

## **BEST PRACTICE & RESEARCH CLINICAL RHEUMATOLOGY**

### **Back Pain Special Edition**

**Title:** Developing implementation science to improve the translation of research to address low back pain: a critical review

#### **Authors:**

Rebecca Kate Hodder (corresponding author),<sup>1,2,3,5</sup> BA (Psyc), MAppPsyc

C/- Hunter New England Population Health Locked Bag 10 Wallsend NSW 2287 Australia

E: [Rebecca.hodder@hnehealth.nsw.gov.au](mailto:Rebecca.hodder@hnehealth.nsw.gov.au) T: + 61 2 4924 6297

Luke Wolfenden<sup>1,2,3</sup>

Steven J Kamper<sup>4,5</sup>

Hopin Lee<sup>1,2,3,5</sup>

Amanda Williams<sup>1,2,3,5</sup>

Kate O'Brien<sup>1,2,3,5</sup>

Christopher M Williams<sup>1,2,3,5</sup>

#### **Affiliations:**

1. The University of Newcastle
2. Hunter New England Population Health
3. Hunter Medical Research Institute
4. The George Institute, University of Sydney
5. Centre for Pain, Health and Lifestyle

#### **Word count:**

## **ABSTRACT**

The evidence-base regarding treatment for back pain does not align with clinical practice. Currently there is relatively little evidence to guide health decision makers how to improve the use, uptake or adoption of evidence-based recommended practice for low back pain. Improving the design, conduct, and reporting of strategies to improve implementation of back pain care will help address this important evidence-practice gap. In this paper, we will:

- 1) describe implementation science models and approaches;
- 2) outline important features of implementation research;
- 3) critically appraise the quality and findings of implementation trials in the low back pain field;
- 4) provide recommendations for the design and conduct of future implementation studies in the field.

**Key words:** implementation science, back pain; clinical practice;

## **INTRODUCTION**

The burden of low back pain is well documented. The condition is the leading cause of disability globally in terms of years lived with disability (YLDs) (1) and was estimated to impact 539 million people worldwide in 2015 (1). Across the globe, a relatively large body of evidence has been produced aiming to reduce this burden. However, research can only impact the health of patients however if it is used in practice.

As noted elsewhere in this special edition, clinical practice guidelines for low back pain have been developed to guide the provision of evidence-based clinical care through explicit recommendation of best practice, based on the synthesis of the large body of research. Many such guidelines exist for low back pain internationally and their recommendations are strikingly consistent. Arguably, this reflects reliability in the development of low back pain guidelines and their 'evidence-based' recommendations, providing a benchmark for best practice evidence-based care for low back pain.

Despite the availability and consistency of guidelines relating to low back pain care, studies have shown that guideline recommended care is not implemented in routine clinical practice. An array of reasons for the failure of guidelines to impact actual care, often relating to barriers to patients and clinician uptake, have been reported. More recently however the role of guidelines in changing practice has been questioned, with passive dissemination of guidelines usually not effective in translating evidence to practice (2). The need for active translation processes to improve the quality of routine care and adopt evidence-based management is now well accepted because guidelines by themselves do not change practice (3, 4).

### **Research translation and implementation research**

The process of translating research into therapeutic benefits for patients has been described in a 5-stage model by the US National Institute of Health. (4, 5). Early translation phases (T1 & T2) focus on basic science, epidemiology and testing the efficacy of health interventions. The third translation phase or 'T3' encompasses research designed to increase implementation of evidence-based interventions, practices or policies (4). In understanding this model it is essential to differentiate the act of implementation itself from research designed to inform implementation. Implementation itself is the use of strategies to increase the use, uptake, adoption or integration of health interventions, to change practice patterns within specific settings (4, 6). Implementation research is the study of those 'implementation strategies', designed to integrate evidence, increase the use, adoption of policy or change practice (i.e. achieve successful 'implementation') (7, 8). Implementation research that assesses and compares implementation strategies provides an empirical basis to guide decisions of how to best improve the implementation of clinical guidelines. It is also important to note that implementation research comes with its own set of outcomes, which are distinct from clinical

outcomes. Typical outcomes assessed in trials for implementation strategies include, clinician adherence to recommended treatment approaches, and rates of (appropriate or inappropriate) referral for medical tests.

The National Institute of Health highlights implementation research as a fundamental component of research translation and a necessary pre-requisite for research to yield health improvements (4). In the back pain field, dedicated implementation research is required to improve the quality of care provided to patients and reduce the global impact of the condition by maximising the translation of guideline recommendations and research findings. In this paper we discuss 1) implementation models and approaches, 2) the important features of implementation research, and 3) critically appraise the quality of implementation research in the low back pain field, including a summary of what implementation strategies have been found to be effective. We conclude with recommendations for the design and conduct of future implementation studies in the field.

## **1. Implementation models, theories and frameworks**

Implementation science is an emerging field of research. The field draws on a number of theoretical models and frameworks to guide the approach, selection of implementation strategies and methods of evaluation. There are numerous implementation models, theories and frameworks that aim to: a) describe and/or guide the process of translating research into practice (process models), b) understand and/or explain what influences implementation outcomes (determinant frameworks, classic theories and implementation theories), and c) evaluate implementation strategies (evaluation frameworks) (9). These approaches have recently been synthesised in a taxonomy to facilitate consistency and comparability between studies (9).

### *a) Guiding translation*

#### *Process models*

Process models used in implementation science aim to provide guidance regarding the steps involved in translating evidence into practice. These models, otherwise known as research-to-practice or knowledge-to-action models, typically describe the steps required following the generation of research evidence regarding detailed and careful planning, and how to execute implementation strategies to maximise research translation. Such process models include the National Institute of Health 5 stages of research translation, the Knowledge-to-Action Framework and the Quality Implementation Framework (QIF). The QIF for example, describes 14 specific steps to facilitate implementation across four phases: initial considerations regarding a host setting, creating a structure for implementation, ongoing structure once the implementation begins, and improving future applications (10) (Table 1). Such process models can be used in intervention trials to ensure

appropriate and systematic consideration is given during the planning phase to factors relevant to maximising research translation in the selected host setting.

Table 1. Quality Implementation Framework

Phase 1. Initiation Considerations Regarding the Host Setting	
Self-assessment strategies	1. Conducting a Needs and Resources Assessment
	2. Conducting a Fit Assessment
	3. Conducting a Capacity/Readiness Assessment
Decisions about adaptation	4. Possibility for adaptation
Capacity-building strategies	5. Obtaining Explicit Buy-in from Critical Stakeholders and Fostering a Supportive Climate
	6. Building General/Organizational Capacity
	7. Staff recruitment/maintenance
	8. Effective Pre-Innovation Staff Training
Phase 2. Creating a Structure for Implementation	
Structural Features for Implementation	9. Creating Implementation Teams
	10. Developing an Implementation Plan
Phase 3. Ongoing Structure Once Implementation Begins	
Ongoing Implementation Support Strategies	11. Technical Assistance/Coaching/Supervision
	12. Process Evaluation
	13. Supportive Feedback Mechanism
Phase 4. Improving Future Applications	
	14. Learning from Experience

Adapted from Meyers et al 2012 (10)

### *b) Understanding what influences implementation outcomes*

#### *Determinant frameworks*

Determinant frameworks describe the factors that are theoretically linked, or have been shown to be associated with implementation outcomes. Determinants are typically categorised as either barriers (that hinder) or enablers (that facilitate) to implementation. Identification of the barriers and enablers to implementation is important in the design of implementation strategies. Examples of determinant frameworks include the Active Implementation Framework, the Ecological Framework, and the Theoretical Domains Framework (TDF). The TDF has previously been applied to low back pain research (11), it draws on organisational change theories and defines 14 domains such as: ‘Knowledge’, ‘Skills’, ‘Beliefs about Capabilities’, and ‘Environmental Context and Resources’(12)

(Table 2). The TDF also has a process for identifying barriers to implementation and selecting appropriate implementation strategies to address them. Determinant frameworks are best applied in the design phase of implementation trials, to identify both the barriers and enablers to implementation within the target population group and setting, and choose implementation strategies that may be effective in addressing them.

Table 2. Theoretical Domains Framework

Domain (definition)	Constructs
1. Knowledge (an awareness of the existence of something)	Knowledge (including knowledge of condition / scientific rationale); Procedural knowledge; Knowledge of task environment
2. Skills (an ability or proficiency acquired through practice)	Skills; Skills development; Competence; Ability; Interpersonal skills; Practice; Skill assessment
3. Social/Professional Role and Identity (A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting)	Professional identity; Professional role; Social identity; Identity; Professional boundaries; Professional confidence; Group identity; Leadership; Organisational commitment
4. Beliefs about Capabilities (Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use)	Self-confidence; Perceived competence; Self-efficacy; Perceived behavioural control; Beliefs; Self-esteem; Empowerment; Professional confidence
5. Optimism (The confidence that things will happen for the best or that desired goals will be attained)	Optimism; Pessimism; Unrealistic optimism; Identity
6. Beliefs about Consequences (Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation)	Beliefs; Outcome expectancies; Characteristics of outcome expectancies; Anticipated regret; Consequents
7. Reinforcement (Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus)	Rewards (proximal / distal, valued / not valued, probable / improbable); Incentives; Punishment; Consequents; Reinforcement; Contingencies; Sanctions
8. Intentions (A conscious decision to perform a behaviour or a resolve to act in a certain way)	Stability of intentions; Stages of change model; Transtheoretical model and stages of change
9. Goals (Mental representations of outcomes or end states that an individual wants to achieve)	Goals (distal / proximal); Goal priority; Goal / target setting; Goals (autonomous / controlled); Action planning; Implementation intention
10. Memory, Attention and Decision Processes (The ability to retain information, focus selectively on aspects of the environment and choose between two or	Memory; Attention; Attention control; Decision making; Cognitive overload / tiredness

more alternatives)	
11. Environmental Context and Resources (Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour)	Environmental stressors; Resources / material resources; Organisational culture /climate; Salient events / critical incidents; Person x environment interaction; Barriers and facilitators
12. Social influences (Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours)	Social pressure; Social norms; Group conformity; Social comparisons; Group norms; Social support; Power; Intergroup conflict; Alienation; Group identity; Modelling
13. Emotion (A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event)	Fear; Anxiety; Affect; Stress; Depression; Positive / negative affect; Burn-out
14. Behavioural Regulation (Anything aimed at managing or changing objectively observed or measured actions)	Self-monitoring; Breaking habit; Action planning
Adapted from Cane et al 2012 (12)	

### *Classic theories*

Classic theories are rooted in other fields such as psychology and seek to explain individual behavioural processes and have been adapted and applied in the field of implementation. These include psychological behaviour change theories (e.g. Theory of Planned Behaviour or Theory of Reasoned Action), sociological theories (e.g. social capital theories) and organisational theories (e.g. Situated Change Theory). The Theory of Diffusion, that describes the influence of individuals such as opinion leaders and change agents in the adoption and implementation of interventions, is also a classic theory (13). Classic theories such as behaviour change theories may be best applied in the planning phase of implementation trials to identify and understand the individual behaviours or processes that may be a barrier or enabler to successful implementation in a particular setting. Such individual behaviours or processes can then be considered in the selection of implementation strategies to maximise successful implementation.

### *Implementation theories*

Implementation theories are typically behavioural theories that have been adapted for understanding a particular aspect of implementation. These include Organisational Readiness theory (14) and the Normalization Process Theory (15), which both aim to understand how and why organisations differ

in their adoption of interventions. The Organisational Readiness theory proposes that organisational readiness for change is a multi-level construct. One level applies to organisational commitment and efficacy for collective change, the second level is individual appraisal of implementation capability based on determinants of task demands, resource availability and situational factors (14).

Normalization Process Theory (NPT) focuses on the identification of barriers or enablers to the implementation of complex interventions into routine practice (15). The application of NPT focuses on four components of how an intervention becomes normalised by individuals and groups: coherence (or sense-making), cognitive participation (or engagement), collective action (work to enable the intervention to happen), and reflexive monitoring (formal and informal appraisal of the benefits and costs of the intervention) (15). Such implementation theories can be applied in the planning phase of intervention trials to identify the readiness of organisations for change and inform implementation strategy selection to enhance organisational commitment or resource availability. Such theories can also be applied to help understand or explain different levels of implementation in different settings or organisations.

### *c) Evaluation frameworks*

Evaluation frameworks describe aspects of implementation processes or outcomes that can be evaluated to assess their impact, such as the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework (16) (Table 3). It is noted (9) that various other models such as the Theoretical Domains Framework and Normalisation Process Theory can also be used for evaluation purposes as they also describe measurable aspects of implementation. Evaluation frameworks are best used to inform the implementation processes and outcomes that will be assessed to measure implementation effectiveness.

Table 3. RE-AIM Evaluation Dimensions

Dimension	Level
Reach (proportion of the target population that participated in the intervention)	Individual
Efficacy (success rate if implemented as in guidelines; defined as positive outcomes minimum negative outcomes)	Individual
Adoption (proportion of settings, practices, and plans that will adopt this intervention)	Organization
Implementation (extent to which the intervention is implemented as intended in the real world)	Organization
Maintenance (extent to which a program is sustained over time)	Individual and Organization

Adapted from Glasgow (16)



## **2. Important features of implementation research: improving the quality and efficiency**

As a scientific discipline, implementation science is in its relative infancy. For example, just 2% of systematic reviews of health interventions report the findings of implementation trials (17). Furthermore, the quality of implementation research has been criticised (18). Implementation trials should possess the same methodological attributes considered to increase internal validity, such as those outlined by Medical Research Council guidance (19). For example, for the purposes of testing implementation intervention effectiveness, randomised controlled trials have lower risk of bias than other research designs. Concealed allocation, and masking where possible are appropriate. This is because the same risks of bias apparent in research of patient level treatments apply to implementation research. Just as there are reporting guidelines such as CONSORT to improve the clarity and consistency of study reports in clinical research, a reporting guideline has been recently released for implementation studies. Preparation of study reports according to the Standards for Reporting Implementation studies of complex interventions (StaRI) guidelines (20) will help generate an interpretable and comparable evidence base in the area.

There are however several additional considerations important in the design, conduct and reporting of implementation research. We propose three particular areas of consideration: theoretically informed development of implementation strategies that target identified barriers and enablers; categorisation of implementation strategies using standardised terminology; and evaluating the effectiveness on both individual and implementation outcomes, as well as the cost of intervention delivery and adverse events. Close attention to these issues has the potential to advance the science of implementation.

### *a) Appropriate intervention development including use of theory or empirical evidence to address identified barriers and enablers*

It is recommended that the development of implementation interventions should be guided by an appropriate theory or implementation framework, such as those described above. Recognising the inherent complexity in implementing best practice, formative evaluation to appropriately identify and consider questions about context as well as barriers to change is required to guide any implementation approach. The use of theory or implementation frameworks helps ensure that researchers consider relevant barriers and enablers in the design of implementation strategies. This application of theory or conceptual models in the design of implementation strategies can make explicit the mechanism(s) by which implementation strategies are hypothesised to work, enabling researchers to identify both *if* and *how* implementation strategies may improve practice. The importance of their use is supported by findings of systematic reviews which suggest that the application of such theory and frameworks is associated with more effective implementation (6). Among the most comprehensive is the Theoretical

Domains Framework (TDF) as described above, which has been applied in the development of successful interventions to improve clinical practice.

*b) Categorisation of implementation strategies using standard terminology*

Inconsistent use of terminology is a problem for implementation science as it obstructs attempts to synthesise and understand implementation processes and outcomes (21). A number of attempts have been made to consolidate and standardise terminology. Of particular importance is the use of taxonomies in the description of implementation strategies. Among the most popular include the Intervention Taxonomy (ITAX) (22) and the EPOC Taxonomy (23). ITAX provides a comprehensive description of the features of implementation strategies, including the mode of delivery, schedule, adaptability and other characteristics (22). The EPOC Taxonomy has been designed to help describe and categorise health system interventions (23). Recently updated to ensure greater alignment with other taxonomies used to classify health system interventions, EPOC includes four major domains: delivery arrangements, financial arrangements, governance arrangements, and implementation strategies (23). While it is primarily used to assist the classification and synthesis of implementation strategies in systematic reviews, the taxonomy also provides researchers with terminology to describe implementation strategies in individual trials (23).

*c) Appropriate outcomes for implementation research: individual, implementation, cost and adverse events*

While the process of research translation typically involves the use or adoption of known effective treatments in routine care, assessment of both implementation and patient outcomes are essential in implementation trials remains important. This is to understand whether selected implementation strategies influence the use of the targeted treatment or practice, and whether such practice changes in turn impact on patient outcomes. For example, an implementation strategy may be effective in improving implementation outcomes, but not impact patient outcomes due to natural adaptations in the delivery of the treatment in routine care. Arguably such understanding is necessary to avert continued implementation and investment in policy or practice that does not impact on real world patient outcomes.

Implementation strategies can also cause harm. For example, the introduction of new interventions into clinical systems can displace other important clinical practices, or incorrect implementation could increase the risk of adverse patient outcomes. Policy makers and practitioners need to weigh the benefits of implementation of effective interventions with potential unintended harms when making decisions regarding therapeutic intervention or health service investment. As such, evaluation of implementation strategies should include evaluation of both benefits and harms. The cost of implementation is also a fundamental consideration for health services that need to manage finite

resources. A recent review of 91 systematic reviews in primary care to improve the implementation of complex interventions (24), concluded that evidence on cost effectiveness was limited and reporting on costs was scarce and of low quality. Reporting of cost data, or formal cost analyses as part of trial of implementation strategies would help fill this gap.

### **3. Critical appraisal of implementation studies in low back pain**

We searched the Cochrane library and PubMed (using the search terms ('low back pain' OR 'musculoskeletal conditions') AND 'implementation' AND 'review')) to identify reviews that assessed the effectiveness of implementation strategies to improve the implementation of low back pain care. We then summarised and appraised the individual studies included in the reviews according to methods (risk of bias assessment, and attention to the three important features of implementation research outlined above), and content (which implementations are effective).

#### *Characteristics of individual studies*

Twenty-one unique trials were included in the five identified systematic reviews (see Table 4). Three studies were excluded because they did not report an explicit implementation strategy. One study aimed to improve the implementation of low back pain care guidelines but did not include an implementation strategy (25), and two studies assessed the publication of guidelines without the addition of active implementation strategies (26, 27). Collectively, they found that passive dissemination of guidelines is not effective in changing practice.

Of the remaining eighteen individual implementation studies, 12 were cluster randomised controlled trials, 4 were randomised controlled trials, and 2 were interrupted time series trials. All studies were conducted within primary care targeting either general practitioners or physiotherapists. Studies were most frequently conducted in the United Kingdom (6 studies) followed by the Netherlands (3 studies), all were published between 1987 and 2013.

#### *Quality and efficiency indicators of implementation research*

a) Theoretically informed development of implementation strategies and identification of barriers and enablers

Only two of the 18 trials cited implementation theories, models or frameworks in the development of implementation strategies to address barriers and enablers to implementation (28-30). One study cited use of a model by Grol (31) for improving the knowledge and management of primary care clinicians to inform intervention design (28, 29). The other study used the Theoretical Domains Framework

(TDF) in the development of an intervention targeting general practitioner adherence to evidence-based guidelines (30). French (31) used the TDF to identify the barriers and enablers to practitioner adherence to two guideline recommendations for low back pain care (plain film x-rays only when fracture is suspected, and advice to stay active including avoidance of more than two days bed rest) then selected behaviour change techniques to target these.

Ten studies described the barriers or enablers targeted by the implementation strategy (28-30, 32-39), of these nine used previous research to identify barriers and enablers (28, 29, 32-39). Three studies identified relevant barriers and enablers in the study population within which the study was planned prior to conducting the study (28-30, 34). For example, Bekkering (28, 29) conducted a survey of physiotherapy practices to identify perceived barriers to physiotherapeutic management of low back pain patients which was used to inform implementation strategies. Barriers and enablers identified included clinician time constraints, knowledge and skills.

With respect to the selection of implementation strategies, one study used a mapping tool (40) to identify evidence-based behaviour change techniques linked to theory that addressed identified barriers and enablers. Nine studies cited empirical evidence from previous studies regarding effectiveness of selected implementation strategies (28, 29, 32, 33, 35, 36, 39, 41, 42).

#### b) Categorisation of implementation strategies using standardised terminology

No study cited a taxonomy to describe the implementation strategies selected, however a number of the identified reviews (43-45) categorised included studies interventions according to the EPOC taxonomy (22). Over half of the implementation interventions from identified studies included distribution of educational materials. This included distribution of low back pain care guidelines, scientific articles and decision tools. Audit and feedback, educational meetings, reminders, educational outreach visits and patient directed strategies were the next most commonly applied intervention strategies. One study each included local opinion leaders and a clinical multidisciplinary team as part of the intervention, and no studies included local consensus processes.

#### c) Effect of intervention on implementation and individual patient outcomes

Seventeen studies assessed implementation outcomes (28-30, 33-36, 38, 39, 41, 42, 46-51) and 5 studies assessed individual outcomes (28, 29, 32, 37, 38, 49). Only four utilised hybrid designs where implementation and individual level outcomes (28, 29, 37, 38, 49) were assessed. Studies targeting imaging commonly measured implementation outcomes such as, number of GP referrals for x-rays or other lumbar imaging. Across all other studies, implementation outcomes assessed were typically GP or physiotherapist concordance with specific low back pain guidelines, such as physical examination procedures, prescription of pain medication, and referrals for physical or exercise therapy, or number of surgical procedures carried out by spine surgeons. The most common individual patient outcomes

were patient functional capacity or disability, pain, days of work loss, and satisfaction with health care.

The cost effectiveness of implementation interventions was assessed for three studies (30, 32, 36). One study aiming to reduce x-ray referrals and increase provision of advice for patients to stay active, found a facilitated interactive workshop intervention with GPs to be more cost effective than usual care (30). Another study, found a seminar and feedback intervention to be equally effective in improving MRI request concordance with guidelines compared with guidelines alone, but less cost-effective (36). A further study (32) that found a multifaceted implementation intervention to improve GP delivered care to be more effective than control (guideline dissemination alone) on both functional capacity and number of pain days, reported in a separate paper that the multifaceted intervention was more cost effective than control (52). A fourth study reported the per community cost of a multifaceted intervention that was effective in reducing surgical rates compared to usual care (34).

No study assessed adverse outcomes.

#### *Risk of bias of individual studies*

Four (30, 33, 34, 49) of the 18 studies had high risk of bias overall, defined as high risk of bias on at least 2 of the 7 domains on the Cochrane risk of bias tool (Table 1). Of those, 2 studies were rated high risk of bias for allocation concealment (33, 49), blinding of outcome assessors (33, 49), incomplete outcome data (30, 34) and other risk of bias (30, 33); one study was rated high risk of bias for selective outcome reporting (30) and one for sequence generation (34).

#### *Which implementation strategies improve low back pain care?*

There was varied evidence for implementation strategies varied across the five identified systematic reviews. Audit and feedback was reported in two reviews. Tzortzio Brown concluded audit and feedback result in a small reduction in GP radiology requests (45), whereas Jenkins reported no evidence that audit and feedback reduced imaging rates across included studies (53). Three reviews assessed provision of educational opportunities or materials for GPs. Tzortzio Brown (45) reported little to no improvement in reducing the number of requested tests for low back pain patients, French (43) reported varying effects, and Jenkins reported no evidence of effect (53) on reducing the rate of imaging. One review assessed clinical decision support involving a modified referral form. Jenkins reported evidence of effect in reducing imaging rates (36.8% reduction (95% CI 33.2% to 40.5%)) (53). Two reviews assessed reminders to primary care physicians. Tzortzio Brown (45) concluded there may be a small effect on number of investigation requests (45), and Jenkins reported 22.5%

reduction (95% CI 8.4%, 36.8%) (53). Three reviews assessed the effect of using (43), multifaceted interventions (applying multiple implementation strategies) (44), or the frequency and duration of interventions (54). French found no effect of interventions with single (such as distribution of educational materials versus control) or multiple components (such as combination of audit and feedback plus distribution of educational materials versus control) on appropriate use of imaging or clinical outcomes (43). Suman found no evidence that multifaceted strategies (defined as interventions consisting of a combination at least two elements from the EPOC implementation strategy taxonomy) improved guideline concordant referral behaviour for x-rays, provision of adequate patient information or prescribing medication compared to usual care or minimal implementation (such as distribution of educational materials alone) (44). Mesner reported that implementation interventions that were continuously ongoing over time were most effective in improving clinical practice, and single or one-off interventions were consistently ineffective (54).

Table 4. Characteristics of individual implementation studies to improve low back pain care

Study / Year/ Country	Study Characteristics	Study quality Risk of bias Implementation study quality criteria	Study findings
Baker 1987 USA (46)	<p>Study design: Interrupted time series;</p> <p>Participants: number of providers not reported.</p> <p>number of tests 1443 in control year and 759 in experimental year;</p> <p>Setting: Hospital;</p> <ul style="list-style-type: none"> <li>Intervention: Reminder: note on x-ray referral form;</li> </ul> <p>Implementation outcomes: Number of emergency lumbosacral spine examinations, use of lumbosacral spine radiography, percentage compliance with limited indications form.</p> <p>Patient outcomes: none.</p>	<p>Overall: Low (43)</p> <p>Theoretically informed intervention: NR</p> <p>Intervention targeted identified barriers/enablers: NR</p> <p>Taxonomy/empirical evidence informed intervention: NR</p> <p>Implementation outcomes: Yes</p> <p>Patient outcomes: NR</p> <p>Cost analysis: NR</p> <p>Adverse events: NR</p>	<p>The intervention was more effective than control on use of lumbosacral spine radiography.</p>
Becker 2008 Germany (32)	<p>Study design: C-RCT</p> <p>Participants: 126 GPs from 118 practices, 1378 participants;</p> <p>Setting: Primary care</p> <p>Intervention:</p> <ul style="list-style-type: none"> <li>Intervention 1: Distribution of low back pain guidelines, interactive seminars, individual academic-detailing sessions, patient leaflets</li> </ul>	<p>Sequence generation: Low</p> <p>Allocation concealment: Low</p> <p>Blinding of participants: NR</p> <p>Blinding of outcome assessment: Low</p> <p>Incomplete outcome data: Low</p> <p>Selective outcome reporting: Unclear</p> <p>Other risk of bias: Low/Unclear (45)</p>	<p>Intervention 2 was more effective than control on functional capacity at 6 months, but not 12 months. Intervention 1 was not effective at 6 months or 12 months on functional capacity.</p> <p>Intervention 1 and intervention 2 were effective on number of pain days at 6 and 12 months.</p>

	<p>(educational material + outreach visits + educational meetings);</p> <ul style="list-style-type: none"> <li>Intervention 2: Distribution of low back pain guidelines, interactive seminars, individual academic-detailing sessions, patient leaflets (educational material + outreach visits + educational meetings), motivational counselling session for GPs, training for practice nurses, patient counselling sessions;</li> <li>Comparison: Distribution of guidelines on low back pain (educational material).</li> </ul> <p>Patient outcomes: Functional capacity, physical activity, days in pain, days of sick leave, quality of life and fear avoidance beliefs.</p>	<p>Theoretically informed intervention: NR</p> <p>Intervention targeted identified barriers/enablers: Yes – previous studies.</p> <p>Taxonomy/empirical evidence informed intervention: Yes – empirical evidence cited from two systematic reviews.</p> <p>Implementation outcomes: NR</p> <p>Patient outcomes: Yes</p> <p>Cost analysis: Yes (reported separately)</p> <p>Adverse events: No</p>	
<p>Bekkering 2005 The Netherlands (28, 29)</p>	<p>Study design: C-RCT</p> <p>Participants: 113 physiotherapists</p> <p>Setting: Primary care physiotherapy practices</p> <ul style="list-style-type: none"> <li>Intervention: Group training sessions, postal dissemination of guidelines and education material;</li> <li>Comparison: Postal dissemination of guidelines and educational material.</li> </ul> <p>Implementation outcomes: Adherence to recommended treatment approaches</p>	<p>Overall: Low (54)</p> <p>Theoretically informed intervention: Yes – Grof 1994</p> <p>Intervention targeted identified barriers/enablers: Yes – previous studies and previous survey of Dutch physiotherapists</p> <p>Taxonomy/empirical evidence informed intervention: Yes - Empirical evidence</p> <p>Implementation outcomes: Yes</p> <p>Patient outcomes: Yes</p>	<p>The intervention was more effective than the comparison in limiting physiotherapist treatment sessions for patients with normal course of back pain, setting functional treatment goals, using mainly active interventions, giving adequate patient education and adhering to recommended treatment approach criteria.</p> <p>Physical functioning and pain in the 2 groups improved substantially in the first</p>



	Patient outcomes: Physical function, pain, sick leave.	Cost analysis: No Adverse events: No	12 weeks, however no difference was found between the intervention and comparison groups at follow up.
Bishop 2006 Canada (47)	<p>Study design: RCT</p> <p>Participants: 462 GPs, 428 patients</p> <p>Setting: Primary care</p> <p>Intervention:</p> <ul style="list-style-type: none"> <li>Intervention 1: Distribution of educational materials to GP, reminders;</li> <li>Intervention 2: Distribution of educational materials to GP and patient, reminders to GP and patient;</li> </ul> <p>Comparison: usual care</p> <p>Implementation outcomes: Concordance with specific clinical guidelines-derived history-taking items, physical examination procedures and treatment recommendations.</p> <p>Patient outcomes: none.</p>	<p>Sequence generation: Low</p> <p>Allocation concealment: High</p> <p>Blinding of participants: NR</p> <p>Blinding of outcome assessment: Unclear</p> <p>Incomplete outcome data: Low</p> <p>Selective outcome reporting: Unclear</p> <p>Other risk of bias: Unclear (45)</p> <p>Theoretically informed intervention: NR</p> <p>Intervention targeted identified barriers/enablers: NR</p> <p>Taxonomy/empirical evidence informed intervention: NR</p> <p>Implementation outcomes: Yes</p> <p>Patient outcomes: NR</p> <p>Cost analysis: NR</p> <p>Adverse events: NR</p>	The intervention was more effective than usual care in guideline-concordant treatments of prolonged bed rest, passive therapies, and recommendations for aerobic exercise.
Dey 2004 UK (48)	<p>Study design: C-RCT</p> <p>Participants: 24 practices, 2187 patients</p> <p>Setting: Primary care</p> <ul style="list-style-type: none"> <li>Intervention: Educational outreach visit +</li> </ul>	<p>Sequence generation: Low</p> <p>Allocation concealment: Low</p> <p>Blinding of participants: NR</p> <p>Blinding of outcome assessment: High</p> <p>Incomplete outcome data: Low</p>	The intervention was more effective than standard practice in referring patients to physiotherapy or a back pain unit. No effect of the intervention on the proportion of patients referred for x-ray,

	<p>guidelines (educational material) + poster of guidelines + referral forms with guidelines + access to fast-track physiotherapy and a back clinic.</p> <ul style="list-style-type: none"> <li>Comparison: Standard practice.</li> </ul> <p>Implementation outcomes: Rate of referral for lumbar spine x-ray within 3 months, number of sickness certificates issues, number of prescribed opioids or muscle relaxants, number referred to secondary care, number referred to physio or educational programme. Patient outcomes: none.</p>	<p>Selective outcome reporting: Unclear</p> <p>Other risk of bias: Low (45)</p> <p>Theoretically informed intervention: NR</p> <p>Intervention targeted identified barriers/enablers: NR</p> <p>Taxonomy/empirical evidence informed intervention: NR</p> <p>Implementation outcomes: Yes</p> <p>Patient outcomes: NR</p> <p>Cost analysis: NR</p> <p>Adverse events: NR</p>	<p>issued with a sickness certificate, prescribed opioids or muscle relaxants, or referred to secondary care.</p>
<p>Eccles 2001 UK (41)</p>	<p>Study design: C-RCT (2 x 2 factorial design)</p> <p>Participants: General practitioners from 247 practices</p> <p>Setting: Primary care</p> <p>Intervention:</p> <ul style="list-style-type: none"> <li>Intervention 1: Distribution of educational materials + audit and feedback (number of practice referrals compared with peers;</li> <li>Intervention 2: Distribution of education materials + reminders (messages on x-ray results);</li> <li>Intervention 3: Distribution of educational materials + audit and feedback + reminders;</li> </ul> <p>Comparison:</p> <ul style="list-style-type: none"> <li>Control group: Distribution of educational</li> </ul>	<p>Sequence generation: Low</p> <p>Allocation concealment: Low</p> <p>Blinding of participants: NR</p> <p>Blinding of outcome assessment: Low</p> <p>Incomplete outcome data: Low</p> <p>Selective outcome reporting: Unclear</p> <p>Other risk of bias: Unclear (45)</p> <p>Theoretically informed intervention: NR</p> <p>Intervention targeted identified barriers/enablers: NR</p> <p>Taxonomy/empirical evidence informed intervention: Yes – empirical evidence cited for specific prompts at time of consultation and audit and feedback</p> <p>Implementation outcomes: Yes</p>	<p>The intervention of routine attachment of educational reminder messages on x-ray results was more effective than control in reducing the request rate of lumbar radiographs. No effect of a 6 monthly feedback of audit data intervention in reducing the request rate of lumbar radiographs.</p>

	materials (guideline). Implementation outcomes: Number of lumbar radiographs requested per 1000 patients for 2 years. Patient outcomes: none.	Patient outcomes: NR Cost analysis: NR Adverse events: NR	
Engers 2005 The Netherlands (33)	<p>Study design: C-RCT</p> <p>Participants: 41 GPs, 531 patients</p> <p>Setting: Primary care</p> <ul style="list-style-type: none"> <li>Intervention: Two-hour workshop (negotiation skills), guideline on low back pain and guidance on low back pain for occupational physicians, 2 scientific articles, a patient education tool and a management decision tool (distribution of educational materials).</li> <li>Comparison: No intervention, usual care</li> </ul> <p>Implementation outcomes: Number of referrals to a therapist (physical, exercise or manual therapist), prescription of pain medication on a time-contingent basis, prescription of paracetamol versus NSAIDs, adequacy of patient education.</p> <p>Patient outcomes: none.</p>	<p>Sequence generation: Low</p> <p>Allocation concealment: High</p> <p>Blinding of participants: NR</p> <p>Blinding of outcome assessment: High</p> <p>Incomplete outcome data: Low</p> <p>Selective outcome reporting: Unclear</p> <p>Other risk of bias: High (45)</p> <p>Theoretically informed intervention: NR</p> <p>Intervention targeted identified barriers/enablers: Yes – previous studies cited</p> <p>Taxonomy/empirical evidence informed intervention: Yes – empirical evidence cited for distribution of the guideline for occupational physicians and scientific articles concerning GP management of nonspecific low back pain.</p> <p>Implementation outcomes: Yes</p> <p>Patient outcomes: NR</p> <p>Cost analysis: NR</p> <p>Adverse events: NR</p>	No effect of the intervention of advice and education provided, prescription of paracetamol or NSAIDs, or overall number of referrals to physical therapist, exercise therapist or manual therapist.
French	Study design: C-RCT	Sequence generation: Low	The intervention was more effective than

2013 Australia (30)	<p>Participants: 78 practices, 92 GPs</p> <p>Setting: Primary care</p> <ul style="list-style-type: none"> <li>Intervention: 2 facilitated interactive educational workshops aiming to facilitate behaviour change plus distribution of educational DVDs to all physicians;</li> <li>Comparison: Usual care;</li> </ul> <p>Implementation outcomes: GP reported behavioural change and number of x-rays and CT requests.</p> <p>Patient outcomes: Planned, but not measured due to low numbers of patients recruited.</p>	<p>Allocation concealment: Low</p> <p>Blinding of participants: NR</p> <p>Blinding of outcome assessment: Low</p> <p>Incomplete outcome data: High</p> <p>Selective outcome reporting: High</p> <p>Other risk of bias: High (45)</p> <p>Theoretically informed intervention: Yes, Theoretical Domains Framework</p> <p>Intervention targeted identified barriers/enablers: Yes - focus group interviews with GPs</p> <p>Taxonomy/empirical evidence informed intervention: Yes – strategies selected using a mapping tool</p> <p>Implementation outcomes: Yes</p> <p>Patient outcomes: No</p> <p>Cost analysis: Yes</p> <p>Adverse events: NR</p>	<p>usual care in GPs intention of practising consistent with the guideline for the clinical behaviour of x-ray referral, GPs adherence to guideline recommendations about x-ray, and advice to stay active.</p> <p>There was no effect of the intervention on imaging referral.</p>
Goldberg 2001 USA (34)	<p>Study design: RCT</p> <p>Participants: Spine surgeons, primary care physicians, patients who were surgical candidates, and hospital administrators</p> <p>Setting: Entire communities</p> <ul style="list-style-type: none"> <li>Intervention: Surgeon study group meetings, use of local opinion leaders, GP education sessions, printed educational materials, audit, patient</li> </ul>	<p>Overall: High</p> <p>Sequence generation: High</p> <p>Allocation concealment: Unclear</p> <p>Blinding of participants: Unclear</p> <p>Blinding of outcome assessment: Unclear</p> <p>Incomplete outcome data: High</p> <p>Selective outcome reporting: Low</p> <p>Other risk of bias: Low (54)</p>	<p>The intervention was effective in reducing surgical rates compared to usual care.</p>

	educational materials, financial data analysis meetings;	Theoretically informed intervention: No	
	<ul style="list-style-type: none"> <li>Comparison: Usual care</li> </ul>	Intervention targeted identified barriers/enablers: Yes –	
	Implementation outcomes: Surgical procedures carried out from the Comprehensive Hospital Reporting System.	previous studies cited and consultation with clinicians and administrators.	
	Patient outcomes: None	Taxonomy/empirical evidence informed intervention: NR	
		Implementation outcomes: Yes	
		Patient outcomes: No	
		Cost analysis: Yes (reported intervention cost)	
		Adverse events: NR	
Hazard	Study design: RCT	Sequence generation: Low	No effect of the intervention on 3-month
1997	Participants: 59 patients	Allocation concealment: High	work absence rate, pain, satisfaction with
USA	Setting: primary care	Blinding of participants: NR	health care, impact of health care on
(49)	<ul style="list-style-type: none"> <li>Intervention: Distribution of educational materials + reminders to GPs (letters regarding the specific patient with advice on how to limit work loss);</li> <li>Comparison: Control</li> </ul>	Blinding of outcome assessment: High	return to work, days or work loss, or days
	Implementation outcomes: Influence of care following information provision;	Incomplete outcome data: Low	until first return to work.
	Patient outcomes: 3-month work absence rate, disability (VDPQ score), satisfaction with health care, impact of health care on return to work, days of work loss, days until first return to work.	Selective outcome reporting: Unclear	
		Other risk of bias: Unclear (45)	
		Theoretically informed intervention: NR	
		Intervention targeted identified barriers/enablers: NR	
		Taxonomy/empirical evidence informed intervention: NR	
		Implementation outcomes: Yes	
		Patient outcomes: Yes	
		Cost analysis: NR	
		Adverse events: NR	

Kerry 2000 UK (35)	<p>Study design: C-RCT</p> <p>Participants: 69 practices, 175 GPs, 43,778 radiological requests;</p> <p>Setting: Primary care</p> <ul style="list-style-type: none"> <li>Intervention: Distribution of guidelines + individual feedback on referral rates + graph of the average radiation dose for different examinations (educational material and audit/feedback);</li> <li>Comparison: Standard care.</li> </ul> <p>Implementation outcomes: number of x-rays requested (chest, limbs and joints, spine) within 12 months;</p> <p>Patient outcomes: None</p>	<p>Sequence generation: Low</p> <p>Allocation concealment: Unclear</p> <p>Blinding of participants: NR</p> <p>Blinding of outcome assessment: Low</p> <p>Incomplete outcome data: Low</p> <p>Selective outcome reporting: High</p> <p>Other risk of bias: Low (45)</p> <p>Theoretically informed intervention: NR</p> <p>Intervention targeted identified barriers/enablers: Yes – previous studies citing GP lack of guidelines knowledge.</p> <p>Taxonomy/empirical evidence informed intervention: Yes – empirical (conflicting) evidence cited for end-user involvement in guideline development.</p> <p>Implementation outcomes: Yes</p> <p>Patient outcomes: NR</p> <p>Cost analysis: NR</p> <p>Adverse events: NR</p>	<p>No intervention effect on the total number of x-ray requests. Practices that received the guidelines requested significantly fewer spinal examinations compared with standard practice.</p>
Matowe 2002 UK (50)	<p>Study design: Interrupted time series</p> <p>Participants: Number of practices and providers not reported. Analysis included 117,747 imaging requests;</p> <p>Setting: Primary care</p> <ul style="list-style-type: none"> <li>Intervention: Professional intervention</li> </ul>	<p>Overall: Low (43)</p> <p>Theoretically informed intervention: NR</p> <p>Intervention targeted identified barriers/enablers: NR</p> <p>Taxonomy/empirical evidence informed intervention: NR</p>	<p>There were no significant effects of the intervention on the total number of requests or requests for individual examinations.</p>

	(distribution of educational materials)	Implementation outcomes: Yes	
	Implementation outcomes: Number of x-ray referrals	Patient outcomes: NR	
	Patient outcomes: None	Cost analysis: NR	
		Adverse events: NR	
Oakeshott 1994 UK (51)	<p>Study design: C-RCT</p> <p>Participants: 62 practices, analysis was of 2578 x-ray examinations</p> <p>Setting: Primary care</p> <ul style="list-style-type: none"> <li>Intervention: Professional intervention (distribution of educational materials)</li> <li>Comparison: Control (not specified)</li> </ul> <p>Implementation outcomes: number of radiology requests within 9 weeks, percentage of radiology requests that confirm to guidelines;</p> <p>Patient outcomes: none.</p>	<p>Sequence generation: Unclear</p> <p>Allocation concealment: Unclear</p> <p>Blinding of participants: NR</p> <p>Blinding of outcome assessment: Low</p> <p>Incomplete outcome data: Low</p> <p>Selective outcome reporting: Unclear</p> <p>Other risk of bias: Low (43)</p> <p>Theoretically informed intervention: NR</p> <p>Intervention targeted identified barriers/enablers: NR</p> <p>Taxonomy/empirical evidence informed intervention: NR</p> <p>Implementation outcomes: Yes</p> <p>Patient outcomes: NR</p> <p>Cost analysis: NR</p> <p>Adverse events: NR</p>	<p>Practices that received the guidelines requested significantly fewer spinal examinations and made significantly higher proportion of requests compared to those who did not receive the guidelines. No intervention effects on proportion of forms giving physical findings or in proportion of positive findings at radiology.</p>
Robling 2002 UK (36)	<p>Study design: C-RCT</p> <p>Participants: 30 practices, 182 MRI requests</p> <p>Setting: Primary care</p> <ul style="list-style-type: none"> <li>Intervention 1: Professional intervention (distribution of educational materials +</li> </ul>	<p>Sequence generation: Low</p> <p>Allocation concealment: Unclear</p> <p>Blinding of participants: NR</p> <p>Blinding of outcome assessment: Unclear</p> <p>Incomplete outcome data: Unclear</p>	<p>No significant differences were found between the four intervention groups in proportion of MRI requests that are in concordance with guidelines.</p>

	<p>educational meetings, practice based);</p> <ul style="list-style-type: none"> <li>Intervention 2. Professional intervention (audit and feedback);</li> <li>Intervention 3. Professional intervention (1 + 2);</li> <li>Comparison: Distribution of educational materials.</li> </ul> <p>Implementation outcomes: proportion of MRI requests that are in concordance with guideline (length of follow-up not clear);</p> <p>Patient outcomes: None</p>	<p>Selective outcome reporting: Unclear</p> <p>Other risk of bias: Unclear (43)</p> <p>Theoretically informed intervention: NR</p> <p>Intervention targeted identified barriers/enablers: Yes – previous studies</p> <p>Taxonomy/empirical evidence informed intervention: Yes – empirical evidence cited for GP education</p> <p>Implementation outcomes: Yes</p> <p>Patient outcomes: NR</p> <p>Cost analysis: Yes – intervention cost</p> <p>Adverse events: NR</p>	
<p>Rossignol 2000 Canada (37)</p>	<p>Study design: RCT</p> <p>Participants: 110 patients</p> <p>Setting: Primary care</p> <ul style="list-style-type: none"> <li>Intervention: Organisational intervention (clinical multidisciplinary team)</li> <li>Comparison: Usual care</li> </ul> <p>Implementation outcomes: proportion of patients who received lumbar imaging (x-ray, CT, MRI or myelogram) within 6 months;</p> <p>Patient outcomes: return to work; function; health care consumption; satisfaction.</p>	<p>Sequence generation: Low</p> <p>Allocation concealment: Unclear</p> <p>Blinding of participants: NR</p> <p>Blinding of outcome assessment: Low</p> <p>Incomplete outcome data: Unclear</p> <p>Selective outcome reporting: Unclear</p> <p>Other risk of bias: High (43)</p> <p>Theoretically informed intervention: NR</p> <p>Intervention targeted identified barriers/enablers: Yes – previous studies</p> <p>Taxonomy/empirical evidence informed intervention: NR</p> <p>Implementation outcomes: Yes</p>	<p>The intervention group used significantly less specialised imaging tests of the spine at 6 months than control.</p> <p>At 6 month follow up: there was no effect of the intervention on return to work, there was evidence of an intervention effect on 3 of 5 functional recovery outcomes compared to usual care.</p>



		<p>Patient outcomes: Yes</p> <p>Cost analysis: NR</p> <p>Adverse events: NR</p>	
Schechtman 2003 USA (38)	<p>Study design: C-RCT</p> <p>Participants: 85 physicians, 2020 patients, 14 group practice sites</p> <p>Setting: Primary care</p> <ul style="list-style-type: none"> <li>Intervention 1. Distribution of guideline on the management of acute low back pain + educational meeting + feedback on back pain encounters + individual follow-up visit by investigator 6 months afterwards and another feedback on back encounters + educational material for patients including a videotape (educational material + meeting + audit + outreach);</li> <li>Intervention 2. Education materials for patients: pamphlet and video and 2 reminders within the first 3 months to clinicians to use these materials (educational material);</li> <li>Intervention 3. 1 + 2;</li> <li>Comparison: Control group;</li> </ul> <p>Implementation outcomes: Proportion of lumbar plain x-rays CT or MRI consistent with guideline within 12</p>	<p>Sequence generation: Unclear</p> <p>Allocation concealment: Low</p> <p>Blinding of participants: NR</p> <p>Blinding of outcome assessment: Unclear</p> <p>Incomplete outcome data: Unclear</p> <p>Selective outcome reporting: Unclear</p> <p>Other risk of bias: High (45)</p> <p>Theoretically informed intervention: NR</p> <p>Intervention targeted identified barriers/enablers: Yes – previous studies</p> <p>Taxonomy/empirical evidence informed intervention: NR</p> <p>Implementation outcomes: Yes</p> <p>Patient outcomes: Yes</p> <p>Cost analysis: NR</p> <p>Adverse events: NR</p>	<p>Intervention 1 (clinician intervention) was effective in increasing guideline-consistent behaviour compared to control. There was no effect of intervention 2 on guideline-consistent behaviour compared to control.</p>

	months, Subspecialty referral, Physiotherapy referral; Patient outcomes: Beliefs about care, satisfaction with care, clinical outcome measures using validated instruments.		
Stevenson 2006 UK (39)	<p>Study design: C-RCT</p> <p>Participants: 30 physiotherapists</p> <p>Setting: Primary care</p> <ul style="list-style-type: none"> <li>Intervention: 5-h education session delivered by a local opinion leader;</li> <li>Comparison: Standard in-service session on knee pathologies;</li> </ul> <p>Implementation outcomes: Change in physiotherapists' clinical practice (discharge summary questionnaire);</p> <p>Patient outcomes: none.</p>	<p>Overall: High</p> <p>Sequence generation: Unclear</p> <p>Allocation concealment: Unclear</p> <p>Blinding of participants: Low</p> <p>Blinding of outcome assessment: Low</p> <p>Incomplete outcome data: Low</p> <p>Selective outcome reporting: Low</p> <p>Other risk of bias: High (54)</p> <p>Theoretically informed intervention: NR</p> <p>Intervention targeted identified barriers/enablers: Yes – previous studies cited.</p> <p>Taxonomy/empirical evidence informed intervention: Yes – empirical evidence cited for continual medical education (CME), printed educational material, feedback, clinical guidelines and use of opinion leaders.</p> <p>Implementation outcomes: Yes</p> <p>Patient outcomes: NR</p> <p>Cost analysis: NR</p> <p>Adverse events: NR</p>	<p>The intervention group was more likely than the control group to give 'advice to increase activity level' and 'change attitudes/beliefs about pain' but was less likely to 'encourage to undertake activities themselves'. The control group was significantly more likely to use 'acupuncture', 'encourage to undertake activities themselves' and give 'postural advice' compared with the intervention group.</p>

Winkens 1995 The Netherlands (42)	<p>Study design: C-RCT</p> <p>Participants: 79 providers</p> <p>Setting: Primary care</p> <ul style="list-style-type: none"> <li>Intervention: Professional intervention (audit and feedback for one set of tests);</li> <li>Comparison: No intervention control</li> </ul> <p>Implementation outcomes: number of diagnostic tests ordered within 2 years; diagnostic tests concordant with guideline;</p> <p>Patient outcomes: none.</p>	<p>Sequence generation: Unclear</p> <p>Allocation concealment: Unclear</p> <p>Blinding of participants: NR</p> <p>Blinding of outcome assessment: Unclear</p> <p>Incomplete outcome data: Unclear</p> <p>Selective outcome reporting: Unclear</p> <p>Other risk of bias: Unclear (43)</p> <p>Theoretically informed intervention: NR</p> <p>Intervention targeted identified barriers/enablers: NR</p> <p>Taxonomy/empirical evidence informed intervention: Yes – empirical evidence cited for GP feedback</p> <p>Implementation outcomes: Yes</p> <p>Patient outcomes: NR</p> <p>Cost analysis: NR</p> <p>Adverse events: NR</p>	<p>The intervention was effective in decreasing the proportion of non-rational requests compared to control.</p>
---	---	--	--

## DISCUSSION

Implementation research in the low back pain field is scarce. Overall there are few high quality RCTs of implementation strategies, and there is a narrow focus on the primary care setting. There appears to be some evidence that audit and feedback, and reminders are effective albeit marginally, in changing practice behaviours towards best practice recommendations. The other strategies tested, including educational opportunities, resources and multicomponent strategies do not appear to change the care patients are provided. The lack of research activity in the area, and the failure to identify useful implementation strategies is concerning. Greater focus on high quality implementation research in back pain is warranted given evidence that patients do not typically receive care that aligns with evidence-based recommendations.

### *General directions to improve implementation research*

There are several general directions that can improve the state of implementation research in the low back pain field. First, the internal validity of implementation studies should be considered and we should expect the same scientific rigour for implementation research as that of patient focussed intervention research. For example, implementation research in back pain should include appropriately controlled randomised designs, concealed allocation, blinding of outcome assessment and attention to other known sources of bias. Second, there is a need to consider implementation in the context of the wider health systems influences. While general practice is a main access point for patient care of low back pain, greater focus on improving care in other settings (e.g. emergency, pharmacy, allied health, specialist clinics) is required, as is understanding about how connections within the wider health systems impact on overall patient care.

Dedicated implementation trials in back pain are scarce. In comparison, there are currently over 2000 treatment focused trials for back pain index in databases such as PEDro and PubMed. One potential solution to increasing the focus on implementation would be to include implementation outcomes in patient focused treatment trials. In the field of implementation science, the use of ‘hybrid’ designs has been recommended. Hybrid designs collect data on the impact of implementation strategies on implementation outcomes, as well as the impact on individual patient clinical outcomes. Three types of hybrid designs have been proposed, depending on the study objective and certainty of evidence regarding the clinical effectiveness of the intervention (55). Type 1 hybrid designs primarily test the impacts of clinical interventions on patient outcomes but also collect data to inform future implementation trials, such as the feasibility and acceptability of specific implementation strategies. These may be most appropriate when the effectiveness of an intervention is uncertain. Type 2 hybrid designs rigorously test both the effects of interventions on patient outcomes and the impacts of strategies to implement the intervention. Type 3 hybrid designs are primarily used to rigorously assess implementation outcomes, secondary measures assess impact on patient level outcomes to assess

vulnerability of the outcomes to the implementation process. This design is more suited when the effectiveness of the intervention is well-accepted. The selection of a hybrid design appropriate to the research being undertaken is an important step in planning implementation trials, it guides; sampling, selection of measures and sample size. Given the large number of clinical trials conducted in low back pain each year, greater use of Type 1 hybrid designs has considerable potential to increase the pool of data available to design implementation initiatives.

#### *Specific directions for design and conduct of future implementation studies to improve back care*

The use of formative evaluation to identify the barriers and enablers to implementation specific to the participants and settings of interest is seldom conducted. To maximise the opportunity for interventions to have an impact, identification of barriers and enablers should be conducted within study populations, such that interventions are designed with this local context in mind.

While many theories and frameworks exist, few have been tested empirically, and so the mechanisms driving improvement in the implementation of best practice care remains elusive. The inclusion of measures of theoretical constructs, that are targets of implementation strategies would facilitate the understanding of how implementation strategies work, and thereby progress the field by the adaptation of implementation strategies. Systematic reviews have identified a range of tools measuring a variety of Consolidated Framework for Implementation research constructs that could potentially be employed in implementation trials (56). Further, there are measures for all TDF constructs that have been validated across settings (11, 12). Embedding measures to assess constructs targeted by strategies to improve implementation should be a priority for trials so that theory can be tested, mechanisms understood, and more effective and efficient implementation approaches developed.

Selection of appropriate measures of implementation outcomes can be a considerable challenge. Often objective measures of implementation are impractical. For example, video or audio recording of clinical consultations, or independent observations are expensive and can cause research reactivity effects. More practical ways of assessing implementation is via care notation in medical records, clinician report of care provision, or patient reported receipt of care. The limitations of such measures and the bias they may introduce, however, have been well documented. In instances where more objective measures are not possible, the use of measurement triangulation may be one way of improving the internal validity of findings of trial assessing implementation strategies. In survey methodologies, techniques such as suggesting participant responses provided may be independently verified (e.g bogus pipeline procedures) have also been shown to improve the accuracy of measurement and could be considered for application in implementation research.

The impending publication of reporting guidelines specific to implementation trials will provide another avenue to improve the quality and reporting of implementation trials (20). The Standards for Reporting Implementation studies of complex interventions (StaRI) (20), developed using established methodology for the development of reporting guidelines for health research, describes the reporting standards for implementation trials similar to the CONSORT statement for intervention trials. The standards include description of barriers and enablers, evidence-based justification for implementation strategies, measurement of process and clinical outcomes, assessment of impact on health care resources, and description of adaptations made in the local context. The lack of research activity in the area, and the failure to identify useful implementation strategies is concerning. Greater focus on high quality implementation research in back pain is warranted given evidence that patients do not typically receive care that aligns with evidence-based recommendations.

### ***Conflict of interest***

The authors report no conflict of interest.

### ***Role of the funding source***

No funding was received by sponsors to complete the study. RKH receives salary support from the University of Newcastle and Hunter New England Local Health District. SK, CW, LW's research is supported by the National Health and Medical Research Council of Australia. Providers of salary support had no role in the collection, analysis, interpretation of data and in the writing of the manuscript.

### ***Summary***

The evidence-base regarding treatment for back pain does not align with clinical practice. There are numerous implementation science models that can be applied to the low back pain field to guide how to improve the use, uptake or adoption of evidence-based recommended practice for low back pain. Such implementation trials should possess the same methodological attributes considered to increase internal validity in research of patient level treatments, including randomised controlled trial study designs, concealed allocation, and masking. To advance the science of implementation it is proposed implementation trials should additionally consider: theoretically informed development of implementation strategies that target identified barriers and enablers; categorisation of implementation strategies using standardised terminology; and evaluating the effectiveness on both individual and implementation outcomes, as well as the cost of intervention delivery and adverse events. Relatively few implementation trials were identified, of which the minority were high quality RCTs. Few implementation trials described theoretically informed selection of implementation strategies, assessed both implementation and individual levels outcomes or assessed cost effectiveness. No trials

used an existing taxonomy to describe implementation strategies or assessed adverse outcomes. There was some evidence implementation strategies of audit and feedback and reminders are effective in changing practice behaviours towards best practice recommendations. Strategies such as educational opportunities, resources and multicomponent strategies do not appear to be effective. The lack of research activity in the area, the evidence that patients do not typically receive care that aligns with evidence-based recommendations, and the failure of existing implementation trials to identify useful implementation strategies is concerning. Greater focus on high quality implementation research in the back pain field is warranted to address this.

### ***Practice points***

Future trials investigating the effectiveness of implementation interventions to improve low back pain care should adopt best practice research methodology and apply implementation science principles including:

- Adopting robust study designs and methodology of the same scientific rigour that is expected of patient focussed intervention research including randomised controlled study designs, concealed allocation, blinding of outcome assessment and attention to other known sources of bias;
- Using implementation theories and approaches in the development of implementation strategies that target identified barriers and enablers;
- Categorising selected implementation strategies using standardised terminology;
- Evaluating the effectiveness on both individual and implementation outcomes, as well as the cost of intervention delivery and adverse events;
- Adhering to the Standards for Reporting Implementation studies of complex interventions (StaRI) guidelines when reporting research from implementation trials.

### ***Research agenda***

- Given the scarcity of implementation trials and the lack of evidence of effective implementation strategies in the low back pain field, future research is warranted to generate the evidence-base for what is effective in improving evidence-based recommended practice for low back pain.
- To advance the science of implementation in the back pain field, it is proposed future implementation trials adopt best practice implementation research methodology;
- To improve both quality and reporting, future implementation trials should adhere to the Standards for Reporting Implementation studies of complex interventions (StaRI) guidelines.

## References

1. Vos T, Allen C, Arora M, Barber RM, Bhutta ZA, Brown A, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet* (London, England). 2016;388(10053):1545-602.
2. Grimshaw JM, Shirran L, Thomas R, Mowatt G, Fraser C, Bero L, et al. Changing provider behavior: an overview of systematic reviews of interventions. *Med Care*. 2001;39(8 Suppl 2):Ii2-45.
3. Buchbinder R, Maher C, Harris IA. Setting the research agenda for improving health care in musculoskeletal disorders. *Nature reviews Rheumatology*. 2015;11(10):597-605.
4. Glasgow RE, Vinson C, Chambers D, Khoury MJ, Kaplan RM, Hunter C. National Institutes of Health approaches to dissemination and implementation science: current and future directions. *Am J Public Health*. 2012;102(7):1274-81.
5. Khoury MJ, Gwinn M, Ioannidis JP. The emergence of translational epidemiology: from scientific discovery to population health impact. *American journal of epidemiology*. 2010;172(5):517-24.
6. Rabin BA, Brownson RC, Haire-Joshu D, Kreuter MW, Weaver NL. A glossary for dissemination and implementation research in health. *Journal of public health management and practice : JPHMP*. 2008;14(2):117-23.
7. Eccles MP, Armstrong D, Baker R, Cleary K, Davies H, Davies S, et al. An implementation research agenda. *Implementation science : IS*. 2009;4:18.
8. Schillinger D. An introduction to Effectiveness, Dissemination and Implementation Research. 2010. In: UCSF Clinical and Translational Science Institute (CTSI) Resource Manuals and Guides to Community-Engaged Research [Internet]. University of California San Francisco: Clinical Translational Science Institute Community Engagement Program. Available from: [http://ctsi.ucsf.edu/files/CE/edi\\_introguide.pdf](http://ctsi.ucsf.edu/files/CE/edi_introguide.pdf).
9. Nilsen P. Making sense of implementation theories, models and frameworks. *Implementation science : IS*. 2015;10:53.
10. Meyers DC, Durlak JA, Wandersman A. The quality implementation framework: a synthesis of critical steps in the implementation process. *American journal of community psychology*. 2012;50(3-4):462-80.
11. French SD, Green SE, O'Connor DA, McKenzie JE, Francis JJ, Michie S, et al. Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the Theoretical Domains Framework. *Implementation science : IS*. 2012;7:38.
12. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implementation science : IS*. 2012;7:37.
13. Rogers EM. *Diffusion of Innovations*. New York: Free Press; 2003.
14. Weiner BJ. A theory of organizational readiness for change. *Implementation science : IS*. 2009;4:67.
15. Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC medicine*. 2010;8:63.
16. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health*. 1999;89(9):1322-7.
17. Yoong SL, Clinton-McHarg T, Wolfenden L. Systematic reviews examining implementation of research into practice and impact on population health are needed. *Journal of Clinical Epidemiology*. 68(7):788-91.
18. Newhouse R, Bobay K, Dykes PC, Stevens KR, Titler M. Methodology issues in implementation science. *Med Care*. 2013;51(4 Suppl 2):S32-40.
19. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *International journal of nursing studies*. 2013;50(5):587-92.



20. Pinnock H, Epiphaniou E, Sheikh A, Griffiths C, Eldridge S, Craig P, et al. Developing standards for reporting implementation studies of complex interventions (StaRI): a systematic review and e-Delphi. *Implementation science* : IS. 2015;10:42.
21. Mazza D, Bairstow P, Buchan H, Chakraborty SP, Van Hecke O, Grech C, et al. Refining a taxonomy for guideline implementation: results of an exercise in abstract classification. *Implementation science* : IS. 2013;8:32.
22. Schulz R, Czaja SJ, McKay JR, Ory MG, Belle SH. Intervention taxonomy (ITAX): describing essential features of interventions. *American journal of health behavior*. 2010;34(6):811-21.
23. Effective Practice and Organisation of Care EPOC. The EPOC taxonomy of health systems interventions. EPOC Resources for review authors. Oslo: Norwegian Knowledge Centre for the Health Services; 2016.
24. Lau R, Stevenson F, Ong BN, Dziedzic K, Treweek S, Eldridge S, et al. Achieving change in primary care--effectiveness of strategies for improving implementation of complex interventions: systematic review of reviews. *BMJ open*. 2015;5(12):e009993.
25. McGuirk B, King W, Govind J, Lowry J, Bogduk N. Safety, efficacy, and cost effectiveness of evidence-based guidelines for the management of acute low back pain in primary care. *Spine*. 2001;26(23):2615-22.
26. Hollingworth W, Todd CJ, King H, Males T, Dixon AK, Karia KR, et al. Primary care referrals for lumbar spine radiography: diagnostic yield and clinical guidelines. *The British journal of general practice : the journal of the Royal College of General Practitioners*. 2002;52(479):475-80.
27. Jackson JL, Browning R. Impact of national low back pain guidelines on clinical practice. *Southern medical journal*. 2005;98(2):139-43.
28. Bekkering GE, Hendriks HJ, van Tulder MW, Knol DL, Hoeijenbos M, Oostendorp RA, et al. Effect on the process of care of an active strategy to implement clinical guidelines on physiotherapy for low back pain: a cluster randomised controlled trial. *Quality & safety in health care*. 2005;14(2):107-12.
29. Bekkering GE, van Tulder MW, Hendriks EJ, Koopmanschap MA, Knol DL, Bouter LM, et al. Implementation of clinical guidelines on physical therapy for patients with low back pain: randomized trial comparing patient outcomes after a standard and active implementation strategy. *Physical therapy*. 2005;85(6):544-55.
30. French SD, McKenzie JE, O'Connor DA, Grimshaw JM, Mortimer D, Francis JJ, et al. Evaluation of a theory-informed implementation intervention for the management of acute low back pain in general medical practice: the IMPLEMENT cluster randomised trial. *PloS one*. 2013;8(6):e65471.
31. RTPM G, JJE Ev, AP C. Een Handleiding voor de Medische, Paramedische en Verpleegkundige Praktijk. [Implementing Guidelines and Innovations. Guide for the Medical, Allied Health and Nursing Practice.] Utrecht: De Tijdstroom; 1994.
32. Becker A, Leonhardt C, Kochen MM, Keller S, Wegscheider K, Baum E, et al. Effects of two guideline implementation strategies on patient outcomes in primary care: a cluster randomized controlled trial. *Spine*. 2008;33(5):473-80.
33. Engers AJ, Wensing M, van Tulder MW, Timmermans A, Oostendorp RA, Koes BW, et al. Implementation of the Dutch low back pain guideline for general practitioners: a cluster randomized controlled trial. *Spine*. 2005;30(6):559-600.
34. Goldberg HI, Deyo RA, Taylor VM, Cheadle AD, Conrad DA, Loeser JD, et al. Can evidence change the rate of back surgery? A randomized trial of community-based education. *Effective clinical practice* : ECP. 2001;4(3):95-104.
35. Kerry S, Oakeshott P, Dundas D, Williams J. Influence of postal distribution of the Royal College of Radiologists' guidelines, together with feedback on radiological referral rates, on X-ray referrals from general practice: a randomized controlled trial. *Family practice*. 2000;17(1):46-52.
36. Robling MR, Houston HL, Kinnersley P, Hourihan MD, Cohen DR, Hale J, et al. General practitioners' use of magnetic resonance imaging: an open randomized trial comparing telephone and written requests and an open randomized controlled trial of different methods of local guideline dissemination. *Clinical radiology*. 2002;57(5):402-7.

37. Rossignol M, Abenhaim L, Seguin P, Neveu A, Collet JP, Ducruet T, et al. Coordination of primary health care for back pain. A randomized controlled trial. *Spine*. 2000;25(2):251-8; discussion 8-9.
38. Schectman JM, Schroth WS, Verme D, Voss JD. Randomized controlled trial of education and feedback for implementation of guidelines for acute low back pain. *Journal of general internal medicine*. 2003;18(10):773-80.
39. Stevenson K, Lewis M, Hay E. Does physiotherapy management of low back pain change as a result of an evidence-based educational programme? *Journal of evaluation in clinical practice*. 2006;12(3):365-75.
40. Michie S, Johnston M, Francis J, Hardeman W, Eccles M. From Theory to Intervention: Mapping Theoretically Derived Behavioural Determinants to Behaviour Change Techniques. *Applied Psychology*. 2008;57(4):660-80.
41. Eccles M, Steen N, Grimshaw J, Thomas L, McNamee P, Soutter J, et al. Effect of audit and feedback, and reminder messages on primary-care radiology referrals: a randomised trial. *Lancet* (London, England). 2001;357(9266):1406-9.
42. Winkens RA, Pop P, Bugter-Maessen AM, Grol RP, Kester AD, Beusmans GH, et al. Randomised controlled trial of routine individual feedback to improve rationality and reduce numbers of test requests. *Lancet* (London, England). 1995;345(8948):498-502.
43. French SD, Green S, Buchbinder R, Barnes H. Interventions for improving the appropriate use of imaging in people with musculoskeletal conditions. *The Cochrane database of systematic reviews*. 2010(1):Cd006094.
44. Suman A, Dikkers MF, Schaafsma FG, van Tulder MW, Anema JR. Effectiveness of multifaceted implementation strategies for the implementation of back and neck pain guidelines in health care: a systematic review. *Implementation science : IS*. 2016;11(1):126.
45. Tzortziou Brown V, Underwood M, Mohamed N, Westwood O, Morrissey D. Professional interventions for general practitioners on the management of musculoskeletal conditions. *The Cochrane database of systematic reviews*. 2016(5):Cd007495.
46. Baker SR, Rabin A, Lantos G, Gallagher EJ. The effect of restricting the indications for lumbosacral spine radiography in patients with acute back symptoms. *AJR American journal of roentgenology*. 1987;149(3):535-8.
47. Bishop PB, Wing PC. Knowledge transfer in family physicians managing patients with acute low back pain: a prospective randomized control trial. *The spine journal : official journal of the North American Spine Society*. 2006;6(3):282-8.
48. Dey P, Simpson CW, Collins SI, Hodgson G, Dowrick CF, Simison AJ, et al. Implementation of RCGP guidelines for acute low back pain: a cluster randomised controlled trial. *The British journal of general practice : the journal of the Royal College of General Practitioners*. 2004;54(498):33-7.
49. Hazard RG, Haugh LD, Reid S, McFarlane G, MacDonald L. Early physician notification of patient disability risk and clinical guidelines after low back injury: a randomized, controlled trial. *Spine*. 1997;22(24):2951-8.
50. Matowe L, Ramsay CR, Grimshaw JM, Gilbert FJ, Macleod MJ, Needham G. Effects of mailed dissemination of the Royal College of Radiologists' guidelines on general practitioner referrals for radiography: a time series analysis. *Clinical radiology*. 2002;57(7):575-8.
51. Oakeshott P, Kerry SM, Williams JE. Randomized controlled trial of the effect of the Royal College of Radiologists' guidelines on general practitioners' referrals for radiographic examination. *The British journal of general practice : the journal of the Royal College of General Practitioners*. 1994;44(382):197-200.
52. Becker A, Held H, Redaelli M, Chenot JF, Leonhardt C, Keller S, et al. Implementation of a guideline for low back pain management in primary care: a cost-effectiveness analysis. *Spine*. 2012;37(8):701-10.
53. Jenkins HJ, Hancock MJ, French SD, Maher CG, Engel RM, Magnussen JS. Effectiveness of interventions designed to reduce the use of imaging for low-back pain: a systematic review. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne*. 2015;187(6):401-8.
54. Mesner SA, Foster NE, French SD. Implementation interventions to improve the management of non-specific low back pain: a systematic review. *BMC musculoskeletal disorders*. 2016;17:258.

55. Bernet AC, Willens DE, Bauer MS. Effectiveness-implementation hybrid designs: implications for quality improvement science. *Implementation Science*. 2013;8(1):S2.
56. Clinton-McHarg T, Yoong SL, Tzelepis F, Regan T, Fielding A, Skelton E, et al. Psychometric properties of implementation measures for public health and community settings and mapping of constructs against the Consolidated Framework for Implementation Research: a systematic review. *Implementation science : IS*. 2016;11(1):148.

Appendix Table 1. Systematic reviews of implementation studies to improve low back pain care by clinicians

Tzortzio 2016 (45)	<p><i>Objectives:</i> to determine the effectiveness of professional interventions for GPs that aim to improve the management of musculoskeletal conditions in primary care.</p> <p><i>Participants:</i> GPs/family doctors</p> <p><i>Interventions:</i> Any professional intervention aimed at GPs/family doctors designed to improve the management of MSK conditions in the community. Conditions included neck pain, back pain and other regional pain, arthritis, osteoporosis, MSK injuries and trauma.</p> <p><i>Type of studies:</i> RCTs, non-randomised controlled trials, controlled before-and-after studies, interrupted time series.</p> <p><i>Outcomes:</i> any objective measure of GP behaviour, patient or economic outcomes (including GP guideline consistent behaviour, number of investigations/tests)</p> <p><i>Results:</i> 30 studies were included in the review, of which 10 studies were specific to patients with low back pain:</p> <ul style="list-style-type: none"> <li>• seven showed that guideline dissemination and educational opportunities for GPs may lead to little or no improvement with regard to guideline-consistent GP behaviour</li> <li>• two studies showed that the combination of guidelines and GP feedback on the total number of investigations requested may have an effect on GP behaviour and result in a slight reduction in the number of tests, while one of these studies showed that the combination of guidelines and GP reminders attached to radiology reports may result in a small but sustained reduction in the number of investigation requests.</li> </ul> <p><i>Quality of included studies:</i> Risk of bias assessed on: sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, “other bias” including baseline imbalance and protection against contamination. Confidence in estimate of effect for each outcome assessed via GRADE.</p> <p><i>Included studies:</i> Becker 2008; Bishop 2006; Dey 2004; Eccles 2001; Engers 2005; French 2013; Hazard 1997; Hollingworth 2002; Kerry 2000; Schectman 2003</p>
Mesner 2016 (54)	<p><i>Objectives:</i> 1) determine whether implementation interventions in non-specific low back pain have been effective in improving healthcare practitioner behaviour or patient outcomes; 2) identify which implementation interventions have been shown to be more effective than</p>

---

others in changing the clinical behaviours of health care practitioners and improving outcomes; 3) summarise the implementation interventions used, the theoretical models behind them and the evidence base supporting them; 4) critically appraise the quality of research studies in this area.

*Participants:* any healthcare practitioner involved in the treatment of NSLBP

*Interventions:* implementation interventions designed to improve clinical practice for the management of NSLBP. The comparator was the type of control or comparison group and could include other types of implementation intervention(s), no implementation intervention ('usual care') or a before/after comparison

*Type of studies:* Randomised controlled trials (RCT), non-randomised controlled trials, controlled before-after studies and studies with an interrupted time series design. cluster RCTs, non-randomised cluster trials and controlled before-after cluster trials were included only if they had at least two intervention sites and two control sites and interrupted time series studies were included only if they had at least three data points before and three data points after the introduction of the intervention.

*Outcomes:* Change in practitioner behaviour and/or patient outcomes (including adherence to best practice guidelines, rates of radiograph requests, effect on patient outcomes such as pain or function)

*Results:* 14 included studies were included in the review, which were analysed by frequency and duration:

- single intervention or one-off implementation efforts were consistently ineffective in changing clinical practice.
- increasing the frequency and duration of implementation interventions led to greater success with those continuously ongoing over time the most successful in improving clinical practice in line with best evidence recommendations.

*Quality of included studies:* Risk of bias assessed for: sequence generation, allocation concealment, similarity of baseline outcome measurements and characteristics, incomplete outcome data, knowledge of allocation intervention adequately prevented, adequate protection against contamination, selective outcome reporting, other risk of bias.

*Included studies:* Dey 2004, Engers 2004, Engers 2005, Matowe 2002, Stevenson 2006, Bekkering 2005 (2 refs), Becker 2008, Bishop 2006, Goldberg 2001, Kerry 2000, Schectman 2003, Winkens 1995, Eccles 2001 (+Ramsey 2003), Baker 1987, McGuirk 2001

---

Suman 2016 (44) *Objectives:* To investigate the effectiveness of multifaceted implementation strategies compared to minimal, single or no implementation

---

---

strategy for the implementation of non-specific low back and/or neck pain guidelines in health care?

*Participants:* Studies were eligible if reporting on patients of either gender (age  $\geq 18$  years) with non-specific LBP or NP (with or without radiating pain) of any duration. Studies of LBP or NP caused by infection, cauda equina syndrome, bone rarefaction, compression fracture of a vertebral body, tumour, or fibromyalgia were excluded.

*Interventions:* Interventions that consist of a combination of two or more elements from the implementation strategy taxonomy of the EPOC classification system. Guidelines that were evaluated in the studies had to be implemented in a healthcare setting (i.e. a setting where individual health care is provided to a patient), for example, primary care (general practitioner (GP) or physiotherapist (PT)), occupational health care, or secondary (hospital) care. Guidelines for healthcare insurance were therefore excluded.

*Type of studies:* a randomized controlled trial (RCT), involving either individual or cluster randomization and including a control group that received a minimal, single, or no implementation strategy

*Outcomes:* Healthcare professional behaviour (the primary outcome for this review, patient outcomes, and/or outcomes on healthcare level).

*Results:* Eight studies were included in the review, of which 7 were specific to patients with non-specific low back pain:

- multifaceted implementation is not more effective than usual care or minimal implementation in improving guideline concordant referral behaviour for xrays, CT-MRI and physiotherapy but not secondary/speciality care;
- no statistically significant difference between multifaceted implementation and usual care or minimal implementation in providing adequate patient information and prescribing medication;
- Three studies reported outcomes on patient level. The most common patient outcomes measured were functional capacity or disability, days of sick leave, and quality of life (QoL). No significant differences on 12-month follow-up were found for any of these outcomes.

*Quality of included studies:* Included studies were assessed for risk of bias (low – low on at least six criteria; high – five or less low risk of bias criteria) and overall quality of evidence for pooled outcomes using the Grading of Recommendations Assessment Development and Evaluation (GRADE) approach.

---

---

*Included studies:* Becker 2008, Bekkering 2005 a/Bekkering 2005 b, Bishop 2006, Dey 2004, Engers 2005, French 2013, Schectman 2003.

---

French 2010 (43) *Objectives:* 1) To determine the effects of interventions that aim to improve the appropriate use of imaging for people with musculoskeletal conditions; 2) Do modifications in the characteristics of the interventions (e.g. timing, content) modify the effects?; 3) Do the effects of interventions vary depending on the setting, type of professionals targeted, type of behaviour (e.g. increasing/decreasing use), or whether or not the intervention is based on theory?

*Participants:* Interventions to improve the use of imaging for musculoskeletal symptoms, such as neck pain, back pain and other regional pain, possible or known arthritis or osteoporosis. We excluded studies where the people included had musculoskeletal injuries and trauma. Interventions to improve the appropriate use of imaging may have been directed toward health professionals, policy-makers and the general public, or a combination of these groups of people.

*Interventions:* Studies that evaluated any intervention designed to improve the appropriate use of imaging for diagnostic, screening or monitoring purposes, including assessing the response to treatment.

*Type of studies:* Randomised controlled trials (RCTs), non-randomised controlled clinical trials (CCTs) and interrupted time series (ITS) studies.

*Outcomes:* Provider performance of appropriate use of imaging (e.g. number of people referred for x-ray), clinical outcomes (e.g. fracture or pain) were primary outcomes (secondary also extracted if study reported primary outcome)

*Results:* 28 studies were included in the review, of which 12 were specific to patients with low back pain (meta-analysis was not conducted due to the heterogeneity of included studies):

- the most common intervention evaluated was distribution of educational materials and this showed varying effects;
- other interventions in low back pain studies also showed variable effects;
- increasing the number of intervention components did not increase effect.

*Quality of included studies:* Risk of bias assessed for parallel group trials using the criteria: (1) sequence generation; (2) allocation concealment; (3) blinding; (4) incomplete outcome data; (5) selective outcome reporting; and, (6) other potential sources of bias, for

---

	<p>example, protection against contamination of the intervention or significant baseline differences between groups.</p> <p><i>Included studies:</i> Dey 2004; Rossignol 2000, Kerry 2000; Oakeshott 1994, Winkens 1995, Hollingworth 2002; Jackson 2005; Matowe 2002; Baker 1987; Rossignol 2000; Robling 2002; Eccles 2001; Schectman 2003.</p>
Jenkins 2015 (53)	<p><i>Objectives:</i> To investigate the effectiveness of interventions designed to reduce imaging rates for the management of low-back pain.</p> <p><i>Participants:</i> patients with low-back pain</p> <p><i>Interventions:</i> an intervention designed to reduce the use of imaging in any clinical setting, including primary, emergency and specialist care</p> <p><i>Type of studies:</i> randomized controlled trials (RCTs), controlled clinical trials and interrupted time series studies. We included interrupted time series studies only if they had at least 3 individual data-collection points before and after the intervention<sup>26</sup> to allow calculation of linear trend lines. The comparator could include any other intervention, usual care or no intervention.</p> <p><i>Outcomes:</i> The outcome had to be measured as either rates of imaging or counts of the number of images, and the imaging modality could be plain radiography, computed tomography (CT) or magnetic resonance imaging (MRI). Studies that reported imaging of the “back” or “spine” because they were not considered sufficiently specific were excluded.</p> <p><i>Results:</i> Seven studies were included in the review (meta-analysis was not conducted due to the heterogeneity of included studies):</p> <ul style="list-style-type: none"> <li>• Clinical decision support involving a modified referral form in a hospital setting reduced imaging by 36.8% (95% confidence interval [CI] 33.2% to 40.5%).</li> <li>• Targeted reminders to primary care physicians of appropriate indications for imaging reduced referrals for imaging by 22.5% (95% CI 8.4% to 36.8%).</li> <li>• Interventions that used practitioner audits and feedback, practitioner education or guideline dissemination did not significantly reduce imaging rates.</li> </ul> <p><i>Quality of included studies:</i> Risk of bias assessed as outlined in the Cochrane Handbook for Systematic Reviews of Interventions with validated modifications based on the EPOC guidelines.</p> <p><i>Included studies:</i> Eccles 2001, French 2013, Dey 2004, Schectman 2003, Kerry 200, Matowe 2002, Baker 1987</p>



