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Discussion

When and how should new therapies become routine clinical practice?

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Abstract

The process by which new therapies enter clinical practice is frequently suboptimal. Often, ideas for new therapies are generated by clinical observations or laboratory studies; therapies based on those ideas may enter clinical practice without any further scrutiny. As a consequence, some ineffective practices become widespread. This article proposes a six-stage protocol for the implementation of new therapies. Hypotheses about therapy based on preclinical research should be subject to clinical exploration and pilot studies prior to rigorous assessment with randomised clinical trials. If randomised clinical trials suggest that the intervention produces clinically important effects, further randomised studies can be conducted to refine the intervention. New interventions should not be recommended, or included in teaching curricula, or taught in continuing education courses until their effectiveness has been demonstrated in high-quality randomised clinical trials.

Keywords: Physical therapy (specialty); Diffusion of innovation; Healthcare reform; Randomised controlled trials as topic

Introduction

Physiotherapy has undergone a remarkable transformation in the last two decades. Whereas practice was once based almost exclusively on clinical experience and theory, practice today is increasingly based on the findings of high-quality randomised clinical trials. This transformation has been built on a rapid proliferation of research evidence [1].

That does not mean that physiotherapy practice is now dominated by high-quality research evidence, or that current clinical practice is primarily evidence based. Several recent studies suggest that physiotherapy practice often departs from that recommended in evidence-based clinical practice guidelines [2–4].

This article considers how innovations in therapy become incorporated into clinical practice. It is argued that the current state is far from optimal because innovative therapies still become accepted practice on the basis of laboratory research alone. The article concludes by making recommendations about how and when new therapies should be incorporated into routine clinical practice.

The life cycle of a medical innovation

In 1981, John McKinlay, a distinguished epidemiologist, described seven stages in the 'career' of medical innovations [5]. The description was offered in a slightly humorous vein, but it illustrates a not unfamiliar phenomenon. The seven stages, slightly modified for the current context, are as follows.

Stage 1. The promising report

A new approach to therapy or a new therapeutic procedure is presented at a conference or in professional journals. Occasionally, the new therapy may be based on a clinical observation. An example is McKenzie's famous observation of a remarkable reduction in low back pain experienced by a patient when lying prone [6]. More often, the therapy is developed by a clinician or clinician-researcher who has read and thought about the implications of preclinical (laboratory)

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research. Claims about the effectiveness of the new therapy are usually based on the presumed mechanisms of action, but may also be supplemented with case reports or descriptions of case series.

Stage 2. Professional adoption

Soon, the most innovative clinicians begin to practice the new therapy. The therapy may be enthusiastically endorsed, in which case it permeates into wider clinical practice.

Stage 3. Public acceptance

Professional enthusiasm spawns enthusiasm from consumers. The public come to expect that the new therapy should be available to those who want it.

Stage 4. Standard practice

Eventually, the new therapy becomes standard practice. It is described in textbooks. Clinicians who do not provide the therapy are considered to be behind the times.

Stage 5. Randomised clinical trials

High-quality randomised clinical trials are conducted which show that the therapy is much less effective than first assumed. Some trials suggest that the effects of the therapy are too small to be worthwhile, or even that the therapy is harmful.

Stage 6. Professional denunciation

The profession defends the therapy against the findings of the randomised clinical trials. The defence often focuses on limitations to the external validity (generalisability) of the trial findings.

Stage 7. Extinction

Damning evidence accumulates. The profession becomes used to negative findings, and individual clinicians start to look for alternative interventions. Eventually, all but the truest believers abandon the intervention for a more recent innovation. Decades later, textbooks continue to recommend the practice.

Every clinician who has practised for more than 10 years has observed parts of this life cycle of new therapies. As one therapy slips quietly into obscurity, others spring up, competing for the attention of clinicians. Sometimes, new therapies adapt to protect themselves from the negative findings of randomised clinical trials. Nowadays, randomised clinical trials increasingly determine which therapies survive, which change and which disappear from practice [3,4,7]. A particularly clear example is the practice of recommending bed rest for people with low back pain or sciatica; this practice has rapidly declined in popularity since the publication of a landmark systematic review of randomised trials which showed that the practice had little effect or was even harmful [7].

Not all interventions go through this cycle. Some therapies are only widely adopted after the publication of high-quality randomised clinical trials, but this is the exception rather than the rule. Other new therapies are too implausible, too difficult to implement or lack a charismatic advocate; such therapies might never be widely adopted, or they might only be practised at the margins of the professions. When randomised clinical trials or systematic reviews of randomised clinical trials provide evidence of a lack of effect, the evidence is rarely definitive and therapists are understandably reluctant to abandon the practice. In physiotherapy, there are few therapies that were practised in the 1950s that are not still practised by some therapists. Of those that have been more or less discontinued (such as the use of infra-red radiation), few have been discontinued because of the findings of randomised clinical trials. Of course, many therapies survive scrutiny; these are found to be effective in well-designed randomised clinical trials [8] and provide a solid core of contemporary professional practice.

McKinlay's observations of the life cycle of a medical innovation were published in 1981, but in many respects, the model is still valid today. Indeed, in 2000, Imrie and Ramey reviewed literature which indicated that while much of medical practice was based on some sort of evidence, only a relatively modest proportion of medical interventions (typically somewhere between one- and two-thirds) was supported by randomised clinical trials [9].

Of course, these observations do not only apply to medicine. They apply equally well to all the health professions, including physiotherapy. In the authors' opinion, the most damning observation made by McKinley is not that randomised clinical trials often disprove the effectiveness of therapies, or that the findings of randomised clinical trials are often disputed by clinicians. The more problematic observation is that many therapies become widely practised prior to demonstration of their effectiveness with randomised clinical trials.

A case study: deep abdominal muscle training for stress urinary incontinence

A case in point is the recent adoption of the practice of training abdominal muscles to treat stress urinary incontinence. Stress urinary continence can be prevented and treated with pelvic floor muscle training, as demonstrated by over 50 randomised clinical trials and several systematic reviews [10]. Recently, Sapsford has advocated a new approach to pelvic floor muscle training [11,12]. She argues that exercise for stress urinary incontinence should involve training of the abdominal muscles, especially the transversus abdominis,

claiming that voluntary activity in the abdominal muscles results in increased pelvic floor muscle activity, and that abdominal muscle training to rehabilitate the pelvic floor muscles may be useful in treating dysfunction of the pelvic floor. According to Sapsford, 'pelvic floor muscle rehabilitation does not reach its optimum level until the muscles of the abdominal wall are rehabilitated as well' [11, p. 627]. Sapsford's recommendations have been received enthusiastically, and many physiotherapists routinely train the abdominal muscles of women with stress urinary incontinence.

This is an example of a therapy which has entered clinical practice on the basis of a promising report. It appears that the first proposal to train the abdominal muscles for stress urinary incontinence was presented by Sapsford and Hodges in 2001 [13]. That proposal was based on the findings of a small laboratory study on healthy women (women without stress urinary incontinence) showing that contraction of the transversus abdominis muscle was associated with co-contraction of the pelvic floor muscles. The theory and recommendations for this training model was first published in *Physiotherapy*, which has a circulation of about 50 000, and later in *Manual Therapy*, which currently has the highest impact factor of all therapy journals. Soon thereafter, many physiotherapists started to incorporate abdominal training into programmes designed to prevent and treat stress urinary incontinence. Now, only a few years after the first laboratory experiments showing that transversus abdominis contractions are associated with pelvic floor muscle contractions, the intervention is endorsed in textbooks [14,15].

In 2004, Dumoulin *et al.* published a randomised clinical trial comparing the addition of deep abdominal muscle training to pelvic floor muscle training [16]. The deep abdominal muscle training was carried out in accordance with recommendations made by Sapsford [12]. Little additional beneficial effect was observed from adding abdominal muscle training to pelvic floor muscle training. The absolute difference in the proportion of women whose incontinence was cured was 4% (95% confidence interval −3 to 22%; positive values favour the group which received abdominal training). These data are not absolutely definitive because the confidence intervals are too wide to rule out, with certainty, clinical benefits of abdominal training, and because the trial has not yet been replicated. Nonetheless, these data, the best available to date, suggest that addition of deep abdominal muscle training does not substantially improve the outcome of pelvic floor rehabilitation beyond the effect provided by specific pelvic floor muscle training.

The early indications are that the innovation of abdominal training to treat stress urinary incontinence is unlikely to be helpful. Unfortunately, the innovation has already become routine clinical practice in many clinical settings. It may eventually prove that it would have been better to wait for the findings of randomised clinical trials before advocating abdominal training for stress urinary incontinence.

What drives choices about implementation of new therapies?

What determines which new therapies physiotherapists choose to adopt? The following paragraphs argue that physiotherapists have gradually developed a more critical approach to the evaluation of new therapies, and there has been an evolution from a reliance on clinical experience to theories based on preclinical research to randomised clinical trials.

Clinical experience

Traditionally, physiotherapy practice, like medicine, was based on clinical experience. Experienced therapists reported their impressions of what worked in their clinical practices. Clinical experiences were communicated informally, by word of mouth, and more formally at continuing education courses and conferences and in professional journals. Sometimes, reports of clinical experiences were supplemented with data, particularly in the form of case reports or case series. Clinical experiences provided the material on which professional education was based. Claims about personal experiences can be difficult to challenge, so experienced clinician teachers established reputations of near-infallibility. The best clinical teachers attained 'guru' status and had therapies named after them. Examples include Bobath, Janda, Maitland, McKenzie, Mensendieck and Voita therapies. This phenomenon has been called, a little disparagingly, 'eminence-based therapy' [17].

Clinical experience or 'practice knowledge' is highly valued in physiotherapy [18]. Practice knowledge underpins the practitioner's ability to respond rapidly and fluently to a situation, and it is the characteristic that most obviously differentiates experienced therapists from new graduates. However, clinical experience is prone to bias because it is based on observations of associations between intervention and outcome. Such associations may be confounded by the natural course of the condition being treated, statistical regression, placebo effects and 'polite patient' effects [19]. Also, few therapists have the opportunity to observe long-term effects of intervention in routine practice. Thus, clinical experience provides an inadequate base on which to build professional practice.

In the course of routine clinical practice, good clinicians use reliable, responsive and valid outcome measures to evaluate their patients' conditions before and after intervention. These data are potentially useful because they can be used to describe clinical outcomes. That is, they can be used to document clinical experience objectively. Such data cannot, however, be used to make strong inferences about the effects of intervention [20].

Theories based on preclinical research

In the 1970s and 1980s, allied health professions began to recognise that they needed to become more research

based if they were to survive. Academic physiotherapists began to undertake research in the fields in which research opportunities were greatest, often in physiology (especially neurophysiology or exercise physiology), biomechanics and psychology (especially motor control and motor learning). In the 1980s and 1990s, 'movement science' emerged as a basic science underpinning clinical practice [21,22].

The consequence was that many leading academic physiotherapists developed expertise in preclinical research fields. Naturally, they used their understandings of physiology, biomechanics and psychology to drive innovations in therapy. Current practices were considered valid if they appeared to be consistent with insights provided by preclinical research. Innovations in clinical practice were often propelled by new understandings from preclinical research. New therapies were inspired by the findings of laboratory studies on animals or humans.

Physiotherapy is currently heavily influenced by laboratory experiments. One example comes from a classic experiment by Hodges and Richardson in which fine-wire electromyography was used to study recruitment of abdominal muscles during an arm-lifting task designed to destabilise the spine [23]. The investigators showed that in patients without low back pain, the transversus abdominis was recruited before the deltoid. In contrast, in patients with low back pain, the transversus abdominis was recruited after the deltoid [23]. This finding was interpreted as showing that the transversus abdominis normally controls spinal motion during destabilising tasks, but that people with low back pain are unable to use the transversus abdominis muscle to control spinal motion. Subsequently, these findings were used to argue that therapy for people with low back pain should be directed towards specific training of control of these and other muscles which control spinal motion [24]. Today, there is evidence from randomised clinical trials showing that there is a large effect of stabilising exercise for patients with spondylolisthesis [25], significant but smaller effects in treatment of non-specific low back pain, and little or no difference in the effects of stabilising exercise and other physiotherapy interventions for low back pain [26,27].

High-quality laboratory studies, such as the elegant experiments by Hodges and Richardson, are important because they provide insights into the nature of the problems treated by physiotherapists. They suggest new directions for the development of improved or novel therapies, so they provide an essential driver of professional progress.

However, as argued elsewhere [19], even when laboratory studies are conducted rigorously and interpreted carefully, they cannot provide convincing evidence of the effectiveness of an intervention. Laboratory studies typically measure impairment-level outcomes, but claims of the effectiveness of interventions must be based on the effects of intervention on disease-specific or generic quality of life [28]. More importantly, decisions about whether or not to implement an intervention in clinical practice must be based on consideration of the magnitude of the effect in clinical settings [19]. Laboratory studies cannot provide such data.

Randomised clinical trials

Satisfying proof of the effectiveness of an intervention can only be provided by randomised clinical trials. Randomised clinical trials provide the best available method for demonstrating the effectiveness of an intervention because, when properly designed and conducted, they can provide a high level of internal validity. That is, high-quality randomised clinical trials can provide estimates of the effect of intervention that are not biased by history (events occurring during the experiment that are not part of the treatment), maturation (changes in participants with the passage of time), testing (effects of one test on subsequent administrations of the same test), instrumentation (changes in instrument calibration, including lack of agreement within and between observers), statistical regression (the fact that groups selected on the basis of extreme scores are not as extreme on subsequent testing), expectancy (outcomes influenced by assessors' anticipations that certain participants will perform better), selection bias (choosing comparison groups that are not comparable with respect to all prognostic factors) or interactions between selection and any of these factors [29,30].

Ultimately, decisions about which interventions should be implemented in clinical practice should be based on the findings of randomised clinical trials. The most useful trials are pragmatic trials which test the effects of interventions as they are usually delivered in clinical practice, on the types of patients for whom they are thought to be indicated [28].

Proposal for a protocol for introduction of new therapies

A protocol for the introduction of new therapies into clinical practice is proposed below (Table 1).

Stage 1. Clinical observation or laboratory studies

In Stage 1, clinicians develop hypotheses about new therapeutic strategies based on their clinical observations. Alternatively, clinicians who read reports of laboratory research or conduct their own laboratory studies generate and

Table 1
A protocol for implementation of new therapies.

Stage 1: Clinical observation or laboratory studies	Development phase
Stage 2: Clinical exploration	
Stage 3: Pilot studies	
Stage 4: Randomised clinical trials	Testing phase
Stage 5: Refinement	Refinement and dissemination phase
Stage 6: Active dissemination	

test hypotheses about the causes of dysfunction and responses to interventions. The studies may be conducted on animals or humans, with or without disease. The result is an unconfirmed hypothesis about clinical intervention. The hypothesis may suggest how the intervention should be administered [31].

Stage 2. Clinical exploration

The hypothesis is subject to clinical exploration. Expert clinicians administer a prototype of the intervention to volunteer patients. Trial and error is used to explore different ways of administering the intervention, including different doses of the intervention, and to assess whether predictions of hypotheses concerning the intervention are borne out by clinical observation. The process is explicitly exploratory. Patients are fully informed of the exploratory nature of the intervention.

Stage 3. Pilot studies

If clinical exploration suggests that administration of the intervention is feasible and that the predictions of the hypothesis appear to be supported, pilot studies (typically case series or small randomised studies) are conducted to document, in a more systematic and objective way, the feasibility and outcomes of the intervention. These data are used to determine whether to proceed to a randomised clinical trial. The data are not used to support claims about the effectiveness of the intervention.

Stage 4. Randomised clinical trials and systematic reviews

If pilot studies are sufficiently promising, randomised clinical trials are conducted. Usually, it is necessary to conduct more than one trial to ensure the robustness and generalisability of the findings. The first trials may be explanatory in orientation, but eventually it is necessary to conduct pragmatic trials, including trials with cost-effectiveness analyses [28]. It is only after several high-quality trials demonstrate consistent findings that claims can be made of the effectiveness of the intervention.

Stage 5. Refinement

If randomised clinical trials suggest that an intervention can have clinically important effects, additional studies are conducted to further test the usefulness of the intervention and to maximise its effectiveness. These could involve randomised head-to-head comparisons of the intervention with competing interventions, and large randomised studies to evaluate the size of the effects of intervention in different patient subgroups. Note that issues of the differential responses of subgroups can only be tested in large randomised studies; such studies are difficult to do well [32].

Stage 6. Active dissemination

The intervention is recommended in clinical practice guidelines, undergraduate teaching curricula and continuing education courses. There is active dissemination of information about the effectiveness of the intervention to therapists, other health professionals and consumers of therapy [3,4].

Stages 1, 2 and 3 can be considered to be the development phase, Stage 4 is the testing phase, and Stages 5 and 6 are the refinement and dissemination stage. This staged process is broadly similar to the familiar classification of the phases of drug development [33]. Importantly, with the possible exception of Stages 5 and 6, the stages should occur in order. There is a case for arguing that the findings of Stages 2 and 3 are best communicated only amongst the clinicians and researchers who are developing the intervention, because positive results may be misinterpreted by the wider professional community as providing substantive evidence of the effectiveness of the intervention. Active promotion of the intervention should not occur until Stage 4 is complete.

Anticipation of some objections

Many clinicians would argue that it is not possible to delay introduction of new therapies until there is strong evidence of the effects of the intervention from randomised clinical trials, because it is not possible to conduct randomised clinical trials on all new interventions. In the past, that may have been true. Until recent times, the publication rate of trial reports was low. However, there has been a spectacular increase in the number of reports of randomised clinical trials published in recent years. For example, the PEDro database [34] shows that in 2005 alone, there were 741 randomised clinical trials of physiotherapy interventions. The rate of production of randomised clinical trials is increasing rapidly (Moseley AM and Elkins M, unpublished data). In the authors' opinion, there is plenty of capacity to subject new interventions to randomised clinical trials prior to their widespread implementation.

Substantial resources are required to conduct high-quality randomised trials. It will certainly be expensive to subject every new therapy to a randomised trial prior to introduction of the therapy into clinical practice. In the long run, however, subjecting new therapies to randomised trials is likely to be a cost-effective strategy, both because it will reduce the costly introduction of ineffective therapies and because questions about efficacy can be resolved more easily, with fewer trials, in the period before the therapy becomes established clinical practice.

Many clinicians are frustrated by clinical research. They believe that the research process is too slow and unresponsive to the ever-growing body of new knowledge generated by preclinical research. They want to see a continuous rapid evolution of clinical practice emerge from a close relationship

between skilled physiotherapists and laboratory researchers. This model, in which laboratory studies influence clinical practice directly, has been the dominant model driving practice in physiotherapy for the last 20 years. However, in the authors' view, it is counter-productive and, in the long-term, damaging to professional progress. Good decisions about whether to implement new therapies into clinical practice must be informed by high-quality randomised clinical trials. By introducing new therapies prior to the conduct of high-quality trials, there is a risk of administering ineffective therapies. History has shown that once new therapies become established in clinical practice, it is very difficult to discontinue them if high-quality evidence subsequently shows that the therapy is ineffective.

That does not mean that all innovation in clinical practice needs to be preceded by clinical trials. It is sensible to distinguish between small changes to the way in which interventions of proven interventions are administered (e.g. new positions for doing exercises) and new therapies (i.e. a new way of intervening based on a new therapeutic hypothesis, or application of a proven intervention to a very different patient group for whom the original hypotheses might not apply). The former is a legitimate part of the day-to-day struggle to administer interventions as well as possible, but the latter, in the authors' view, represents a degree of clinical innovation that requires scrutiny. New therapies need to be subjected to an explicit protocol of development.

Conclusions

The process by which new therapies enter clinical practice is often suboptimal. This article proposes a six-stage protocol for the implementation of new therapies. In the authors' view, observance of this protocol would enhance the quality of physiotherapy.

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References

[1] Moseley AM, Herbert RD, Sherrington C, Maher CG. Evidence for physiotherapy practice: a survey of the Physiotherapy Evidence Database (PEDro). Aust J Physiother 2002;48:43–9.

[2] Swinkels IC, van den Ende CH, van den Bosch W, Dekker J, Wimmers RH. Physiotherapy management of low back pain: does practice match the Dutch guidelines? Aust J Physiother 2005;51: 35–41.

[3] Rebbeck T, Maher CG, Refshauge KM. Evaluating two implementation strategies for whiplash guidelines in physiotherapy: a cluster randomised trial. Aust J Physiother 2006;52:165–74.

[4] 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. Phys Ther 2005;85:544–55.

[5] McKinlay JB. From 'promising report' to 'standard procedure': seven stages in the career of a medical innovation. Milbank Memorial Fund Q Health Soc 1981;59:374–411.

[6] McKenzie R. The lumbar spine: mechanical diagnosis and therapy. Waikanae: Spinal Publications; 1981.

[7] Hagen KB, Hilde G, Jamtvedt G, Winnem M. Bed rest for acute low-back pain and sciatica. Cochrane Database Syst Rev 2004;4: CD001254.

[8] Herbert RD, Maher CG, Moseley AM, Sherrington C. Effective physiotherapy. BMJ 2001;323:788–90.

[9] Imrie R, Ramey DW. The evidence for evidence-based medicine. Complement Ther Med 2000;8:123–6.

[10] Bø K, Morkved S, Berghmans B, van Kampen M. Evidence-based physical therapy for the pelvic floor—bridging science and clinical practice. Oxford: Elsevier; 2007.

[11] Sapsford R. Rehabilitation of pelvic floor muscles utilizing trunk stabilization. Man Ther 2004;9:3–12.

[12] Sapsford R. The pelvic floor. A clinical model for function and rehabilitation. Physiotherapy 2001;87:620–30.

[13] Sapsford RR, Hodges PW. Contraction of the pelvic floor muscles during abdominal maneuvers. Arch Phys Med Rehabil 2001;82:1081–8.

[14] Godel-Purrer B. Training and functional exercises for the muscles of the pelvic floor. In: Carriere B, Feldt CM, editors. The pelvic floor. New York: Georg Thieme Verlag; 2006.

[15] Jones RC. Pelvic floor stability and trunk muscle co-activation. In: Laycock J, Haslam J, editors. Therapeutic management of incontinence and pelvic pain. Pelvic organ disorders. 2nd ed. London: Springer–Verlag; 2008. p. 99–104.

[16] Dumoulin C, Lemieux MC, Bourbonnais D, Gravel D, Bravo G, Morin M. Physiotherapy for persistent postnatal stress urinary incontinence: a randomized controlled trial. Obstet Gynecol 2004;104: 504–10.

[17] Isaacs D, Fitzgerald D. Seven alternatives to evidence based medicine. BMJ 1999;319:1618.

[18] Higgs J, Richardson B, Dahlgren MA. Developing practice knowledge for health professionals. Edinburgh: Butterworth-Heinemann; 2004.

[19] Herbert RD, Jamtvedt G, Mead J, Hagen KB. Practical evidence-based physiotherapy. Oxford: Elsevier; 2005.

[20] Herbert R, Jamtvedt G, Mead J, Hagen KB. Outcome measures measure outcomes, not effects of intervention. Aust J Physiother 2005;51: 3–4.

[21] Carr JH. Movement science: foundations for physical therapy in rehabilitation. London: Heinemann Physiotherapy; 1987.

[22] Winstein CJ, Knecht HG. Movement science and its relevance to physical therapy. Phys Ther 1990;70:759–62.

[23] Hodges PW, Richardson CA. Inefficient muscular stabilization of the lumbar spine associated with low back pain. A motor control evaluation of transversus abdominis. Spine 1996;21:2640–50.

[24] Richardson C, Hodges PW, Hides J. Therapeutic exercise for lumbopelvic stabilisation; a motor control approach for the treatment and prevention of low back pain. 2nd ed. Edinburgh: Churchill Livingstone; 2004.

[25] O'Sullivan PB, Twomey LT, Allison GT. Evaluation of specific stabilizing exercise in the treatment of chronic low back pain with radiologic diagnosis of spondylolysis or spondylolisthesis. Spine 1997;22:2959–67.

[26] Ferreira ML, Ferreira PH, Latimer J, Herbert RD, Hodges PW, Jennings MD, *et al.* Comparison of general exercise, motor control exercise and spinal manipulative therapy for chronic low back pain: a randomized trial. Pain 2007;131:31–7.

[27] Ferreira PH, Ferreira ML, Maher CG, Herbert RD, Refshauge K. Specific stabilisation exercise for spinal and pelvic pain: a systematic review. Aust J Physiother 2006;52:79–88.

[28] Herbert RD. Explanatory and pragmatic clinical trials. In: Gad SC, editor. Handbook of clinical trials: Wiley; in press.

[29] Campbell DT, Stanley JC, Gage NL. Experimental and quasi-experimental designs for research. Chicago: Rand McNally; 1966.

[30] Cook TD, Campbell DT. Quasi-experimentation: design and analysis issues for field settings. Chicago: Rand McNally; 1979.
[31] Herbert RD, Bø K. Analysis of quality of interventions in systematic reviews. BMJ 2005;331:507–9.
[32] Herbert RD. Dealing with heterogeneity in clinical trials. Man Ther 2007;12:1–2.
[33] Pocock SJ. Clinical trials: a practical approach. Chichester: Wiley; 1983.
[34] Centre for Evidence-Based Physiotherapy. PEDro (the Physiotherapy Evidence Database). Available at: www.pedro.fhs.usyd.edu.au. (last accessed 27/01/2008).