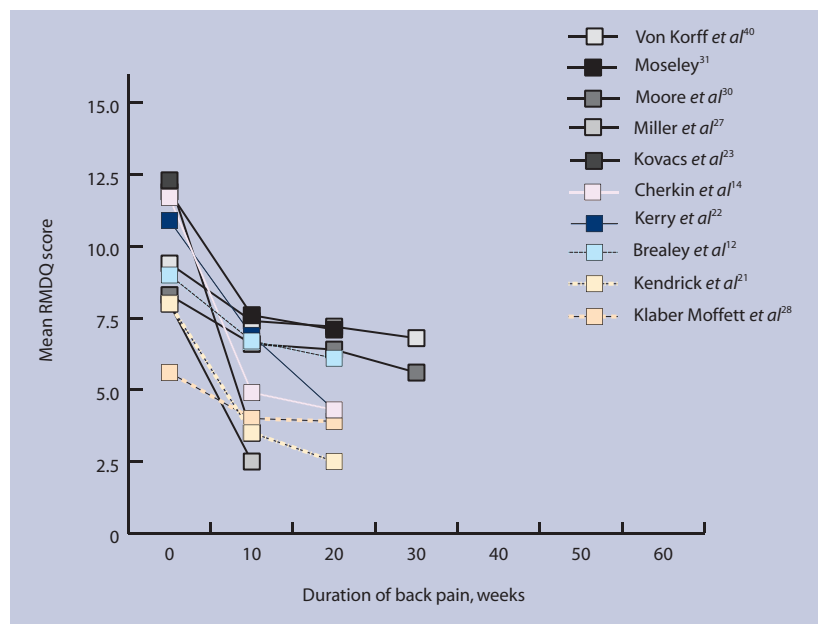


Figure 2c. Change in Roland-Morris Disability Questionnaire (RMDQ) scores over time according to duration of mixed back pain.

and Appendix 2). This includes information about radiology usage, other investigations ordered, medications used (prescribed or over-the-counter), sick notes issued, use of written materials, recording of activity levels, details of exercise advice given, consultation rates, physiotherapy undertaken, and hospital referrals.³

Content of usual care

It is difficult to draw any firm conclusions about how frequently primary care consultation is allowed or what actually happens in the usual care approaches. Marked differences existed in the control groups due to the country involved, variation in the study designs, and methods of recording consultation activity; only half of studies reported data and the results showed no pattern.

Similarly, the overall recording of medication use was quite poor. This is disappointing in that medication use has significant financial costs for the patient and the health economy, and is associated with a not-insignificant number of side-effects.

This review found that many patients take over-the-counter medication for their back pain, and GPs often provided additional medication. Data were limited, but there was a suggestion that levels of opioid prescription were quite high,^{3,15} given the message in back-pain management guidelines that suggest using weak opioids as 'add-on' treatments when paracetamol or non-steroidal anti-inflammatory drugs provide insufficient pain relief.^{8,45} Compound analgesics are not recommended as they do not allow separate titration of the constituent medications, and there are concerns about dependence with strong opioids.^{8,45}

Unfortunately, in the studies in this review,

information was not recorded about the strength of opiates or whether combination products were used. It may be that the concerns about strong and combination opioids are overemphasised, particularly when the majority of patients will recover from their back pain in a few weeks. A GP faced with a patient who is in pain, despite taking simple painkillers, may well decide that it is appropriate to prescribe these drugs in the short term, but with close monitoring for side-effects and over-usage. It is important to record more detailed information about the types of drugs used to treat back pain, and their effectiveness and safety.

It is generally accepted that plain-film X-rays are not helpful in the management of most patients with back pain and represent an avoidable source of radiation.^{6,46-48} This review found that the use of X-rays varied widely between countries, from 4% of cases in the UK,²⁹ to 53.6% in Canada.³³ Reasons for requesting investigations are complex and involve many factors including patient and doctor beliefs and knowledge, country-specific healthcare systems, and patient satisfaction.

The tension between guideline advice and actual clinical behaviour is illustrated by a survey of GPs that found that they would almost always or sometimes refer for X-ray in 70% of patients with non-recurrent backache of less than a month's duration: 88% per cent of requests were to reassure the patient, and 78% to reassure the doctor.⁴⁹ This finding is not confined to low back pain consultations, and it has been shown that perceived patient pressure, rather than clinical need, is the reason behind a significant minority of investigations.⁵⁰ Clearly, it is desirable to reduce patient exposure to radiation, but to achieve this goal a guideline must be of practical use to doctors in primary care. The guideline must include adequate explanation of the rationale behind each recommendation, address the needs for reassurance on the part of the patient and doctor, and be adaptable to local resources (for example, it is no use advocating magnetic resonance imaging instead of plain-film X-rays if it is not readily available).

The clear messages from trials and guidelines are that patients with low back pain should continue with normal activities, even if uncomfortable, and stay at or return to work.⁸ The papers included in this review did not, in general, report on this important aspect of patient care. One possible reason for this might be that is not the normal practice of GPs to record this information. Also GPs may not feel able to give specific advice about exercise, due either to lack of training or fear of litigation should the patient develop a problem related to exercising. GPs are well placed to give exercise advice to patients, and there is a need to address these issues to encourage and support

people who would benefit from increasing their activity.⁵¹

Course of symptoms

The relatively small number of studies involved makes it difficult to undertake a meaningful data synthesis and arrive at firm conclusions. However, Figures 2a and 2b suggest that the speed at which the RMDQ score changed over time depended on the duration of the back disorder. For acute pain there was a trend for RMDQ scores to fall rapidly over the first few weeks (Figure 2a), and this improvement was maintained throughout the study period. For chronic pain sufferers the outlook was much less promising, and RMDQ scores did not tend to improve with time.

Usual care groups in the studies in this review were given a range of treatments but, despite this, it appears that the effectiveness of usual care (if measured as improvement of RMDQ score) may be related more to the duration of the episode than to the type of care given.

Usual care is variable in content and effectiveness. That it is also poorly described compounds this problem and makes comparison between studies even more difficult. As such, it is important that usual care is not regarded as a uniform control against which interventions are compared without attempting to understand what it consists of. This heterogeneity may undermine the fundamental basis for calculating sample sizes in future trials. Agreement is needed as to what information should be recorded in future trials, and conformity to CONSORT needs to be improved.

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Competing interests

The authors have declared that there are none

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Appendix 1. Search strategy for identification of studies.

Relevant studies meeting the inclusion criteria were identified by:

1. A computer search of MEDLINE (1966–2007), EMBASE (1966–2007), CINAHL (1982–2007), AMED, DARE, and ISI Web of Science. The following search strategies were used. They were restricted to adults, human participants, and publication since 1998:

► MEDLINE

(random\$ OR clinical trial\$([pt,sh, ti, ab]) AND (low back pain OR back pain or backache [sh,ti,ab.]) AND (physicians-family OR family pract\$ OR general pract\$ OR family medicine OR primary health care OR primary medical care [sh,ti,ab.]

► EMBASE

(random\$ OR clinical trial\$ [pt,sh,ti,ab]) AND (low back pain OR back pain OR backache OR lumbago [sh,ti,ab]) AND (physicians-family OR family pract\$ OR general pract\$ OR family medicine OR primary health care OR primary medical care [sh,ti,ab.]

► CINAHL

(random\$ OR controlled clinical trial\$ [pt,sh,ti,ab]) AND (low back pain OR back pain or backache) AND (low back pain OR back pain or backache [sh,ti,ab.]) AND (physicians-family OR family pract\$ OR general pract\$ OR family medicine OR primary health care OR primary medical care [sh,ti,ab.]

2. Examination of the Cochrane Central Register of Controlled Trials.
3. Examination of references given in the identified randomised controlled trials and appropriate reviews.

Appendix 2. Study characteristics.

Study (first author)	Setting	Duration of back pain	Participants: n, mean age in years, % female	Baseline mean RMDQ score (SD)	Intervention	Control	Outcome of usual care: mean (SD) unless stated	Outcome of intervention in comparison with usual care	Methodological quality score (0-5, with 5 being best)
Brealey ²²	UK general practice	Mixed	338, 42.5, 53	9 (3.9)	Physical treatments; exercise	Best care	RMDQ: base 9 (3.9), 3 months 6.8 (0.3), 12 months 6.1 (0.3) versus exercise group. Pain (MVK): base 60.5 (17.6), 3 months 49.3 (1.6), 12 months 48.4 (1.7) versus exercise group	Compared with best care – exercise: small benefit at 3 months, nil at 12 months. Manipulation: small to moderate benefit at 3 months and small benefit at 12 months. Manipulation + exercise: moderate benefit at 3 months and small benefit at 12 months	3
Burton ²³	UK 5 general practices and 1 osteopath practice	Acute	79, 44.7, 48	9.7 (4.6)	Back book (biopsychosocial) or handy-hints pamphlet (biomedical)	Usual care + pamphlet	RMDQ: base 9.7 (4.6), 12 months ~4.5 (-). Pain (VAS 0-100) worst/best: base 68.7 (18.5)/50.8 (27.8) 12 months 15.6 (18.7)/10.6 (17.8)	Improved beliefs about low back pain; reduced fear-avoidance and RMDQ score; no effect on pain	5
Cherkin ¹⁴	US primary care	Acute	66, 40.1, 42	11.7 (5.4)	Physical therapy; chiropractic booklet	Usual care + booklet	RMDQ: base 11.7 (1.3), 4 weeks 4.9 (1.1), 12 weeks 4.3 (1.2)	Physical and chiropractic therapy improves satisfaction, but nothing else	4
Curtis ²⁵	US, primary care	Acute	143, 42.7, 57	15.6 (5.4)	Manual therapy given by GP	Enhanced care patient-centred approach, careful examination, including palpation and functional assessment, use of national guidelines and patient handouts regarding activities of daily living and exercise. Option to use standard prescription, bed rest, trigger-point injections referral to others	RMDQ at base 15.6 (5.4); improvement in RMDQ from randomisation: base 2.6 (5.7), 2 weeks 8.7 (8.0), 4 weeks 9.8 (7.3), 8 weeks 11.1 (7.9). Pain (0-10): 4.6 (2.1). Satisfaction (1-5, 1 = best): endpoint 2.1 (1.1)	GP giving limited manual therapy offers very modest benefit compared with enhanced care alone. However, only 43% of patients in manual treatment group given full treatment course by the GP	4
Damush ¹⁶	US inner-city health centres and emergency rooms	Subacute	106, 45.5, 75	13.9 (6.8)	Self-management programme for patients on low income with acute low back pain; long-term outcomes (1 year)	Usual care referral to occupational health, physical therapy, or a neurologist; analgesics, back exercise advice sheets	RMDQ: base 13.9 (6.8), 12 months 11.3 (8.1). Satisfaction (higher score better): base 24.3 (5.7), 12 months 25.4 (5.4)	At 12 months patients who participated in the self-management programme showed significantly better RMDQ scores, mental functioning, self-efficacy to manage acute low back pain, time in physical activity, and reduced fear of movement/re-injury	4
Dey ²	UK primary care	Mixed	1138, 41.3, 54.3	-	Education of GPs to promote use of guidelines on low back pain	Usual care	Patients receiving the following (%): X-ray 13.7, sick note 19.2, opiates/muscle relaxant 18.7, referral to secondary care 2.3, referral to physiotherapy 13.8	No difference between study and control patients in terms of proportion referred to X-ray, given a sick certificate, prescribed opioids or muscle relaxants, or referred to secondary care. Only 21% of patients had evidence that they were given advice about avoiding bed rest; 0.6% in both arms recommended to take bed rest. Suggested that GPs know about guidelines but feel pressurised by patient expectations to behave differently	4
Molde Hagen ¹⁷	Norway spine clinic	Chronic	220, 41.1, 48	-	Light mobilisation	Usual care	19.6 days of compensated sick leave in 2 years	Brief examination, information giving, reassurance and encouragement to resume physical activity reduces long-term sick leave in the first year. Those returning to work mainly do so in the first year	3

continued...

Appendix 2. Study characteristics (continued).

Study (first author)	Setting	Duration of back pain	Participants: n, mean age in years, % female	Baseline mean RMDQ score (SD)	Intervention and advice	Control	Outcome of usual care: mean (SD) unless stated	Outcome of intervention in comparison with usual care	Methodological quality score (0-5, with 5 being best)
Hagen ¹²	Norway spine clinic	Subacute	457, 41, 48	-	Reassurance about prognosis	Usual care	-	-	3
Jellema ¹⁸	The Netherlands primary care	Subacute	171, 42, 47	12.2 (5); median 13 IQR (8-16)	Assessment and modification of psychological factors	Usual care as per Dutch College of GP guidelines	RMDQ: base 12.2 (5.0); base 13 (8-16), 6 weeks 4 (1-10); 13 weeks 2 (0-5), 26 weeks 1 (0-3), 1 year 1 (0-4). Pain (0-10): base 5 (3-6), 6 weeks 2 (0-4), 13 weeks 1 (0-3), 26 weeks 0 (0-2), 1 year 0 (0-2)	No difference in outcome measures versus usual care	4
Karjalainen ¹⁹	Finnish primary care	Subacute	57, 43, 60	-	Mini-intervention versus usual care, 2-year follow-up	Leaflet + usual care	Disability (ODI) mean (range): base 34 (13-67), 3 months 25 (0-76), 6 months 21 (0-51), 1 year 19 (0-51), 2 years 18 (0-51). Pain (0-10): base 5.7 (1-10), 3 months 4.1 (0-9), 6 months 3.7 (0-10), 1 year 3.7 (0-10), 2 years 3.4 (0-9)	Examination, information, support, and simple advice reduces daily symptoms and sick leave, and increases satisfaction and adaptation by patients, without increasing healthcare costs	3
Karjalainen ²⁰ primary care	Finland	Subacute	57, 43, 60	-	Mini-intervention (involving light mobilisation, graded activity programme, addressing patient concerns) versus usual care, 1-year follow-up	Leaflet + usual care	As above	As above	3
Kendrick ²¹	UK primary care	Subacute	211, 39, 60	8 (4-12) ^a	X-rays for low back pain	Usual care	Median (IQR) RMDQ: base 8 (4-12), 3 months 3 (1-7). Pain (0-10): base 2 (1-2), 3 months 1 (0-2). Satisfaction (EuroQol): base 20 (17.75-22), 3 months (19-23)	X-rays don't improve care of low back pain sufferers, but increase doctors' workload	3
Kerry ²²	UK primary care	Mixed	332, 41.1, 53	10.8 (5.4)	X-rays for first presentation of low back pain	Usual care	RMDQ: base 10.8 (5.4), 6 weeks 5.4 (0.3), 1 year 4.2 (0.3). Pain (SF-36 BP): base 45 (26), 6 weeks 56 (2), 1 year 65 (2)	Referral for lumbar X-ray doesn't improve pain, function, or disability. There is a small possible improvement in psychological status, but need to balance against radiation risk	3
Kovacs ²³	Mallorca primary care	Chronic	45, 45.6, 66.7	12.17 (-)	Neuroreflexotherapy	Usual care	Median (range) RMDQ: base 12.2 (6.5-18.0), 1-year improvement 2.1 (-1.5 to 6.7). Pain (VAS): base 5.2 (4.1-8), 1-year improvement 1.9 (-1.3 to 2.0)	Neuroreflexotherapy reduced pain, disability, specialist referral, X-ray requests, drug costs, and sick leave	4
Licciardone ²⁴	US university clinic	Chronic	20, 49, 65	7.3 (5.4)	Osteopathic manipulation in chronic low back pain	Usual care	RMDQ: base 7.3 (5.4). Pain (VAS): base 3.1 (2.3), 6 months -3.9 (-). Global satisfaction: base -1.8 (-), 6 months -2.1 (-)	Osteopathic manipulation improved pain, treatment satisfaction, function, and mental health compared with usual care. Sham manipulation improved pain, treatment satisfaction, and function compared with usual care. There were no differences between osteopathic and sham manipulation	4
Linton ²⁵	Sweden primary care	Chronic	70, 45, 71	-	CBT and different forms of information	Pamphlet	Pain (0-10): base 4.8 (0.45), 1 year 4.0 (0.55)	CBT caused a nine-fold reduction in sick leave and physician and physiotherapy usage	4
Meng ²⁶	US various clinics in private and hospital sectors	Chronic	24, 70, 62.5	11.8 (5.3)	Acupuncture for chronic low back pain	Usual care (narcotics, muscle relaxants, transcutaneous electrical nerve stimulation, epidurals, trigger-point injections prohibited)	RMDQ: base 11.8 (5.3), 6 weeks improved by 0.6 (2.7). Pain (VAS): base 1.7 (1.0), 6 weeks worsened by 0.6 (1.2)	Acupuncture reduced RMDQ scores and was safe	3

continued...

Appendix 2. Study characteristics (continued).

Study (first author)	Setting	Duration of back pain	Participants n, mean age in years, % female	Baseline mean RMDQ score (SD)	Intervention	Control	Outcome of usual care: mean (SD) unless stated	Outcome of intervention in comparison with usual care	Methodological quality score (0-5, with 5 being best)
Miller ²⁷	UK primary care	Subacute	211, 39, 16	8 (4-12) ^a	Cost effectiveness of X-rays	Usual care	Median (IQR) RMDQ: base 8 (4-12) Pain (VAS, 0-10): base 2 (1-2) Satisfaction (0-27): base 20 (17.8-22), 9 months (16-21)	X-rays are only cost-effective when patient satisfaction is high. Other ways of obtaining satisfaction are to be preferred	2
Klaber Moffett ²⁸	UK primary care	Mixed	98, 42.6, 56	5.56 (3.94)	Exercise programme	Usual care	RMDQ: base 5.56 (3.94), % of patients with improvement ≥ 2 points: 6 weeks 46, 6 months 47, 1 year 47.5	High fear-avoiders benefit most from an exercise programme and the effect is maintained at 1 year. Patients who are depressed/distressed gained a short-term benefit	4
Moffett ²⁹	UK primary care	Mixed	98, 42.6, 56	5.56 (3.94)	Exercise programme	Usual care	RMDQ: base 5.56 (3.94), improvement from base 6; 6 weeks 1.94, 6 months 1.64, 1 year 1.77. Pain (ALBPS): 25.52 (10.85), improvement from base: 6 weeks 8.99, 6 months 8.11, 1 year 8.48	Exercise programme reduced pain, disability, and healthcare usage	3
Moore ³⁰	US HMO clinics	Mixed	113, 49.1, 49.6	8.29 (5.88)	Self-care (CBT)	Book on back care	RMDQ: 8.29 (5.88), 3 months 6.55 (6.13), 6 months 6.4 (5.99), 1 year 5.56 (5.8). Pain (0-10): base 5.2 (1.95), 3 months 4.06 (2.17), 6 months 3.71 (2.28), 1 year 2.98 (1.99)	CBT approach reduced back-related worry, fear-avoidance, pain, and functional problems	2
Moseley ³¹	Australia physiotherapy clinic	Chronic	28, 398, 54	11.9 (3.2)	Combined physiotherapy and education	Usual care	RMDQ: base 11.9 (3.2), 1-year improvement 4.3. Pain (0-10): base 4.7 (1.5), 1-year improvement 1.4	A combined programme of manual therapy, exercise, and education reduced pain and disability	4
Roberts ³²	UK primary care	Acute	28, 29.2, 32	-	Back-care leaflet	Usual care	-	The leaflet improved posture but had no effect on function	3
Rossignol ³³	Canadian worker compensation scheme	Subacute	56, 38.3, 23.2	-	Advice and support for physicians treating low back pain	Usual care	Pain (VAS, 0-100): base 52.4 (20.7), 3 months 10.9 (24.0), 6 months 12.8 (27.0). Satisfaction (0-65, best-worst): base 30.3 (12.8), little change during trial	Advice and support to doctors about management of low back pain reduces patient sick leave, pain, dysfunction, and X-ray usage. It improves exercise levels	4
Schechtman ³⁴	US HMO clinics	Acute	590, 45.5, 54	-	Physician education versus patient educational material versus both versus neither	Usual care	-	Education of physicians improves compliance with low back pain guidelines. Patient educational material has no effect	1
Seferlis ³⁵	Sweden hospital clinic	Acute	60, 38, 47	-	Manual therapy versus intensive training versus usual care	Usual care	-	Most patients return to work by 1 month regardless of treatment. Satisfaction is improved by manual therapy or intensive training	4
Seferlis ³⁵	Swedish hospital clinic previous study	Acute	60, 38, 47	-	Cost-minimisation analysis of conservative treatment for back pain	Usual care	-	Usual care has lowest cost	4
Skouen ³⁷	Norway hospital clinic	Chronic	86, 44, 64	-	Extensive versus light multidisciplinary treatments versus usual care	Usual care	-	Light programme more effective than usual care. Extensive programme no more effective than usual care	3
Staal ³⁸	The Netherlands occupational health airline	Subacute	67, 37, 7	13 (4.9)	Graded activity	Usual care	RMDQ: base 13.0 (4.9), improvement frame base: 3 months 4.9 (6.2), 6 months 6.4 (6.6). Pain (0-10): base 6.4 (1.7), improvement frame base: 3 months 2.5 (2.8), 6 months 2.7 (2.8)	Graded activity reduces days of work lost due to low back pain	4
Thomas ³⁹	UK acupuncture clinics and primary care	Mixed	241, 44, 58	-	Acupuncture	Usual care	Disability (ODI): baseline 31.4 (4.2), 12 months 19.6 (15.4), 24 months 21.0 (14.2). Pain (SF-36 BP; 0-100): baseline 30.4 (18.0), 12 months 58.3 (22.2), 24 months 59.5 (23.4). Pain (MPQ): baseline 2.7 (1.0), 12 months 1.53 (0.9), 24 months 1.71 (1.1)	Weak evidence that acupuncture has an effect on persistent back pain at 2 months, stronger evidence of a smaller effect at 24 months	3

continued...

Appendix 2. Study characteristics (continued).

Study (first author) ³⁹	Setting	Duration of back pain	Participants: n, mean age in years, % female	Baseline mean RMDQ score (SD)	Intervention	Control	Outcome of usual care: mean (SD) unless stated	Outcome of intervention in comparison with usual care	Methodological quality score (0-5, with 5 being best)
Underwood ³⁹	UK primary care	Acute	40, 41, 45	-	Back extension exercises	Usual care	Disability (ODI): base 35.6, 1 year 24% patients had a score <20. Pain (VAS): base 50.4, 1 year 18% had score <20	No evidence to show that it is more effective than usual care	4
Von Korf ⁴⁰	US primary care	Mixed	126, 50.3, 56	9.4 (6.5)	Lay-led self-management	Usual care	RMDQ (approximate): base 9.0, 3 months 7.4, 6 months 7.3, 1 year 7.0. Pain (average): base 5.7 (2.1), 3 months 4.0 (2.1), 6 months 4.1 (0.9), 1 year 3.8 (2.4)	Self-help group reduced worried, produced positive attitudes, and reduced activity limitations	3
Williams ⁴¹	UK primary care osteopathy clinic	Subacute	106, -, -	-	Effectiveness and healthcare costs of a primary care osteopathy service	Usual care	Pain (VAS, 0-100): base 46.3 (22.4), 2 months 6.8 (23.4), 6 months 10.1 (24.1)	Primary care osteopathy improved short-term physical and long-term psychological outcomes at a little extra cost	3

³⁹Media (interquartile range). ALBPS = Aberdeen Low Back Pain Scale (0-100, 0 = best). CBT = cognitive behavioural therapy. HMO = health maintenance organisation. IQR = interquartile range. MPQ = McGill Pain Questionnaire (0-5, 0=best). MVK = modified Von Korf Pain Scale (0-100, 0 = best). ODI = Oswestry Disability Index (0-100, 0 = best). SF-16 BP = SF-16 Bodily Pain (0-100, 0 = best). RMDQ = Roland-Morris Disability Questionnaire (0-24, 0 = best). VAS = Visual Analogue Scale (0-100 or 0-10, best = 0).

Appendix 3. Record of activities within the consultation.

Study (first author)	Case mix	Radiology figures	Other investigations	Any drug details (prescribed or OTC)	Sick note detail	Written advice recorded	Activity level details	Exercise prescription details	Physio- therapy details	Hospital referral details	Consultation rate details	Item score (out of 10)
Burton ¹³	Acute				Y	Y					Y	3
Cherkin ¹⁴	Acute					Y						1
Curtis ¹⁵	Acute	Y		Y	Y	Y		Y	Y		Y	7
Roberts ³²	Acute					Y	Y					2
Schechtman ³⁴	Acute	Y							Y	Y		3
Seferlis ³⁵	Acute				Y							1
Seferlis ³⁶	Acute	Y			Y					Y	Y	4
Underwood ³⁹	Acute			Y	Y				Y		Y	4
Damush ¹⁶	Subacute											0
Hagen ⁴²	Subacute				Y							1
Jellema ¹⁸	Subacute				Y				Y		Y	3
Karjalainen ¹⁹	Subacute				Y	Y					Y	3
Karjalainen ²⁰	Subacute				Y	Y	Y				Y	4
Kendrick ²¹	Subacute	Y		Y	Y				Y	Y	Y	6
Kovacs ²³	Subacute	Y	Y		Y				Y	Y	Y	6
Miller ²⁷	Subacute	Y										1
Rossignol ³³	Subacute	Y		Y	Y		Y	Y	Y	Y	Y	8
Staal ³⁸	Subacute			Y	Y				Y			3
Williams ⁴¹	Subacute	Y	Y	Y					Y	Y	Y	6
Molde Hagen ¹⁷	Chronic				Y							1
Licciardone ²⁴	Chronic			Y	Y							2
Linton ²⁵	Chronic			Y	Y	Y			Y		Y	5
Meng ²⁶	Chronic			Y								1
Moseley ³¹	Chronic			Y	Y			Y	Y		Y	5
Skouen ³⁷	Chronic				Y							1
Brealey ¹²	Mixed				Y	Y						2
Dey ³	Mixed	Y		Y	Y				Y	Y	Y	6
Kerry ²²	Mixed	Y							Y		Y	3
Klaber Moffett ²⁸	Mixed											0
Moffett ²⁹	Mixed	Y			Y				Y	Y	Y	5
Moore ³⁰	Mixed				Y							1
Thomas ⁴³	Mixed							Y	Y		Y	3
Von Korff ¹⁰	Mixed					Y						1
Number of studies giving data		11	2	11	22	9	3	4	15	8	17	
% of studies giving data		33	6	33	67	27	9	12	45	24	52	

OTC = over the counter. Y = number of items recorded (out of 10).