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Feasibility of carrying out an ergonomics intervention study to prevent the incidence of musculoskeletal disorders

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Feasibility of carrying out an ergonomics intervention study to prevent the incidence of musculoskeletal disorders

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This work examines the feasibility of assessing the effectiveness of workplace ergonomic interventions to prevent the onset of musculoskeletal disorders (MSDs). It reviews existing models of causation of MSDs and the scientific literature on interventions to prevent MSDs. It describes relevant epidemiological methods and research protocols.

Many previous studies of the risk factors for MSDs have not been able to assess causation and the need remains for intervention studies of high methodological quality to do this. A longitudinal Cluster Randomised Trial is the most appropriate study design for assessing MSD causation in an occupational setting. Measurement of injury rates generally requires very large samples and/or long follow-up times to provide adequate statistical power. It is likely that the study would need to be carried out across multiple employers.

Because of the scale of the MSD problem, it is recommended that HSE consider funding or part-funding a study designed to test the effectiveness of workplace ergonomics interventions to prevent the onset of episodes of musculoskeletal disorders. Consideration should be given to making the study a multi-centre, possibly international, collaborative study. Such a study would be high risk due to the scale and duration needed and the practical and organisational difficulties involved.

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EXECUTIVE SUMMARY

Objectives

This work is in response to the Health and Safety Executive (HSE) tender specification entitled: "Feasibility of Assessing the Effectiveness of Preventative Workplace Ergonomic Interventions". This requested an examination of the feasibility of assessing the effectiveness of such interventions to prevent musculoskeletal disorders (MSDs). Reducing the risk of workers suffering these problems would reduce the resultant burden of pain, medical treatment and work-loss.

Preventative (primary) interventions are distinct from secondary interventions, as these are aimed at preventing chronic disability in individuals already experiencing musculoskeletal problems, and from tertiary interventions, which are aimed at rehabilitating or getting back to work individuals suffering from chronic musculoskeletal disorders.

This report reviews existing models of causation of MSDs, reviews the scientific literature on interventions to prevent MSDs, and summarises the relevant epidemiological methods and research protocols. It illustrates the methodological issues through an example project plan and provides checklists for evaluating proposals and reports of randomised intervention studies.

Main Findings

An integrated model for understanding MSD causation has recently been proposed by Karsh (2006). This integrates physiological and psychological demands of work, the social and cultural context, the work organisational context and the physical environment with the factors unique to the individual and proposes pathways and feedback loops through which all these factors can affect the detection and labelling/attribution of symptoms so that a case of a work-related MSD occurs.

There is strong evidence (Waddell and Burton, 2001) that:

- Most adults (60-80%) experience low back pain (LBP) at some time, and it is often persistent or recurrent.
- Physical demands of work (manual materials handling, lifting, bending, twisting and whole body vibration) can be associated with increased reports of back symptoms, aggravation of symptoms and 'injuries'.
- Physical demands of work (manual materials handling, lifting, bending, twisting and whole body vibration) are a risk factor for the incidence (onset) of LBP, but overall it appears that the size of the effect is less than that of other individual, non-occupational and unidentified factors".
- Care seeking and disability due to LBP depend more on complex individual and work-related psychosocial factors than on clinical features or physical demands of work

Waddell and Burton (2001) argued that while it is reasonable to seek to reduce the incidence and prevalence of LBP by reducing exposure to known occupational risk factors, the complexity of the causal factors may limit the effect of occupational interventions in reducing the societal impact of LBP. There is evidence that multi-dimensional workplace interventions can be recommended to reduce some aspects of LBP, but there is insufficient evidence to recommend specific combinations of interventions (Burton *et al.*, 2004; 2005).

A less despairing view of mechanical issues and back pain (McGill, 2002) criticised the view that psychosocial variables dominate any biological or mechanical variables. McGill argued

that the position that biomechanics plays no role in back health and activity tolerance can be held only by those who have never performed physical labour and have not experienced first hand the work methods that must be employed to avoid disabling injury.

The consensus of the guidelines and the many systematic reviews that have been carried out is that many of the previous studies of risk factors for low back pain are of low methodological quality and that there is still a need for methodologically high-quality intervention studies.

There are current worldwide efforts to carry out such studies, but there is clear recognition of the practical difficulties involved, which include:

- Statistically intractable issues in many situations.
- Complex and partially uncontrollable situations in which interventions must be implemented, thus weakening and confusing the studies.
- The difficulty of recruiting sufficient subjects in jobs that are suitable for intervention.
- The difficulty of measuring the effects of the interventions on health and other possible outcomes such as productivity changes.

There are published methods of assessing the quality of project proposals and reports of epidemiological studies. The CONSORT statement (Moher *et al.,* 2001) gives guidance on reporting Randomised Controlled Trials (RCTs). The Epidemiological Appraisal Instrument (EAI) (Genaidy *et al.,* 2007) gives rigorously tested criteria and detailed specifications for assessing epidemiological studies.

Investigating the prevention of MSDs with a workplace intervention requires that the study design be able to assess causation and the effects of an experiment, not just association. This requires that the study be a longitudinal RCT where a cohort of workers is split into one or more intervention groups and one or more control groups and followed over time. It is very likely that the appropriate type of RCT would be a Cluster Randomised Trial (CRT). This is where randomisation is done at the group or cluster level instead of the individual level, and is often a natural study design in an occupational setting.

It is impossible to give figures for sample sizes and study duration before decisions have been made as to the detailed study design and analysis methods to be used. Measurement of injury rates generally requires very large samples and/or long follow-up times to provide adequate statistical power. Therefore such a study is likely to involve several thousand subjects and a follow-up period of at least a year, and it is likely that 500-1000 individuals will be required per group. Few employers have enough staff for such a trial to be carried out within one organisation. It is therefore to be expected that workers will need to be recruited from multiple employers.

Recommendations

Because of the scale of the MSD problem, HSE should consider funding or part funding a study designed to test the effectiveness of workplace ergonomics interventions to prevent the onset of episodes of musculoskeletal disorders. Consideration should be given to making the study a multi-centre, possibly international, collaborative study. Such a study would be high risk due to the scale and duration needed and the very significant practical and organisational difficulties that would be faced.

Detailed recommendations are given in Section 6.4.

1 INTRODUCTION

1.1 PURPOSE OF THIS REPORT

This work is in response to the Health and Safety Executive (HSE) tender specification entitled: "Feasibility of Assessing the Effectiveness of Preventative Workplace Ergonomic Interventions". This is a request for a report looking at the feasibility of assessing the effectiveness of preventative workplace ergonomic interventions, specifically looking at musculoskeletal disorders (MSDs). Musculoskeletal disorders are problems of the musculoskeletal system, particularly of soft tissues such as tendons or muscles. Symptoms can range in severity from transient aches or pains through to long-lasting disabling conditions such as carpel tunnel syndrome or tenosynovitis. The most commonly affected region of the body is the low back, followed by the upper limbs and then the lower limbs. In some circumstances, MSDs are caused or made worse by work and are then referred to as "Work-related Musculoskeletal Disorders" (WMSDs or WRMSDs).

The tender is therefore solely concerned with preventative interventions in the workplace that are designed to reduce the risk of workers suffering from musculoskeletal disorders. It is not concerned with secondary interventions (those aimed at preventing problems for individuals who have already experienced musculoskeletal problems) or tertiary interventions aimed at rehabilitating or getting back to work sufferers from chronic musculoskeletal disorders.

Intervention studies are known to be difficult, time consuming and costly. Musculoskeletal disorders are seen as complex, multi-causal, often episodic problems that are often difficult to diagnose and treat.

This report is intended to review existing studies, provide a description of research protocols and describe sound methodology for intervention studies.

1.2 WHY INTERVENTIONS?

The purpose of an intervention study in the workplace is to demonstrate that changes in the workplace can have an effect on health outcomes. Since MSDs are a major source of reports of ill health, work absence and disability with consequent costs to the economy, it is almost axiomatic that interventions that can be shown to prevent or alleviate such problems are desirable in a civilised society. It is therefore of interest to HSE to investigate how effective in preventing such problems are interventions that apply ergonomics to the workplace.

Moreover, the history of intervention research shows that despite intervention studies being very costly in terms of time and manpower, they are well worth the effort involved (Kristensen, 2005). They provide two benefits when performed well: theoretical conclusiveness and practical usefulness.

That there is need for more information about the feasibility of intervention studies is shown by a complaint of the lack of a clear, prescribed methodology for intervention design (Loisel *et al.*, 2005). While Loisel *et al.* are writing specifically in the context of prevention of work disability rather than from an occupational viewpoint, the complexity of the area means that each study design will need to be carefully thought out in its own context. This is inevitable in an area where there are many variables to be considered in many different occupational settings. Therefore, any ergonomics intervention study must define its methodology carefully at the planning stage rather than rely on applying a standard methodology unmodified.

1.3 THE NATURE OF MSDS

Because of the complexity of the musculoskeletal system, a large number of problems can fall under the MSD label. These may include:

- Reports of pain (e.g. in the lower back) with no detectable pathology;
- Serious cases of joint or motion dysfunction;
- Problems caused by short-duration life events, such as pregnancy;
- Acute trauma, often involving specific tissues, caused by discrete events, which may transfer significant amounts of energy to the tissues;
- Serious pathologies, such as Cauda Equina syndrome;
- Life-threatening conditions, such as cancer.

Depending on the factors, exposure to risk factors for MSDs may cause immediate effects (such as trauma) or may cause symptoms after a long induction period. For example, an exposure such as lifting may or may not have latent periods before chronic low-back pain results. MSD symptoms are often transient, intermittent and episodic (Burdorf and van der Beek, 1999a). The normal metabolic processes of tissue repair will lead to the resolution of many cases. As a result, the causes of reports of pain are often not investigated in detail, especially if the case is likely to resolve itself in a short period. However, there is much variability in the prognosis of individual cases. Risks of recurrence are high and a percentage of cases become chronic. While it is reassuring to the patient that it is highly likely that an acute episode of low back pain (LBP), in the absence of indications of serious pathology ("red flags") will resolve in a relatively short time-scale, the risk of the individual suffering a future episode is elevated. Thus, even if an initial episode is due to non-work related causes, the risk is elevated of a second episode due to exposures at work.

The extent to which MSDs are work-related has been a cause of controversy, particularly in the USA (Punnett and Wegman, 2004). They noted that: "The presence of one risk factor does not negate another. Whether occupational factors account for few or many MSDs in the *general* population, is not the same question as to what extent people can be protected from preventable risks at work." In their overview of the evidence and the controversy, they also remarked that the relationships between MSDs and workplace risk factors "cannot be represented by a simple one-to-one mapping". Many risk factors have been implicated in the causation and maintenance of MSDs, though the evidence of the sizes of the associations is quite varied. The risk factors are believed to interact in complex and wide-ranging ways. The multi-factorial nature of MSDs is also a consequence of many individuals being exposed to risk factors outside the workplace.

1.4 TERMINOLOGY

1.4.1 Primary, secondary and tertiary interventions — prevention and care

Interventions related to MSDs can entail either prevention or clinical care. Both types of intervention can be subdivided into "primary", "secondary" or "tertiary".

Primary prevention "represents interventions with the uninjured worker population and the workplace to avoid injury (and thus the subsequent need for primary care)" (Gatchel, 2004). It therefore occurs either in the general population or in workplaces.

Primary care is concentrated on passive modes of treatment of MSDs in the early stages (the acute phase) of reports of musculoskeletal problems. In other words, it involves symptom

control when “acute pain predominates”. Gatchel (2004) suggests this is normally 0-10 weeks after injury occurrence.

Secondary prevention “refers to interventions with the freshly injured patient to avoid chronic disability habituation by efforts to return the patient to productivity as soon as possible” (Gatchel, 2004). According to him, both primary and secondary care can be part of this process, along with workplace intervention and job-modification programs. It generally occurs first in health care settings but may also occur in the workplace.

Secondary care (“reactivation care”) helps patients transfer from acute care back into the workplace. It is usually provided in the first six months after injury or postoperatively as a limited rehabilitation approach. It is the first level of rehabilitation when primary care does not resolve the problem. It is “designed to facilitate return to productivity before progressive deconditioning and psychosocial barriers supervene” (Gatchel, 2004). It is based on the rationale that early recognition and management of risk factors for developing disabilities can prevent chronic or permanent disability.

Tertiary prevention “attempts to avoid high costs associated with the permanent loss of productivity of the small fraction of disabled workers who ultimately become the ongoing disabled workers” (Gatchel, 2004). It will occur almost exclusively in health care settings.

Tertiary care is designed for the small fraction of individuals who exhibit chronic entrenched disability. It provides intensive and individualised treatment to help them overcome biomechanical dysfunction, physical deconditioning and psychosocial stressors (Anagnostis *et al.*, 2004; Gatchel, 2004).

1.4.2 Biopsychosocial models/interventions and psychosocial factors

The biopsychosocial model of musculoskeletal pain and disability “views pain and disability as a complex and dynamic interaction among physiologic, psychologic and social factors” (Gatchel, 2004). Gatchel contrasts it with what he calls “the outdated biomedical reductionistic approach” in an attempt to emphasise the importance of the psychological and social factors and that physiological explanations are by themselves inadequate to explain musculoskeletal pain and its possible sequelae such as disability. The term “biopsychosocial” must be clearly distinguished from “psychosocial” as they are not synonymous, especially in the context of MSDs. Engel (1977) coined “biopsychosocial” to highlight the relationships between the biological aspects, the psychological aspects, and the social aspects of illness that a physician must consider when deciding how to treat a patient. The use of the term by authors such as Gatchel (2004) and Waddell (1998) is in precisely this sense.

The term “psychosocial factors” when used in relation to MSDs does not refer to the status of an injured, ill or disabled individual. Instead, it refers to the combination of psychological and social factors that occur in the workplace that can influence how individuals perform their jobs and hence can modify their behaviours in ways that can also affect their risk of suffering from MSDs and hence of reporting problems or of taking sickness leave. It is “a non-specific term” that “has served as catch-all in reference to non-physical elements of the job/work environment” (Sauter and Swanson, 1996). In some circumstances “psychosocial factors” have been linked to the Demands — Control — Support model of Karasek and Theorell (Engstrom *et al.*, 1999; Karasek and Theorell, 1990; Theorell, 1996; Theorell, 2004). Since the term “psychosocial” has such a broad scope, there is clearly overlap with “biopsychosocial”, and considerable scope for confusion. Where possible this report will use “psychosocial” in the context of work and “biopsychosocial” in the context of illness/health care.

It is clear that both psychosocial and physical risk factors "share a common upstream determinant" (Punnett and Wegman, 2004) since the organisation of a work process influences both physical load patterns and psychosocial features such as job demands. Moreover, as Punnett and Wegman note, "items such as "low job satisfaction" may represent a tautological outcome of physical and/or psychosocial strain at work and/or the experience of MSD pain while working". It is therefore clear that any intervention that considers only one aspect of such a complex situation is highly likely to be confounded or ineffective. As they also note, intervening on the up-stream organisational characteristics could be expected to be effective on both physical and psychosocial pathways, even if they are not independent.

1.4.3 Types of intervention evaluations

The methods that can be used to evaluate workplace interventions have been summarised under six headings (Robson *et al.*, 2001):

Table 1. Types of intervention evaluations

	Evaluation type	*Evaluation purpose*
1	Needs assessment	Determines what type of evaluation is needed
2	Process evaluation	Assesses the quality of the intervention delivery and identifies areas for improvement
3	Effectiveness evaluation	Determines whether an intervention has had the effect intended on outcomes, and estimates the size of the effect
4	Cost-outcome analysis	Determines the net cost of an intervention relative to its health effect
5	Cost-effectiveness analysis	Compares different intervention alternatives using cost-effect ratios
6	Cost-benefit analysis	Compares different intervention alternatives using net benefits

It is the feasibility of the third type, "Effectiveness evaluation", that is of direct interest in this report. The first two types must be considered in planning an ergonomics intervention. The cost considerations of types 4, 5 and 6 will also need to be taken into account. While this will be possible to a certain extent, before a full effectiveness evaluation is completed, measurements of effect sizes will be needed from such studies to allow realistic cost-based evaluations to be performed.

1.5 FRAMEWORKS FOR UNDERSTANDING MSDS AND IDENTIFYING POSSIBLE INTERVENTIONS

Recently Karsh (2006) has reviewed previous models (Armstrong *et al.*, 1993; Carayon *et al.*, 1999; Feuerstein, 1996; Hagberg *et al.*, Kuorinka and Forcier, 1995; Kumar, 2001; Moon and Sauter, 1996; National Research Council and Institute of Medicine, 2001; National Research Council, 1999; Sauter and Swanson, 1996) for the causation of MSDs.

The major differences between the models related to the specificity of proposed pathways and proposed mechanisms of action but the theories had the following factors in common:

- Physical and psychological exposures leading to doses, causing responses moderated by individual factors

- Feedback mechanisms or cascading effects
- Several important considerations were not specified, particularly indication of specific magnitudes, duration of exposure or latency periods.

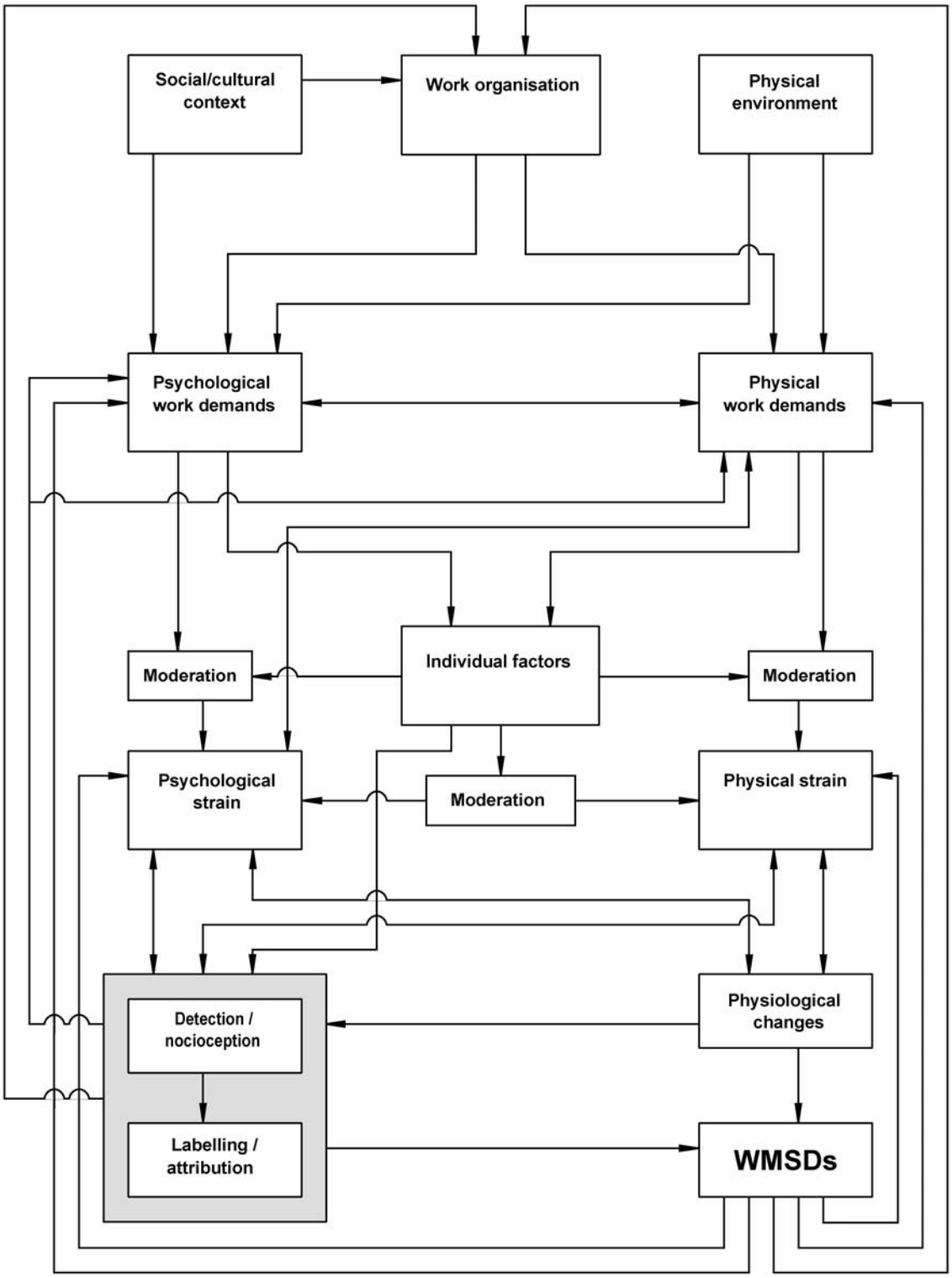


Figure 1. Karsh's integrated model for WMSD causation

Based on the previous models, Karsh (2006) has proposed an integrated model that is reproduced in a slightly simplified form in Figure 1. It links the social/cultural context, the work organisation and the physical environment to the physical and psychological demands of the job. The resultant physical and psychological strains depend on the moderating effects of the physical capacity and psychological coping mechanisms of the exposed individual. These strains then lead to physical and psychological responses that can then lead to the detection of MSD symptoms and possibly a diagnosis of a WMSD. Symptom detection and WMSD diagnosis can lead to modification of work demands, and work organisation, thus creating feedback loops.

Karsh (2006) noted that the model indicated that many different factors acting simultaneously can impact both doses and responses. In other words, interactions between factors need to be considered. He described his model as yielding abundant information for intervention research. He recommended that known "exposures" (by which he appears to mean "risk factors") should be the target of intervention research and that doses, responses and capacity factors should be measured to the extent possible. He noted that typically it is not known how much exposures should be reduced. In cases where complete elimination of an exposure is not possible there is a clear need to examine varying degrees of reduction.

In the previous models "psychosocial risk factors" came within "Work organisation" (Armstrong *et al.*, 1993; Sauter and Swanson, 1996; Feuerstein, 1996) or were conceptualised as a profile of the individual (Carayon *et al.*, 1999) or as part of the workplace (National Research Council and Institute of Medicine, 2001). Because the focus is on the workplace, the biopsychosocial context of concern to clinicians (Waddell, 1998) is not in view.

Leboeuf-Yde (2004) proposed that instead of considering risk factors for the development of LBP, the focus should be on "persons at risk". She suggested that LBP is "but one expression" of being generally frail and that therefore early identification of high-risk populations would allow for a "selective preventive approach". It is not clear how this proposal could be implemented either at the stage of the identification of high-risk individuals/groups or at the later stage of "selective intervention". The main risk factor for an episode of low back pain is a previous episode of low back pain, so this is a risk indicator that is not useful for primary prevention. However, if individuals with a recent history of time off work due to back pain were identified as "persons at risk" of new episodes, the difficulty would then be of selecting the correct interventions without considering "risk factors".

Griffiths noted that understanding the mechanisms that mediate successful interventions is a crucial step to understanding organisational interventions and that such principles will be more generalisable than the outcome of any particular intervention (Griffiths, 1999).

It is therefore recommended that any tender specification should use the integrated model proposed by Karsh (2006) as a basis for identifying pathways that should be explored and of evaluating proposals in response to the tender. It would be up to the drafter of the specification to decide whether to specify the pathways that proposals should examine or to leave tenderers to decide which factors to address.

1.6 MODEL OF AN INTERVENTION STUDY

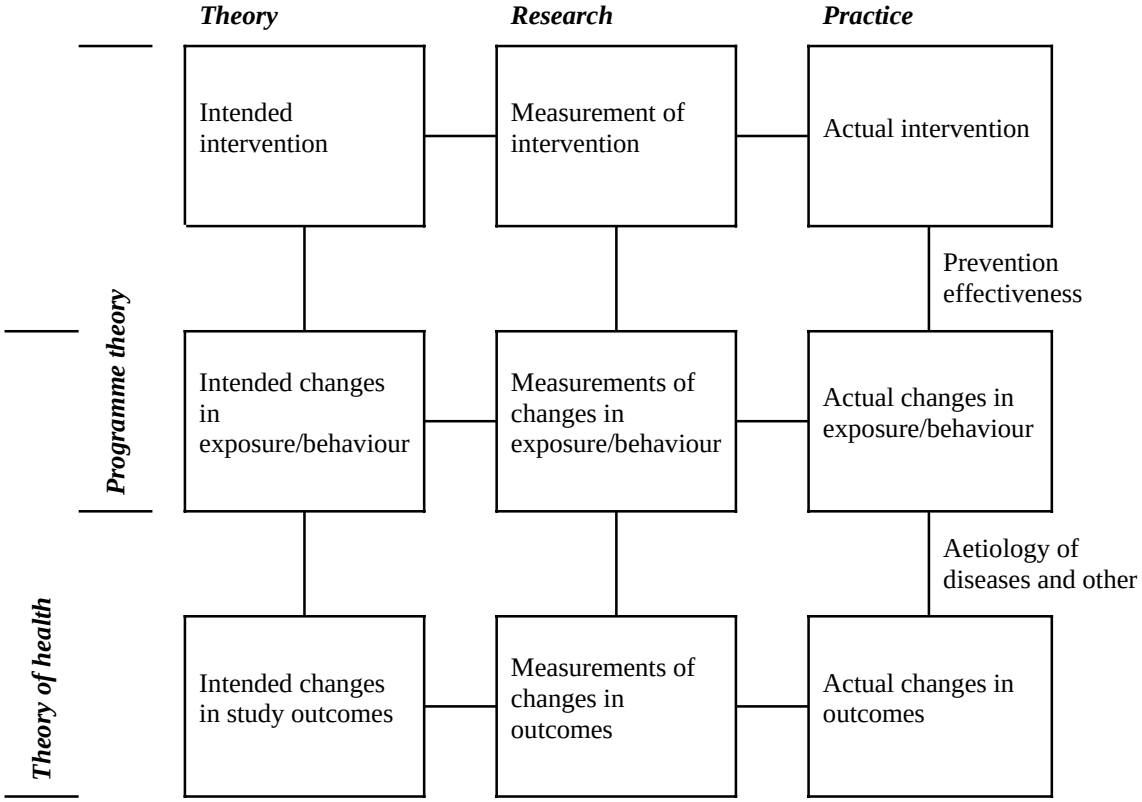
A theoretical model of key elements in occupational intervention studies (Kristensen, 2005) clarifies the relationships between theory, research and practice (Figure 2). Working down the *Theory* column of the diagram shows that the intervention is intended to lead to reduced exposure and hence to better health. The *Practice* column shows what the actual course of events is and that, at all three levels, the actuality can differ from the intention. The *Research*

column in the middle shows how a research project seeks to measure all three levels of an intervention using valid techniques.

The model highlights a number of quality assurance issues for the intervention process that need to be addressed at the reporting stage of an intervention study:

- Was the planned intervention actually implemented?
- Did the intervention as implemented lead to the intended change in exposure?
- Did the actual change in exposure have the intended/predicted effect on the study outcomes?

Figure 2. Model of occupational intervention studies



To illustrate these issues, Kristensen (2005) distinguishes between "programme failure" and "theory failure" (or success). In other words, it does not help if the intervention is effective if the target recipient does not receive it (programme failure); nor is the recipient of an actual intervention helped if the intervention has no effect (theory failure). His point is that the way to distinguish between the two is to study all steps in the intervention programme.

Another important consideration is the possibility that the intervention model under consideration is ambiguous — in other words, even if an intervention works, it may not be known exactly what worked (Lipsey, 1996). It is the realisation that simple interventions are often not effective in tackling MSDs, which has led to the examination of multi-component interventions.

A review (Denis *et al.*, 2008) considering whether the "traditional MSD prevention model" was actually put into practice in workplace interventions found that only slightly more than a third of studies reviewed actually applied this model. "Shortened" interventions skipped stages involving work-description and risk factor identification, and "turnkey" interventions went

straight from a preliminary analysis to solution development and implementation. "Complete" interventions were uncommon in changing environments, but it was rare for the intervention process to be justified. They concluded that intervention processes require a better and more detailed framework than currently exists, with a need for the application context, and their advantages and limitations to be defined. They suggested that more complete intervention processes are preferable when MSDs are the target of the intervention, but that the quick "turnkey" interventions can be appropriate in well-understood situations.

A final possibility that must be considered is that an implemented intervention, even if successful, can have negative side-effects or unintended consequences that undermine the benefits of the intervention (Lipsey, 1996).

1.7 PURPOSE OF THE INTERVENTION

Kristensen (2005) draws a sharp distinction between aetiological intervention studies and prevention effectiveness intervention studies. He argues that once enough is known about the association between an exposure and a disease, there is no need to carry out aetiological studies, and that prevention effectiveness studies are appropriate. Two examples he gives are 1) heavy lifting and low back pain and 2) low decision latitude and absence from work. His characterisation of the differences is set out in Table 1. This view is also expressed in one earlier paper (Skov and Kristensen, 1996). However, as noted in Section 2.1, the consensus of the others that have considered the need for MSD intervention studies is that the existing studies have largely been of poor methodological quality and that further (aetiological) intervention studies are needed to demonstrate the actual effectiveness of ergonomics interventions in preventing MSDs. He is explicit that large samples are not needed for prevention effectiveness studies, but that case studies in different settings are suitable instead. These will allow the practicalities of implementing an intervention programme to be tested.

Table 2. Characteristics of intervention studies (Kristensen, 2005)

Aetiological interventions	*Prevention effectiveness interventions*
Large samples	Small samples
Endpoint: health/disease	Endpoint: exposure, behaviour
Randomisation, blinding	No randomisation or blinding
Aetiological theory	Programme theory
Quantitative methods	Quantitative and qualitative methods
Representative groups and workplaces	Case studies

There is a case to be made for carrying out prevention effectiveness studies while aetiological studies are ongoing rather than waiting until there is universal acceptance of the results of the definitive aetiological studies. These could be used to help define the variables that should be studied aetiologically since, if the actual implementation of a suggested intervention is difficult or impossible, then there is little point in attempting an aetiological study of it.

This said, there is the severe danger that bodies such as HSE when asked to fund intervention studies will decide on cost grounds to fund prevention effectiveness studies to the exclusion of aetiological studies. This approach would fail completely to address the vital underlying scientific issues that only aetiological studies can address and would therefore represent a waste of resources akin to buying land and building materials for a house without checking whether the site is on a flood plain and therefore totally unsuitable.

1.8 EPIDEMIOLOGY OF MSDS

Burton *et al.* (2005) summarised the basic epidemiology of non-specific low back pain (i.e. LBP that cannot be attributed to specific pathologies or lesions) as follows:

- Lifetime prevalence 60-70%
- One year prevalence 15-45%
- Adult incidence per year 5%
- Peak prevalence Ages 35-55
- Poor correlation between symptoms, pathology and radiological findings.
- In 85% of cases, low back pain cannot be attributed to pathology or neurological encroachment.
- There is recent evidence of genetic liability to back pain.
- Between 2 and 7% of people with acute low back pain develop chronic low back pain.
- Two thirds of people with an episode of low back pain will suffer another episode within the next 12 months.
- One third of people absent from work due to low back pain will have another low back pain related work absence in the next 12 months.

The epidemiology of musculoskeletal problems with specific pathologies can be quite different to non-specific problems. Prevalence rates in the general population can be quite high, and in some chronic conditions, such as rheumatoid arthritis, will tend to increase with age.

1.9 RISK FACTORS ("FLAGS") FOR THE DEVELOPMENT OF CHRONICITY OF MSDS

Gatchel (2004) has summarised the various "warning flags" that have been described for use in clinical evaluations of patients with acute episodes of low back pain. These are:

Red Serious clinical pathology/physiological conditions

Yellow [Bio]Psychosocial risk factors that can increase the risk of an acute case of low back pain becoming chronic. These are summarised as "ABCDEFW":

- Attitudes and beliefs about pain — so-called "fear-avoidance", passivity and catastrophizing.
- Behaviours of the patient, particularly avoiding activity
- Compensation issues
- Diagnosis and treatment — misunderstanding of the severity and prognosis of their condition
- Emotions — hopelessness
- Familial factors — particularly to do with social support in the home
- Work related risk factors — perceptions that their work is harmful and dangerous, job dissatisfaction

Blue Occupational factors [psychosocial factors] believed by patients to impede their recovery

- High demand/low control
- Negative perceptions of management
- Perceived time pressures
- Perceived poor social support

Black Objective occupational factors that may initially lead to the onset of low back pain and may promote disability once the acute episode has occurred.

- National and local policies such as sickness systems, wage rates, the availability of modified duties
- Working hours/shift patterns
- Physical factors such as biomechanical demands of the job

2 REVIEW OF EXISTING SCIENTIFIC LITERATURE

2.1 SYSTEMATIC REVIEWS

A number of wide-ranging reviews of the science regarding musculoskeletal disorders have been completed, particularly in the USA. In 1997 one was published by the National Institute for Occupational Safety and Health (NIOSH), part of the US Department of Health and Human Services (DHHS) (Bernard, 1997). A report was published as a result of a workshop held by the National Research Council (NRC) (1999). A subsequent report written jointly by the NRC and Institute of Medicine (IOM) (2001) in response to a request from the US Congress, examined more formally the overall patterns of evidence. One paper (Smith *et al.,* 1999) presented at the NRC workshop was the basis for a more comprehensive systematic review (Karsh *et al.,* 2001). Karsh (2006) has also summarised and attempted to synthesise the existing theories of the causation of MSDs.

In the UK and European Union a similar review has been carried out for the Faculty of Occupational Medicine (Waddell and Burton, 2001) as part of the development of guidelines for managing low back pain in the workplace (Carter and Birrell, 2000). A more recent review underpins European guidelines on prevention of low back pain (Burton *et al.,* 2004; 2005).

A series of systematic reviews of treatment methods/secondary prevention methods for back pain have been published in *Spine* by the Cochrane Collaboration Back Review Group (Clarke *et al.,* 2006; Furlan *et al.,* 2002; 2005; Hagen *et al.,* 2000; 2002; 2005; Heymans *et al.,* 2005; Karjalainen *et al.,* 2001a; 2001b; Niemisto *et al.,* 2003; van Tulder *et al.,* 1999; 2000a; 2000b; 2003b). The Cochrane Collaboration originated with a specific focus on clinical issues and therefore largely does not seek to address primary prevention (Bouter *et al.,* 2003). A single study (Jellema *et al.,* 2001) has been found that addresses both primary prevention and secondary treatment through the use of lumbar supports in seating.

Recently the focus of the Cochrane Back Group seems to have broadened to include primary prevention where it overlaps with secondary prevention. Thus there is a review of manual handling advice and assistive devices (Martimo *et al.,* 2007) and there are current protocols for reviews to be carried out looking at exercise (Choi *et al.,* 2007) and work conditioning (Schonstein *et al.,* 2003). A protocol for worksite intervention (Aas *et al.,* 2005) is specific to secondary interventions.

The Cochrane Library (http://www.cochrane.org) contains The Cochrane Central Register of Controlled Trials that holds details of relevant Randomised Controlled Trials (RCTs) and Controlled Clinical Trials (CCTs). As of 24 April 2007 there were 1788 records out of a total of 495002 in the database that were identified by the search term SR-BACK, which is used to identify studies relevant to low back pain (Bouter *et al.,* 2003).

Many more focussed reviews of intervention studies have been carried out (Bongers *et al.,* 2002; Boocock *et al.,* 2007; Bos *et al.,* 2006; Brewer *et al.,* 2006; Hignett, 2003; Hooftman *et al.,* 2004; Jellema *et al.,* 2001; Silverstein and Clark, 2004; Sobeih *et al.,* 2006; Tveito *et al.,* 2004; van Poppel *et al.,* 2004; Village *et al.,* 2005). While there does not appear to be a formal group systematically reviewing intervention studies seeking to prevent new episodes of MSDs, many of these reviews have used the Cochrane criteria for systematic reviews (van Tulder *et al.,* 2003a). The consensus is that many of the studies reviewed are methodologically weak, especially in their reporting, and that the available evidence is often limited and inconclusive.

Tuncel *et al.* (2006a) carried out a meta-analysis of international studies attempting to prevent the occurrence/reoccurrence of lower back disorders in manufacturing workplaces. The inclusion criteria were that:

- The study had to employ a controlled workplace intervention in a manufacturing setting and had to be aimed at reducing the (re)occurrence of Low Back Disorders (LBDs).
- Participants had to be employees in a manufacturing setting.
- The reported outcome measures had to include one or more of self-reported back pain episodes, pain intensity, or company records of sick leave due to LBDs.
- The study had to be published in English in a full journal article between January 1965 and July 2004.
- The data had to report data that allowed effect sizes to be calculated.

The meta-odds ratio (OR) they obtained showed an insignificant reduction in LBDs. Their appraisal showed that the four studies that met their inclusion criteria had at best a marginal methodological quality and therefore they cautioned against interpreting the low OR they obtained as evidence of no effect. Their primary conclusion was that further research was required and that it needed to be rigorous and high quality.

2.2 SPECIFIC MSD RISK FACTORS

A number of risk factors have been associated with a risk of low back pain. The most widely quoted one is hard physical work but genetic predisposition, co-morbidity, possible weak spinal structures and weak psychological stamina have also been reported (Leboeuf-Yde, 2004). However, the evidence does not exist for a sedentary life style, smoking, obesity and alcohol consumption (Leboeuf-Yde, 2004).

Heritability analysis among twin pairs has shown that life-time prevalence of LBP has a genetic component (Leboeuf-Yde, 2004). Hestbaek *et al.* (2004) discuss the "heritability of liability" to low back pain, but it is not clear how a liable genotype is modified by environmental factors to produce a phenotypic case of low back pain. Nor is it clear how selection/screening could be used to help liable individuals avoid the relevant environmental factors.

Individual/demographic factors can be seen as "non-workplace factors" that contribute alongside work factors to the causation of MSDs. They can also be seen as physiological or psychological attributes that affect personal responses to workplace factors (Cole and Rivilis, 2004). It has been noted that few individual factors are readily modifiable, especially in the workplace and therefore there is little use in including them when planning workplace interventions (Frank *et al.*, 1996). The individual factors identified by Cole and Rivilis are shown in Table 3. They note that gender and socio-economic status can affect both reporting and recognising cases of MSDs. They also commented that the impact of combined interventions can be substantially modified by individual factors such as differential responsiveness to secondary interventions. However, there are potentially complex interactions between individual factors and other workplace variables, making separating the contributions of different factors very complex.

Table 3. Individual factors relevant to MSDs (Cole and Rivilis, 2004)

Usual naming of factor types	*Individual factors*	*Potential construct(s)*
Demographic	Gender Differential responses to stress	Differential labour market
Age	Cumulative exposure	Decreased tolerance Different skills and experience
Work	Work-style	Different biomechanical exposures
Anthropometry	Height and weight	Mismatch between equipment and person Differential tissue demands
Psychological	Personality	Differential kinematics Differential coping capacity
Lifestyle	Physical activity, hobbies, sports Smoking, drugs	Additional loads or physical exposures Additional exposures
Comorbidity	Diabetes, pregnancy Distress, depression	Additional internal exposures Altered biochemistry, different pain perception threshold
Past history	History of MSD episodes	Lower tolerance
Social	Divorce-widowed Minority race Poverty	Lower social support Discrimination Complex socio-health contexts

An exploration of the pathways between physical and psychosocial risk factors (Swanson and Sauter, 2006) used an intervention that provided an alternative keyboard in an office environment. Their model is based on changes in office technology affecting the physical demands of the job and the way the work is organised with consequent changes in both psychological and biomechanical strain. Their results showed only small effects of the intervention. The relatively small number of subjects involved and the relatively small intervention may have been a cause of this.

2.3 GUIDELINES

The evidence review (Waddell and Burton, 2001) underlying the Faculty of Occupational Medicine (FOM) guidelines on the management of low back pain at work (Carter and Birrell, 2000) concluded that:

- Physical demands of work can precipitate individual attacks of low back pain.
- Certain individuals may be more susceptible.
- Certain jobs may be higher risk.
- Overall, physical demands of work account for only a modest proportion of the total impact of LBP occurring in workers.

Their specific evidence statements contained the following:

"Most adults (60-80%) experience LBP at some time, and it is often persistent or recurrent." [Strong evidence]

"There is strong epidemiological evidence that physical demands of work (manual materials handling, lifting, bending, twisting and whole body vibration) can be associated with increased reports of back symptoms, aggravation of symptoms and 'injuries'." [Strong evidence]

"There is limited and contradictory evidence that the length of exposure to physical stressors at work (cumulative risk) increases reports of back symptoms or of persistent symptoms." [Limited or contradictory evidence]

"There is strong evidence that physical demands of work (manual materials handling, lifting, bending, twisting and whole body vibration) are a risk factor for the incidence (onset) of LBP, but overall it appears that the size of the effect is less than that of other individual, non-occupational and unidentified factors". [Strong evidence]

"There is strong epidemiological and clinical evidence that care seeking and disability due to LBP depend more on complex individual and work-related psychosocial factors than on clinical features or physical demands of work". [Strong evidence]

When discussing prevention they acknowledged that it is reasonable in principle to seek to reduce the incidence and prevalence of LBP by interventions designed to reduce exposure to known occupational risk factors. However, because of the complex set of causal factors for LBP, of which occupational physical demands are only one, they queried the extent to which occupational interventions can realistically be expected to reduce the societal impact of LBP. They considered that

"There is a lack of convincing evidence that it is possible to reduce the incidence or prevalence of the symptom of LBP substantially."

The European guidelines (Burton *et al.*, 2004; 2005) on prevention of low back pain took the same approach of arguing that there is limited scope for preventing its incidence (first time onset). They therefore noted that primary causative mechanisms remain largely undetermined and that risk factor modification will not necessarily achieve prevention. They focused therefore on the prevention of the consequences of LBP through reduction of the impact of recurrences, care seeking, and disability and work loss.

Their overarching comment was that there was acceptable evidence that the prevention of various consequences of LBP (e.g. recurrence, care seeking, disability and work loss) is feasible but that the effect sizes of the interventions are rather modest. They concluded that the most promising approaches were physical activity/exercise and biopsychosocial education.

In the context of workers, their recommendations were:

- To encourage physical exercise for prevention of incidence and recurrence of LBP and for prevention of recurrence of sick leave due to LBP;
- Not to use back schools based on biomedical/biomechanical information;
- Not to provide lumbar supports or back belts;
- Not to provide shoe inserts/orthoses;
- To provide temporary modified work and ergonomics workplace adaptations to facilitate earlier return to work for workers on sick-leave due to LBP.

They found that multi-dimensional interventions at the workplace might be recommended to reduce some aspects of LBP but they did not find sufficient evidence to recommend specific dimensions and how they should be balanced.

They did not find sufficient consistent evidence in the following areas to make recommendations:

- Standalone physical ergonomics interventions to prevent LBP;
- Standalone organisational interventions;
- The content of organisational/participative interventions associated with a physical ergonomics programme.

2.4 THE VALUE OF MECHANICAL INTERVENTION IN PREVENTION OF MSDS

While these guidelines offer a pessimistic view of the possible effectiveness of ergonomics interventions, they do make an urgent call for "good quality RCTs" to investigate them further. A less despairing view of mechanical issues and back pain is espoused by McGill (2002). In a section in his book entitled "Deficiencies in Current Low Back Disorder Diagnostic Practices" he writes:

> *"It is currently popular for many authorities to suggest that back trouble is not a medical condition. They assert that physical loading has little to do with low back injury compensation claims; rather they believe workers complain of back problems in order to benefit from overly generous compensation packages or to convince physicians they are sick. According to this view, any biomechanically based injury prevention or rehabilitation program is useless. Variables within the psychosocial sphere dominate any biological or mechanical variable. If this is true, then this book is of no value—it should be about psychosocial intervention."*

He is hardly gentle when he comments that:

> *"The position that biomechanics plays no role in back health and activity tolerance can be held only by those who have never performed physical labor and have not experienced first hand the work methods that must be employed to avoid disabling injury. While the scientific evidence is absolutely necessary, it will only confirm the obvious to those who have this experience."*

While he does not discuss the epidemiological literature with the approach usually taken in systematic reviews or meta-analyses, McGill (2002) provides an overview of the epidemiological literature and highlights studies that support his contention that both psychosocial and biomechanical factors are important risk factors for LBP. He then provides an extensive discussion of the anatomy and normal and injury mechanics of the lumbar spine. Finally, he discusses, in detail, firstly risk reduction guidelines aimed at reducing the overloading stressors that cause occupational LBP and, secondly, rehabilitation and exercise programs.

In a subsequent article (McGill, 2004) he lists three new recommendations for workers to reduce the risk of injury as:

- Avoid repeated full-flexion of the low back;
- Avoid long-duration flexion postures;
- Avoid flexion under acute loads immediately after getting out of bed.

2.5 EFFECTIVENESS OF DIFFERENT INTERVENTIONS

Karsh *et al.* (2001) carried out a comparison of the intervention effectiveness of various study designs and intervention types from 101 studies. The findings are summarised in Table 4. They noted that 84% of all the studies had some positive effect, though the majority (55%) had mixed results. Where mixed results occurred, the vast majority were a combination of mostly positive results with some non-effects. Only rarely were the results of the interventions actually negative. However, this could be publication bias or pre-selection of interventions likely to be effective rather than experimental error or interpretation bias (halo effect). However, only 32% of studies reviewed used an experimental or quasi-experimental design.

They concluded, with a "qualified 'yes'" that the review had shown that interventions to control WMSDs are effective. Restricting the analysis to randomised designs reduced the evidence for back belts and training and removed it for new tools and technologies. The evidence for exercise and multiple component interventions was strengthened.

2.6 COST EFFECTIVENESS OF INTERVENTIONS

A study (Lahiri *et al.,* 2005) of the cost-effectiveness of the interventions that have been attempted estimated that back pain/injury incidence could be reduced by 20% with training, by 56% with engineering/administrative controls, by 60% with a combination of engineering/administrative controls and training and by 74% by a comprehensive Workplace Ergonomics Program. They considered cost effectiveness of these programs taking into account worldwide differences in levels of industrialization. Their findings suggested that full ergonomics programs would be cost-effective in both developed and developing countries for their health effects alone. However, they did conclude that training appeared to be the most cost-effective intervention, despite the impact of training on health outcome being rather limited. While they were more expensive, engineering and ergonomics interventions had a far greater impact on total health outcome than training due to the greater reduction in back pain incidence.

They recommended prospective studies of the recurrence of back pain and studies of workers who are the "working hurt". They believed that worker training is a low-cost feasible first step towards the reduction of work-related back pain in developing countries where resources are scarce and that it should be encouraged through public policy and regulation. However they considered it unquestionable that ergonomics programs should be encouraged in highly developed countries for both health and productivity effects and that when additional resources become available they should go straight to the full ergonomics programs.

One of the drivers of the current interest in musculoskeletal disorders is the concern about the economic costs associated with them, particularly in relation to health care, income replacement by state or insurance benefits, and litigation/compensation costs. The hope is that interventions will be widely adopted if they can be shown to be effective, either at preventing MSDs or at getting an individual back into productive paid work more quickly. Though the topic appears to be relatively unexplored in the MSD field, an economic evaluation will be part of a full consideration of an intervention, and is best done by comparing two or more interventions (Korthals-de Bos *et al.,* 2004).

Table 4. Summary of intervention effectiveness (Karsh *et al.*, 2001)

Intervention	*Results*			*Study design*						
Number of studies (percentage of studies)	*Positive*	*No effect*	*Mixed*	*Experimental*	*Quasi-experimental*	*Pre-post one group*	*Post only non-equivalent comparison*	*Post only, one group*	*Other*	*Total*
Back belt	2 (25%)	4 (50%)	2 (25%)	4 (50%)		2 (25%)			2 (25%)	8
Training		6 (29%)	14 (67%)	7 (33%)	7 (33%)	5 (24%)		1 (5%)	1 (5%)	21
Tools/technologies	4 (40%)		5 (50%)		1 (10%)	7 (70%)	1 (10%)			10
Exercise	4 (29%)	2 (14%)	8 (57%)	7 (50%)	1 (7%)	5 (36%)			1 (7%)	14
Job design		1 (100%)				1 (100%)				1
Multiple component	19 (40%)	1 (2%)	27 (57%)	2 (4%)	3 (6%)	29 (62%)	2 (4%)	4 (9%)	7 (15%)	47
Total	29 (29%)	14 (14%)	56 (55%)	20 (20%)	12 (12%)	49 (49%)	3 (3%)	5 (5%)	11 (11%)	101

2.7 MULTI-COMPONENT INTERVENTIONS

Multi-component interventions (also referred to as multi-disciplinary interventions (Tveito *et al.,* 2004)) are ones that apply a range of different measures to try to prevent low back pain and/or its consequences. This makes it easy for them to be applied at more than one level of prevention. Thus, one study (IJzelenberg *et al.,* 2007) applied the biopsychosocial model through education and training (primary prevention) and through provision of immediate treatment along with ergonomics advice to LBP cases (secondary prevention).

A multi-component study (Mancini *et al.,* 2005) showed that this kind of intervention was effective, in this case, in reducing the incidence of work-related eye injuries. Because it was a "reactive" rather than a "proactive" study they argued that a randomised study would have been ethically inappropriate. Therefore, they compared the study population with other industry sectors in the region.

A systematic review (Tveito *et al.,* 2004) concluded that there was limited evidence of the effect of multidisciplinary interventions on pain outcomes, but that there was no evidence of an effect on episodes of LBP.

Recent recommendations regarding ergonomic intervention studies have been that multi-component study designs should be favoured (Silverstein and Clark, 2004; Waters, 2004a). As Smith *et al.* (1999) explain, the primary purpose of workplace interventions to control MSDs is to reduce the stress load to eliminate strain. This can be coupled with increasing the capacity of the individual to handle greater loads, thereby reducing the possibility for a misfit.

It has been recommended that epidemiological studies be conducted to evaluate the interactive effects of various risk factors, such as physical and psychosocial stressors, individual and genetic factors (Hartvigsen *et al.,* 2004; Leboeuf-Yde, 2004), and other factors that may affect reporting of MSDs (Waters, 2004a). Karsh *et al.* (2001) reported that 97% of the multiple component interventions in the studies they reviewed produced some positive results, with the most effective design being randomised assignment and control groups. Such a study needs to show that each of the multiple components was successful in meeting its goal, not just that the whole intervention was successful. This should involve examining intermediate outcomes to demonstrate that each component was successfully implemented. It must be noted that considerations of statistical power become more complex for such studies. In the study (IJzelenberg *et al.,* 2007) that used the biopsychosocial model, incident cases were offered workplace advice/ergonomic adjustments or further training. The power calculations reported are for the primary intervention and are based on detectable changes in prevalence rates; they are not based on utilisation of health care or provision of further advice. The study found that only 10 subjects utilised the workplace health care while 66 utilised similar care outside the workplace. Of the 10 subjects utilising the health care, only four accepted the further advice. Given these tiny sample sizes, there was no chance of the secondary interventions having sufficient power to demonstrate their effectiveness.

2.8 RETURN TO WORK POLICIES

A "Prevention and Early Active Return-to-Work Safely" (PEARS) program (Badii *et al.,* 2006; Davis *et al.,* 2004) was a combined primary prevention and return to work intervention. It was found to be effective at returning to work more quickly employees that had reported musculoskeletal injuries. Consequently, it showed significant reductions in total days lost and financial costs. Badii *et al.* (2006) found an associated increase in the overall incidence of musculoskeletal injuries and the subset resulting in time-loss. They interpreted this as a shift in reporting culture specific to musculoskeletal injuries. This raises issues of the difficulty of

separating different types of intervention. Their finding of a change in reporting culture with an increase in musculoskeletal injury reporting and in short duration absences (1-2 days) associated with an overall decrease in lost time and consequent costs led them to suggest that allowing injured workers to take short periods of time off might be associated with reduced morbidity and costs in the long run. Any study therefore that measures lost-time without any kind of measure of the incidence and prevalence of problems among participants that do not lead to lost-time is in danger of being confounded by such a change in reporting and short duration absence culture. The study would need to be carefully designed to control for different reporting systems and cultures, and different absence management expectations and milieus.

2.9 RECENT PROSPECTIVE STUDIES

A prospective study (van Nieuwenhuyse *et al.*, 2006) of young workers investigated the effect of work-related factors and individual characteristics on the incidence of LBP in initially pain-free individuals working in health care and distribution companies. After one year of follow-up 12.6% of 716 individuals had experienced back pain lasting seven or more days. They found univariate evidence of a dose-response relationship for pushing and pulling heavy loads but not for lifting or carrying weights. None of the psychosocial factors they measured was predictive. Multivariate analysis using Cox regression showed that inability to change posture regularly, working with the trunk bent or twisted for more than two hours per day, back pain in the previous year, and pain related fear were significant predictors. They concluded that a more effective primary prevention of LBP might be achieved by addressing both the ergonomic work environment and attitudes to pain. They concluded that as a potential preventative measure, addressing pain-related fear seems as promising as physical work factors. However, as they do not discuss this conclusion in terms of a model such as that in Figure 1, it is difficult to know how such an intervention would act as primary prevention rather than secondary or tertiary.

A longitudinal study (Gerr *et al.*, 2005) involved an RCT of a postural intervention among newly recruited computer users. It showed that the specific workplace postural interventions used were unlikely to reduce the risk of upper extremity musculoskeletal symptoms among computer users. They had the problem of relatively low compliance with all aspects of the intervention due to the inflexibility of workplace configurations

2.10 RECOMMENDATIONS FOR FUTURE WORK

The NRC/IOM (2001) study identified important gaps in the science base on MSDs and recommended that workplace intervention studies should be carried out directed towards:

- "Conducting rigorous evaluations of workplace interventions including but not limited to randomized controlled trials or other scientifically valid approaches.
- "Promoting investigation of multi-factorial interventions.
- "Developing effective methods to measure the efficacy and cost-effectiveness of interventions on the reduction of workplace injuries.
- "Coordinating studies of interventions between the research community and industry.
- "Validating techniques, standards, and manuals for target industries."

The National Occupational Research Agenda (NORA) of NIOSH in the USA identified priorities for intervention research (Waters, 2004a) to evaluate the effects of a number of factors on the development and prevention of MSDs:

- "Alternative (product and/or tool) design criteria (force, spatial requirements of work);

- "Optimization of mechanical (force, movement and posture) work demands and temporal patterns of exposure;
- "Manual handling alternatives in posture, movement, force, productivity and quality;
- "Ergonomic training and education;
- "Costs and benefits of ergonomics interventions; and
- "Job assignment, selection and choice."

The consensus of the many systematic reviews referred to in Section 2.1 is that because of the low methodological quality of the many studies to date, there is still a significant need for methodologically high-quality intervention studies to be carried out.

The European guidelines on prevention of LBP (Burton *et al.*, 2004; 2005) recommended further research to address (among others) the following issues:

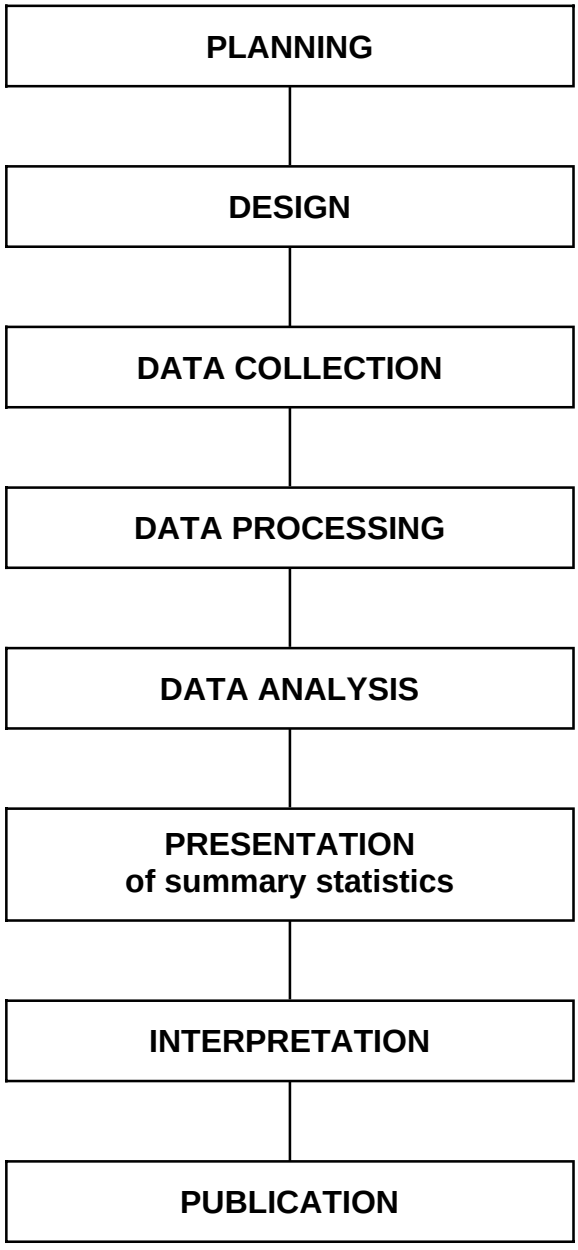
- Cost-benefit and risk-benefit analysis;
- Good quality Randomised Controlled Trials (RCTs) to study the effectiveness of daily physical activity for prevention of LBP and recurrence of LBP;
- Good quality RCTs on the role of information orientated to reducing fear avoidance beliefs and improving coping strategies;
- "Good quality RCTs are urgently needed to study the effectiveness of physical, psychosocial and organisation ergonomic interventions on a large variety of outcomes, ranging from prevention of (recurrence of) LBP and prevention of (recurrence of) sick leave due to LBP up to compensable LBP."
- Whether interventions can be applied to all workers, irrespective of gender, age, seniority and/or past history of LBP. If necessary, the optimal approach for each sub group should be examined.

3 EPIDEMIOLOGICAL METHODS

3.1 INTRODUCTION

The ideal process of conducting an epidemiological research study is illustrated in Figure 3. It is important to be aware of the issues related to these stages. The following sections discuss these in further detail.

Figure 3. General sequence of steps in a research project (Altman, 1991).



Guidance had been provided by NIOSH on evaluating the effectiveness of interventions/strategies to prevent work injuries (Robson *et al.*, 2001). This is written at an introductory level to encourage students, researchers and practitioners to become involved in designing and evaluating work place safety interventions. This guidance is generic to all safety interventions and not specific to ergonomics interventions.

3.2 PLANNING

A successful study will have been planned well. The planning includes:

- Deciding the research question;
- Choosing a suitable study design to ensure that the aims of the study are met. For an intervention study, this means ensuring that the design is able to assess causality;
- Determining study sample size using power considerations;
- Taking great care in deciding what information will be collected;
- Taking into consideration confounding and bias;
- Realistically planning study management and financing;
- Getting ethical approval.

The MRC (2000; Campbell *et al.,* 2007) has produced a discussion document setting out a possible stepwise framework for developing and evaluating RCTs for complex interventions. They are explicit that though they draw a comparison with the evaluation of new drugs, they "in no way intend to imply that the evaluation of a complex package is like the development and evaluation of a new drug". Their framework is advice to be applied "to the extent to which it is relevant" at each stage of the proposed intervention evaluation. The five steps they identify are:

- Theory — why should this intervention work?
- Modelling — How could this intervention work in practice?
- Exploratory trial — Pilot trials to choose optimised study designs;
- Definitive RCT — The central step;
- Long-term implementation — possibly supported by an observational study.

From reviews and theoretical papers such as by Volinn (1999), it is clear that the ergonomics of MSDs field has reached the stage where definitive RCTs should be attempted though earlier stages should be considered in the planning of such an RCT.

3.2.1 Research question

The study must be designed around the research question and this must be defined extremely carefully. It is possible that "an omnibus hypothesis on the effect of an intervention on musculoskeletal outcomes may in fact be testing something quite different and any inference drawn misleading" (Dempsey, 2007). It is therefore essential to be clear as to what is being investigated and what the measured outcomes will be. Dempsey (2007) goes as far as to suggest that the research question may need to be constrained to one that is answerable, though this does have the disadvantage that the outcome may be a surrogate measure of effectiveness. He gives the example of demonstrating reduced mechanical exposure, rather than attempting to demonstrate reduced morbidity due to decreased mechanical exposure. Unfortunately, until there is no questioning of the link between mechanical exposure and morbidity, this can only be described as begging the question and is not a suitable design for demonstrating the effectiveness of ergonomics interventions. Dempsey (2007) also expresses reticence over the call for more intervention research in ergonomics for three reasons:

- In many situations, the question is statistically intractable.
- The complex and partially incontrollable situations in which interventions must be implemented weaken and confuse the studies.

- Alternative measures to morbidity such as productivity gains have the potential to backfire and to lead to further changes to the job, such as increases in work pace that can be detrimental to employees.

Dempsey considers the kind of evidence accepted in quality engineering where small incremental changes are routinely implemented and argues that no more should be expected from ergonomists. The weakness of his argument is that MSDs are a health problem as well as a work design problem and therefore medical epidemiologists have an interest in the topic. They are unlikely to be prepared to abandon the sophisticated epidemiological methods they have developed in clinical trials, particularly of drugs, where many of the same problems are found. Moreover, there is much to be gained by a consideration of the way that clinical trials are demanded before new, "alternative" or "complementary" treatments become accepted as part of standard medicine. The vested interests, emotional commitment and junk science involved in unproven treatments are all factors that can be seen in the field of ergonomics interventions.

Karsh *et al.* (2001) noted that "Randomized experimental designs are exceedingly difficult to carry out in the field", and of the 47 multiple component interventions they reviewed, only two used experimental designs. They also reported that of the 101 studies reviewed, only two reported having conducted a power analysis.

3.2.2 Inferring/detecting causal relationships

Investigating the prevention of MSDs with an intervention study requires detecting causal relationships. The first stage of investigating causality is to establish an association, usually with an observational study, and then to consider what the particular association appears to imply. However, establishing an association, although necessary, is not a sufficient condition to establish causation. Guidelines have been written on how to evaluate the evidence of a causal relationship between two associated variables (Hill, 1963) and the major criteria are:

- Temporal relationship;
- Biological plausibility;
- Consistency and alternative explanations (confounding);
- Dose-response relationship;
- Strength of the association;
- Cessation of effects.

To decipher the difference between association and causation requires very careful statistical analysis. Interpretation from panel studies (longitudinal cross-sectional studies) can often infer causation, when in fact it is more likely to be association. However, any two quantities changing over time will show a statistical association. Thus, only in randomised trials and other experiments can we reasonably describe an observed effect as caused by the preceding change, because of the controlled nature of the investigation (Altman, 1991). Even with randomised trial data there must be an assumption that no bias occurred in allocation and compliance, or that any such bias can be handled by adjustment procedures as such assumptions are not always correct (Greenland *et al.*, 1999).

Causal pathways can be either direct or indirect and causal diagrams can be used to illustrate these. On any individual pathway, the relationship can be an accumulation of risk (independent or clustering) or chain of risks (additive or trigger). A number of methods have been developed to describe these cause and effect relationships and include Directed Acyclic Graph (DAGs) (Pearl, 2000a; Hernan *et al.*, 2004) and Influence Networks/Influence Diagrams. Using such

techniques allows the study designer to ask which variables need to be controlled to estimate the causal effect of the intervention on the outcome. Therefore, the study design is more likely to identify and quantify the causal effects. Causal diagrams can reveal unnoticed shortcomings of those criteria when used in considering multiple potential confounders (Greenland *et al.*, 1999). However, it appears that such techniques have not yet been applied to MSDs and additional work would be needed to develop existing models (Karsh, 2006) to use these techniques.

All studies that assess causation include time in the design and are thus longitudinal studies, either prospective or retrospective. Prospective studies usually follow individuals forwards from some point in time, whereas retrospective studies, select individuals and factors that have occurred in the past.

3.2.3 Determining study sample size and power

As part of the proposal for any epidemiological study, there will be a sample size calculation identifying how many people need to be included for the study to have sufficient power to answer the questions posed. The absence of such a calculation can be considered unethical, since the study then carries a considerable risk of failing to demonstrate a treatment difference when one is really present (i.e., Type II error) (Pocock, 1983). The inclusion of too many people in the study is also considered unethical, especially in a clinical trial where there are considerations of the risks to the well being of the subjects, as well as the unnecessary use of medical and financial resources. The study should be representative of the population to which the results will be generalised and calculating the sample size is one part of achieving this.

The magnitude of the intervention is a crucial consideration since, if a genuine dose-response relationship exists, the dose of the intervention has to be sufficiently large for the effect on the response variable to be detectable and this needs to be considered in the power calculations that are used to determine the target sample size. Sample size calculations should be based on the principles of hypothesis testing and should state:

- The proposed analysis methods;
- The size of the increased risk that it is desired to detect, i.e. the effect size;
- The chosen significance level (or P-value);
- The probability of achieving this level of significance (power);
- Standard deviation of the variable (in each group);
- The follow-up period required for the target significance level and power;
- Cluster size;
- Number of clusters;
- Projected initial participation rates;
- Projected drop out rates.

The type of power (sample size) calculation used will depend on the precise study design selected so detailed estimates are not appropriate and are not provided in this report.

The study protocol should define which individuals are to be recruited (inclusion and exclusion criteria), intervention schedules, data to be collected, analysis methods, contingency plans for foreseeable problems, and study personnel.

Account must be taken of potential difficulties in finding appropriate individuals prepared to participate. Given the likely need to use a clustered design in an intervention study, this will

start with the need to find workplaces containing clusters of individuals in jobs that are suitable targets for interventions.

The calculated sample size must take into account the inevitable loss of data because of non-responding and loss of subjects to follow-up. Further adjustments should be made if the final analysis is to be adjusted for the effect of confounding variables, if the examination of subgroup effects is planned (Kirkwood and Sterne, 2006), or if there will be testing of multiple dependent variables or of interactions between risk factors.

Power calculations for complicated trials including sequential and clustered trials involve complex statistical methods, for example, CRTs have two components of variation (within cluster and between cluster). These sources of variation should be estimated separately and both must be taken into account when calculating sample size for CRTs. This can be done through using the intra-cluster correlation coefficient (ICC) (IJzelenberg *et al.*, 2007) or the between-clusters coefficient of variation (CV) (Hayes and Bennett, 1999; Medical Research Council, 2002; Ukoumunne *et al.*, 1999). Generally, increasing the number of clusters offers more increase in power than increasing the number of individuals per cluster.

Because of the complexity of power calculations and the ease with which mistakes can be made, all study design decisions and power calculations will need to involve a statistician. A recommended software package for performing power calculations is PASS 2005 (Hintze, 2005). It is essential to carry out sample size calculations for several different scenarios, so that the project team can make an educated decision on the study design, weighing up the logistics and costs (Kerry and Bland, 1998). An iterative approach will allow testing of a number of different designs to evaluate the most suitable design, and simulation may be used as part of this process (Hopkins, 2000).

Non-technical considerations will also need to be taken into account in determining target sample size (Rothman and Greenland, 1998). In effect, this is a cost-benefit analysis of the trade-off between increased precision and the cost of the increased sample size. The greater precision has a value to the beneficiaries of the research but this value is ultimately indeterminate as the number of beneficiaries is always uncertain. In addition, many potential benefits involve social, political and biological factors that are almost never quantified. "Consequently, only informal guesses as to a cost-efficient size for a epidemiologic study are feasible" (Rothman and Greenland, 1998) and it must take into account unquantified practical constraints and the practical implications of the study size.

A different and pragmatic approach to sample size calculations termed "sample size on the fly" has been suggested (Hopkins, 2000). This depends on defining a target confidence interval for the variable of interest and continuing recruiting subjects until the size of the confidence interval is reduced to the target value. Hopkins' argument is that for non-null effects this allows much smaller sample sizes to be used. While he gives examples of how this approach can be used in some longitudinal designs, such as pre-post studies, he does not indicate that the approach has been extended to methods such as Cox regression (Proportional Hazards Models, PHMs) that are used to evaluate time-to-event data. Any proposal to take such an approach should therefore be evaluated very carefully to test the robustness of the proposed design.

The following give some indications of the scale of studies that may be needed:

- Lipsey (1996) noted that: "When the number of respondents in a study is less than 500-1000 *per group* (e.g., treatment and control) sampling error can easily be large enough to obscure meaningful effects".

- Kraus *et al.* (1997) discussed an example sample size calculation for a hypothetical back pain cohort study comparing exposed and non-exposed groups and recommended a conservative estimate of at least 1500 subjects.
- Zwerling *et al.* (1997) cited a personal communication of a calculation that reduction of injuries by 25% would take 6 or 7 years follow-up of 3800 workers to achieve power of 80% at 5% significance. They noted that measurement of injury rates "generally requires very large sample or long follow-up times, or both" and that "few companies have enough employees to even enter into a trial".
- IJzelenberg *et al.* (2007) reported that the design of their CRT was based on a sample size calculation using an ICC of 0.05, an average of 20 workers per cluster, an initial participation of 75% and a loss to follow-up of 30%. This was anticipated to be able to detect a difference of 10% in prevalence between the intervention and control groups (power 80%, one sided significance of 5%) with 350 workers in nine intervention clusters. (It appears that the figure of 20 workers per cluster relates to those completing the study, not the number employed in the workplace).

3.2.4 Controlling confounding and bias

Occupational studies often need complex statistical methods to take account of confounding and bias. Confounding is not a source of error in an intervention study, but rather a phenomenon that must be understood. However, failure to take confounding into account in interpreting the results of a study can lead to errors and can bias the conclusions of the study (Gordis, 2000).

The definition of confounding is that there are alternative explanations for an observed association between a risk factor and a health outcome, making it difficult to assess the effect of each risk factor on the outcome variable. Furthermore, most occupations involve exposure to more than one potential risk factor and the possibility of confounding by other occupational exposures must be considered in the context of each study (Checkoway *et al.*, 2004). Many observational epidemiological studies assume a true association has been observed and might derive a causal inference when, in fact, the relationship may not be causal, but rather a result of confounding by a third factor that is both a risk factor and associated with the exposure in question. Therefore, as most causal questions involve the relationships of multiple exposures, confounding and interaction characterise virtually every situation in which aetiology is addressed (Gordis, 2000). If confounding cannot be avoided at the design stage of a study, then disentangling the causal links is often difficult and requires more complex statistical methods (Mullner *et al.*, 2002). However, if the relevant variables are measured, confounding can be addressed.

Bias, on the other hand, is a result of an error in the way the study has been carried out and is defined as "any systematic error in the design, conduct or analysis of a study that results in a mistaken estimate of an exposure's effect on the risk of diseases" (Schlesselman, 1982). This can result in either an overestimate or an underestimate of the difference between interventions. Possible biases are numerous and need to be assessed and, if possible, eliminated as they affect the validity of the findings (Gordis, 2000). Sackett (1979) identified 35 different biases that can occur in case-control studies. Other study designs will have biases typical to that design, for example, volunteer bias is more common in cross-sectional studies (i.e. questionnaire non-responders are usually less-healthy) whereas case-control studies are susceptible to recall bias (Altman, 1991). Bias can also be due to systematic differences between individuals

There are also issues of recruitment and differential attrition biases. Inevitably, there will be individuals in any workplace who choose not to participate in or cooperate with the study and this may be a source of recruitment bias. Differential attrition is similar, but results in

individuals dropping out of the longitudinal phase of a study due to uncontrolled differences between clusters that are not relevant to the study.

3.2.5 Randomisation and alternatives

Random allocation can be used to prevent bias or judgement in the selection of individuals to participate in the different interventions (Altman and Bland, 1999). The technical meaning of randomisation is for each individual to have a known chance, usually an equal chance, of being given each intervention, and the intervention to be given cannot be predicted. There are different ways of conducting randomisation including stratified randomisation, cluster randomisation and block (or restricted) randomisation, simple randomisation and random permuted blocks. Block randomisation ensures that similar numbers of subjects in each group stay close, and stratified randomisation keeps the groups balanced for certain prognostic subject characteristics (Altman and Bland, 1999). Cluster randomisation is used for numerous reasons, including administrative convenience for investigators, improving subject compliance, avoiding contamination of the control group by the intervention group or cross-talk between groups (Karsh *et al.,* 2001) and because workplace interventions are naturally applied at the cluster level (Donner and Klar, 2004). Unequal randomisation, although relatively uncommon, is useful in small intervention studies where there is no prior information on the efficacy of a new intervention (Pocock, 1983).

In occupational epidemiology, multi-centre studies are often used to aid recruitment, increase geographical spread and increase the number of staff available to run the study. Balancing for institutions is a relevant method of randomising and stratification by institutions entering subjects should be considered since different institutions can show very different response rates for their subjects for reasons of participant selection and experimental environment. For further discussion on stratifying with institutions (by using random permuted blocks within strata to balance for individual factors other than institution), see Zelen (1974; 1979).

With regards to MSD interventions, it has been noted that randomising engineering controls in multiple workplaces is extremely difficult and that it is much easier to randomise interventions (such as exercise, education and treatment) aimed at personal behaviours (Silverstein and Clark, 2004). One such study (Lavender *et al.,* 2007) argued that randomisation within workplaces was necessary to control for potential differences in organisational cultures with regard to injury reporting despite the risk of cross-contamination of the two study groups by individuals working alongside each other.

An acceptable alternative to randomisation is minimisation, which aims to balance control and intervention groups with respect to factors likely to influence the outcome (Altman, 1991). Differences between groups will almost certainly exist despite the use of random allocation and this allows direct control of these differences on important variables. Minimisation avoids randomisation solely by chance, as it reduces any difference in the distribution of known or suspected determinants of outcome, so that any effect can be attributed to the intervention under test. Researchers should determine at the planning stage of the study which factors they would like to see equally represented in the two groups (Treasure and MacRae, 1998). In general, minimisation is of greatest value in relatively small trials (say with less than 100 subjects) where several subject factors are known to be of research importance since in a small trial a large difference can occur in one or more of the prognostic factors purely by chance. However, if used, it is easy to include institution as another subject factor (stratum) (Pocock, 1983). Minimisation is a technique mainly used in clinical trials, but is likely to use up too many resources for occupational experimental trials and is therefore not recommended for intervention studies.

3.2.6 Blinding and prior knowledge

Studies involving human volunteers are required in almost all circumstances to ensure that the consent ("informed consent") that volunteers give to participate is informed by knowledge of the purpose of the study, the procedures involved and the potential risks and benefits. In the case of MSDs, there is widespread knowledge in the community as to their prevalence and nature and of the risk factors for them. Moreover, there have been widespread publicity campaigns to raise the profile of the biopsychosocial approach to managing sickness absence and return to work. In the UK, these have included publications such as *The Back Book* (Roland *et al.*, 2002), media campaigns such as *Working Backs Scotland* (Waddell *et al.*, 2007), and inspection and enforcement campaigns such as the joint HSE/LA *Better Backs!* campaigns in 2005, 2006 and 2007/8 (http://www.hse.gov.uk/betterbacks). It is therefore to be expected that a significant proportion of any subjects recruited to an intervention study will have heard the "stay active with back pain" message. A significant proportion will also be aware of the importance of work-place ergonomic factors as risk factors for back pain.

From this, and from the nature of work-place interventions, it follows that it would be almost impossible to blind participants as to their status as a member of an intervention group or a control group. On the same basis, it would be difficult to conceive of a placebo intervention in such circumstances. This raises an important methodological issue: Is it meaningful to take a concept such as placebo that was developed in the context of trials involving the administration of medication to patients, and to apply it to workplace intervention studies? There is almost no discussion of this issue in the literature on ergonomics interventions, with one notable exception (Volinn, 1999). There is some discussion in the wider occupational medicine literature by Kristensen (2005), who noted that "blinding and the use of placebo are not core elements of the RCT" but that they have special relevance for biomedical research.

Earlier discussion (Skov and Kristensen, 1996) had identified the importance of the effect of the presence of researchers and their interest in the workers on the behaviour of subjects and their likelihood to report MSD symptoms. They described these as the "placebo effect" and the "nocebo effect" which are respectively positive and negative health effects resulting from patient beliefs about treatments which are in themselves inert or ineffective. However, they comment that, if the presence of observers increases workers' awareness of safety measures, the presence of the observers cannot be inert. They therefore argue that blinding and randomisation could be superfluous in prevention effectiveness studies aimed at testing methods of reducing exposure to known risk factors.

Volinn (1999) suggested that "sham" interventions are possible but would clearly need to be carefully specified to be appropriate for any particular intervention or study design. He noted that in double-blinded trials of analgesics, the size of the placebo effect depended on how powerful the active ingredient was perceived to be. The implication is that if a sham ergonomic workplace intervention is used, it must be perceived by the recipients as potentially beneficial. Volinn (1999) also suggested that an intervention study should compare three groups: an intervention group receiving the active intervention that is of interest; a placebo group receiving a sham inactive intervention; and a control group receiving no intervention.

Volinn (1999) also raises a number of practical difficulties including the need for the individuals who actually implement ergonomics interventions to be unaware of which interventions are active and which are the placebo so that they communicate to the recipients a belief in the effectiveness of the intervention they are delivering. However, the topic of MSDs is topical and relevant to many people and the biopsychosocial approach and the early return to work message have been, and will continue to be, widely disseminated and information about them is available almost instantaneously via the Internet. It is therefore highly likely that a

motivated individual could easily find sufficient information to allow them to determine which was the control and which was the active intervention.

If it is difficult to blind participants to their membership of an experimental group or a control group, then different attitudes may arise in the two groups. The MRC (2000) framework guidance warns that 'The use of a control group in psychosocial and behavioural research can produce "resentful demoralisation" among the control group triggered by a perception of differential benefit for the intervention group among participants or providers.' Related to this, an employer or workplace may not permit inclusion of employees within a control group on the basis that the proposed intervention has a perceived benefit and they cannot justify continuing to expose the control group to the existing risks (Karsh *et al.*, 2001).

One solution would be to move away from using a placebo group to a study which compares the control group that does not receive an intervention to two intervention groups, without any prejudgement as to the effectiveness of either. However, unless the effectiveness of one of the interventions is already known, this makes it impossible to determine the absolute effectiveness of either intervention compared to no intervention (Lavender *et al.*, 2007). This situation should be avoided if possible. Another possible solution would be a study based on a crossover design where the initial control group receive the intervention at a later stage. In a true crossover study, the intervention group would then revert to the control condition. This is very likely to be impossible in this kind of study as removing a successful implementation is unlikely to be acceptable to participants.

Given the nature of the implementation process for an intervention study, it is likely that there will be not only a period while access to a site or group of workers is negotiated, but also an extended period while the intervention is being designed and its implementation planned. Consideration should therefore be given to treating the pre-intervention phase as a control phase.

The effect of these factors on reporting of cases of MSDs will need to be considered at the project design stage. If the target outcome is solely lost-time then it will be confounded by differing expectations about when an individual decides that an MSD is sufficiently severe to justify taking time off work. If it is taking time off to seek care, then the availability of health care through the employer or outside working shifts will be confounders that will affect decisions to take time off. Compensation systems and the early reporting/return-to-work and sickness absence systems of employers will also be relevant.

3.2.7 Implementation

All intervention studies should include a pilot period, unless this is impractical. In addition, all variables should be validated in previous studies, since if they are not validated, the study could end up analysing the efficacy of the new measuring system as opposed to measuring the outcome of interest.

3.2.8 Study documentation

A large-scale intervention study that runs over an extended period will require careful documentation, especially to reduce the risk of information loss if members of the study team leave. Documentation will be required in order to communicate the purpose of the study to potential stakeholders and participants. The precise form that such documentation takes will depend on the study protocol and the amount of information that needs to be collected or communicated. The layout and wording will need to take into account the literacy level of the target readers and the means of delivery. Where data are being collected using paper documents, account will need to be taken of the ways in which the data will be recorded and

how they will be managed and aggregated for analysis. The accuracy of the data entered will need to be ensured using error checking techniques and, possibly, double entry. Privacy and security of data will also need to be planned, especially when data are being collected or transmitted electronically. Documents are likely to include:

- Study protocols and training material
- Submission for ethical approval
- Information packs
- Consent forms
- Baseline questionnaires
- Follow-up questionnaires
- Baseline and post-intervention survey protocols
- Baseline clinical examination protocols
- Diagnostic criteria
- Validation of all methods of measurement
- Follow-up timetables
- Progress reports and final reports
- Conference and peer-reviewed scientific papers

3.2.9 Access to the workplace

Carrying out an intervention study will require full and willing cooperation from the employer where the intervention takes place. The precise design of the study will determine both the direct and indirect costs to the employer. Direct costs are likely to include management time, loss of output by production staff while being recruited and studied, and provision of facilities to the study team. The lower the projected cost to the organisation; the more likely it is to be willing to cooperate with the study.

Gaining access to working populations is becoming increasingly difficult (Punnett and Wegman, 2004; Waters, 2004a). Security and commercial issues are very likely to lead to some organisations being unwilling to allow access to an external study team. While interventions among small and medium-size employers (SMEs) have been reported (Straker *et al.,* 2004), many SMEs may decline to participate due to having insufficient resources to be able to participate without major cost to or disruption of their business. The "gatekeepers" within each employer (Stephens *et al.,* 2004) will need to be persuaded that participation is worthwhile.

The relationship between the study team and the employer will also need to be considered. The perceived relationship between HSE and the study team will have a significant effect on the willingness or otherwise of a firm to participate. If a firm has a positive relationship with HSE and a proactive approach to health and safety, they might be willing to accept a study team with direct involvement by HSE employees, such as staff from HSL. If they are afraid that involvement in such a study could result in enforcement action by HSE inspectors they will be unlikely to volunteer to allow the study to take place in workplaces under their control even if the study team were from an outside organisation.

In order to minimise risks to the study, it will be necessary to ensure that support for an intervention is obtained throughout the organisation it is implemented in. This will need to start with commitment from senior management and safety management. This commitment will

need to be spread down through the organisation so that line managers fully cooperate. In organisations where they have members, Trade Unions will need to be approached to obtain support, which is often given and is usually extremely valuable.

It is likely that firms undergoing change for other reasons will not be suitable locations for the study to take place as such a firm will have as its primary concern implementing its own changes, and possibly ensuring that the business is additionally compromised.

3.2.10 Participant recruitment and retention

The ideal study would attract interest from large numbers of potential participants, have inclusion criteria that fit a wide pool of individuals, be of obvious benefit, have minimal negative aspects and be easy to participate in. Other considerations that will affect the ease of recruitment of participants include:

- The nature of the intervention;
- Efficiency of contacting potential participants;
- Top-down commitment in the organisation to the project;
- The industry sectors targeted;
- The job types targeted;
- The inclusion/exclusion criteria for organisations, jobs and individuals;
- Individual histories of symptoms/problems;
- Literacy issues.

In occupational studies, it must be expected that there will be turnover of staff employed in jobs included in the study and that there will be changes to jobs that participants carry out. Some employment sectors and firms are more prone to change than others and wider macro-economic factors, such as a decline in economic activity, can lead to individuals losing their jobs.

3.2.11 Follow-up

In order to have a successful study, with limited dropouts and good data, the follow-up period in a prospective longitudinal study is vital. To maintain a high response rate, the study should ideally provide suitable incentives to participation and retention, make sure the researchers have up-to-date and accurate individual details, and consider the follow-up methods to be utilised. Some of the issues needing to be considered in the follow-up period are:

- Duration of follow-up;
- Frequency of follow-up, hence number of follow-ups;
- Whether to repeat baseline measures;
- Measurement methods for outcome measures;
- Address/contact details checking;
- Multiple contact methods — visit, interview, clinical examination, post, phone, web page, email, text messages;
- Data triangulation — validating data by seeking confirmatory data from other sources.

Multiple follow-ups involve regular contact with study participants and are advantageous in improving data quality through more frequent measurement. They also reduce the likelihood of

memory limitations making data inaccurate and therefore allow more precise measurements of when incidents of interest occur and hence better estimation of latency periods (Karsh, 2006).

Every effort should be made to get as high a response rate as possible at each stage of recruitment and follow-up. However, it must be recognised that there will always be losses to follow-up in cohort studies as some individuals will not be followed up for the full length of the study, even with a short follow-up period. Such "right-censoring" will be due to a variety of reasons, including companies going out of business or laying off workers, or individuals changing jobs, refusing to continue participating, moving without leaving forwarding addresses, changing phone numbers or email addresses, leaving the workforce due to illness, death or pregnancy. On top of these, individuals that suffer the outcome of interest to the study are thereafter treated as right-censored, so the available pool of individuals still at risk in the study decreases with every incident case.

3.2.12 Study management and financing

The issue of project management and finance is considered in detail in Section 4 of this report. However, it is vital that study protocols should consider:

- Probability and consequence of cost and time overrun;
- Budget constraints and cutbacks;
- Changes in staffing of the study team over an extended study duration.

3.2.13 Ethics considerations/approval

All proposals for studies involving human subjects are scrutinised by an ethics committee to ensure that the potential benefits from the intervention/treatment outweigh the potential risks. The fundamental ethical principles underpinning research on human beings are described in national and international guidelines (Council for International Organisations of Medical Sciences, 1993; 2002; Medical Research Council, 1998; Council of Europe, 2005; The General Assembly of the International Statistical Institute, 1985). The World Medical Association (WMA) (2004) developed the Declaration of Helsinki as a statement of ethical principles to provide guidance in medical research involving human individuals, including research on identifiable data.

Key issues considered are:

- Respect for the dignity of the subject and his/her well being;
- The free, informed consent of the subject to participation without undue inducement;
- The benefit–harm balance of the study (beneficence and non-maleficience), particularly where the subject will not benefit directly;
- Distributive justice, i.e., the equitable distribution of both the burdens and the benefits of participation in research;
- Confidentiality and hence data storage issues;
- The use of appropriate statistical methods in design and analysis.

Moreover, the WMA declared that any study that uses substandard statistical methods should be deemed unethical. Ethical issues for clustered randomised trials are more complicated (Medical Research Council, 2002), as consent is often obtained at the group level, the level at which the intervention is implemented. Even so, where feasible, individual consent should be obtained and related matters taken into consideration.

3.3 STUDY DESIGN

3.3.1 Choice of study type

There are important issues relating to study design in interventions studies. In particular, "Observers of the medical literature have long noted a particular relationship between study design quality and the results of intervention studies: study design quality and reported outcomes are often inversely related". Even more worryingly, it has recently been argued on statistical grounds that the majority of published research findings are likely to be false (Ioannidis, 2005), especially where effect sizes are small, a field uses variable study designs, definitions and outcome measures and where there are strong vested interests and prejudices in a field. Therefore, it is essential that the planners of a study designed to test the effectiveness of ergonomics interventions be realistic about its prospects for success and take proper account of meeting the requirements for methodological rigour and adequate power.

Epidemiological studies can be divided into two main types: descriptive and analytical. Descriptive epidemiology describes disease and/or exposure and may consist of calculating rates, for example incidence and prevalence. Descriptive studies do not use control groups and can only generate hypotheses, not test them. Analytical epidemiology compares an exposed group with a control group and usually tests a specific hypothesis. It includes two types of studies: observational, such as case-control or cohort studies of incidence; and experimental studies, including randomised controlled trials and intervention studies, where variables are directly manipulated to test their effects on the outcomes of interest. These are generally prospective as they monitor the impact of an intervention over time and are therefore able to give confidence about causation.

The two types of intervention study are clinical trials and community trials (Woodward, 1999). The key feature of an intervention study is that the allocation of an individual to an intervention or a control group is planned, even if randomisation and blinding are used to prevent observer bias. Thus, the investigators initially assign the intervention to whomever they wish and then observe what happens prospectively. They either apply the intervention to individuals with health problems to decide on an appropriate clinical treatment or to those presently free of symptoms in order to decide upon an appropriate preventive strategy in the community or workplace. There is an important difference between a controlled clinical trial and a workplace intervention study (Skov and Kristensen, 1996); in a clinical trial the subject group is actively exposed to a particular treatment method, such as a drug or a surgical method, and the comparison group are not exposed or are exposed to a non-active placebo. In an intervention study, generally the purpose is to remove the active exposure from the intervention group and to investigate what happens to people whose exposure is stopped relative to those whose exposure continues. As a consequence, this kind of study design is only suitable to conditions where the exposure has reversible effects so that symptoms regress when the exposure is reduced or ceases. It is eminently suited therefore to WRMSD studies since MSDs are typically of short duration and liable to repeated occurrence. It would not be suited to chronic or degenerative musculoskeletal problems, such as ankylosing spondylitis or to rare serious spinal pathologies such as cauda equina syndrome.

The main advantage of intervention studies is their efficiency in investigating causality, as they ensure that the 'cause' precedes the 'effect'. They can also control for confounding and ensure that interventions are compared efficiently. A reason for avoiding this study type would be if the intervention were potentially harmful as this would limit recruitment and raise ethical concerns. Another disadvantage is that the study selection criteria may screen out categories of individuals as inappropriate, perhaps because of job type, age, or other factor, restricting extrapolation of the results. Another disadvantage arises because randomisation of subjects to

groups is very difficult within the operational constraints encountered by researchers entering functioning organisations as little more than tolerated guests (Griffiths, 1999).

In order to illustrate the differences between epidemiological studies, the basic designs are listed in Table 5, and their relative merits for assessing the efficacy of interventions in an occupational setting on MSDs are listed. The information in the table is not intended to be exhaustive, as, for example, medical research studies often use mixed versions of basic designs, such as nested case-controls, case-cohort, case-crossover, and panel study (or repeated cross-over).

Despite the acknowledged difficulties, it is concluded that because of the need to assess causation and the effects of an experiment, longitudinal randomised controlled trials are the most appropriate study type for assessing the effectiveness of ergonomics interventions in the workplace.

3.3.2 Cross-sectional studies

The simplest kind of observational study is the cross-sectional survey, where a set of individuals are observed or questioned to seek information on their risk factor exposure and/or disease status. As they only provide a snapshot in time, they can measure the prevalence of disease only. Cross-sectional studies will, therefore, not inform the researcher if the intervention had worked or not and have limited usefulness as it is important to consider before and after effects to assess if the intervention is causal.

Repeated cross-sectional studies can be carried out at different time points to assess trends over time. However, as these studies can involve different groups of individuals at each time point, it can be difficult to assess whether apparent changes over time simply reflect differences in the groups of individuals studied.

It is recommended that cross-sectional study designs are not used to research preventative intervention MSD questions as they are unable to assess causation.

3.3.3 Case-control studies

In a case-control study, a group of individuals with the disease or condition of interest (cases) and an unaffected group (controls) are identified and their past exposures to the factors of interest are compared. This is in contrast to the design of a cohort study, which begins with a group of exposed people and compares them to a non-exposed group. The advantages of the case-control approach are practical as it is relatively simple and thus quick and cheap. It is also valuable when the condition of interest is very rare.

There are several problems with case-control studies. One of the major problems involves subject recall; some individuals may have limited memory of their exposure, thus resulting in them being misclassified (i.e. as cases when they were not exposed and should be controls). Another difficulty is that cases and controls may differ in characteristics or exposures other than the one that is targeted for study. To avoid the two groups being very different, the cases and controls can be selected and matched, either on group or individual characteristics (Gordis, 2000). Finally, a case-control study is not appropriate for measuring the effect of an intervention, as sampling is carried out according to disease rather than exposure status. However, the most significant restriction of case-control studies in measuring preventative measures in MSDs is that they are unable to demonstrate causality (Woodward, 1999) and therefore, should be avoided for assessing preventative interventions in MSDs.

Table 5. Epidemiological study designs

Type of study	*Timing*	*Form*	*Main features*	*Pros*	*Cons*
Cross-sectional	Cross-sectional	Observational	Association vs. causality Incidence/prevalence cases	Useful for generating hypothesis	Unable to establish causality
Repeated cross-sectional	Multiple cross-sectional (over time)	Observational	Cross-sectional data are recorded in a succession of surveys at two or more points in time, with new sample on each occasion.	Permit measurement of differences or change in variable over time Used to located sleeper effects (connections between events that are widely separated in time)	Unable to detect changes within individual as a different group is measured each time
Panel	Multiple cross-sectional (over time)	Observational	Same individuals studied repeatedly.	Can detect and establish the nature of individual change	Panel attrition due to refusals, changes of residence or death of respondent Course of events between discrete recording points remains unknown Conditioning of individuals
Ecological	Cross-sectional/ Longitudinal	Observational	Population level (grouped)	Use of readily available data Useful when risk factor measurement at individual level is particularly prone to error	Can only analyse population level /not individual level May encounter ecological fallacy
Cross-over	Longitudinal	Experimental/ Intervention	Analyse accounting for paired data	Cheap Limits within individual variation Smaller sample size	Lacks statistical power in detecting treatment effect Carry-over effects Only suitable for long-term conditions with intervention providing short-term relief Takes longer

Type of study	*Timing*	*Form*	*Main features*	*Pros*	*Cons*
Case-control	Longitudinal	Observational	Retrospective Selection of cases/controls Matching	Suitable for rare diseases Quick and cheap Multiple risk factors can be studied Smaller sample sizes than equivalent cohort studies Able to evaluate confounding and interaction	Suffer from bias error Observer/respondent bias No time sequence Can investigate only 1 disease outcome Provide approximate estimates of relative risk
Cohort	Longitudinal	Observational	Exposure/outcome measurement	Suitable for rare exposures thus able to study wide range of diseases Give sequence/causality Multiple diseases can be studied simultaneously	Loss to follow-up Expensive and time-consuming Not suitable for rare diseases Conditioning of individuals Exposure may change
Nested case-control (based on cohort)	Longitudinal	Observational	Exposure/outcome measurement	Provides results before the cohort finishes Saves resources Individuals matched Limits bias error	Not suitable for rare diseases Conditioning of individuals
Trial	Longitudinal	Experimental/ Intervention	Intervention	Can demonstrate causality Compares interventions efficiently Control for confounding	Can be costly Ethical issues with giving experimental interventions Selection bias (restricting generalisability of results)

3.3.4 Cohort studies

Cohort studies track the same people over time, and therefore the observed differences in the members of the cohort are more likely to be the result of genuine changes than differences between individuals. By doing repeated measures at the individual level, longitudinal studies have more power than cross-sectional observational studies, by being able to exclude time-invariant unobserved individual differences and by observing the temporal order of events.

A cohort study could be used to assess the effect of a "found" or uncontrolled intervention and allow the researcher to control for confounders and measure various outcome measurements at different time points (thus having the possibility of conducting a nested case-control study). Because of the need to observe unaffected individuals until a fair proportion develop the outcome of interest, cohort studies can take a long time and may thus be very expensive. They are usually unsuitable for studying rare outcomes, as it would be necessary to follow a very large number of individuals to get an adequate number of events (Altman, 1991).

A number of potential biases must be either avoided or taken into account in conducting cohort studies. The major biases include information, analytic, non-response and loss to follow-up, and in assessment of the outcome.

When trying to assess the aetiological effect of a risk factor, individuals recruited to cohorts should ideally be symptom or disease-free at the start of the study. Ensuring that any exposure to the risk factor occurs before the outcome enables a causal role for the factor to be postulated.

Advantages of cohort studies include being able to give sequence of events, providing information on a wide range of outcomes and allowing changes in exposure over time to be studied. Because of their longitudinal nature, cohort studies would be the most appropriate type to assess ergonomic interventions (Punnett and Wegman, 2004; Waters, 2004a).

3.3.5 Randomised Control Trials

An RCT would probably be the optimal approach for assessing the effectiveness of preventative workplace ergonomic interventions (Waters, 2004b) as it can separate the effects of the intervention from those of extraneous factors such as natural recovery and statistical regression (Herbert and Bo, 2005). RCTs can manipulate the intervention so that groups are allocated without bias and so avoid any possible problem due to confounding factors (Woodward, 1999).

A disadvantage of RCTs is that they are generally costly and labour intensive, especially to keep individuals in the study, and usually have small numbers of participants, which means that they need to detect large differences between interventions. One way of improving RCTs, is to increase a study's sensitivity by carefully selecting individuals, intervention measures and the study endpoints (Rothman and Greenland, 1998). When conducted well, RCTs have the advantage of demonstrating causality and compare interventions efficiently.

A group of scientists and editors have developed the CONSORT (CONsolidated Standards Of Reporting Trials) statement (Begg *et al.,* 1996; Moher *et al.,* 2001; Altman *et al.,* 2001). This consists of a checklist and flow diagram recommended for use by authors when reporting an RCT (see Section 5.2).

3.3.6 Clustered Randomised Trials

In order to assess an intervention in an occupational setting, randomisation is likely to be done at the group or cluster level (i.e. by factory) instead of the individual level and hence the study is

termed a Clustered Randomised Trial (CRT). If the intervention involves supplying equipment or staff to an administrative unit then by randomising these units rather than individuals only a subset of the units receives the equipment or staff (Medical Research Council, 2002). This avoids cross-contamination, is cheaper than doing randomisation at the individual level and is administratively more convenient.

Although CRTs retain many of the essential features of individually randomised trials, they do have extra logistical, ethical and statistical issues to consider (Elbourne and Campbell, 2001; Kerry and Bland, 1998), and should usually be avoided unless RCTs are practically impossible. However, it appears to be a practical study design for a workplace intervention study. IJzelenberg *et al*. (2007) recently reported a CRT of an intervention to prevent low back using the CONSORT recommendations.

3.3.7 Crossover studies

In a crossover study design, the individuals receive different interventions during different periods of time. For example, the effect of intervention 1 can be individually compared with the effect of intervention 2 on each subject, allowing within-individual differences to be calculated.

Unfortunately, there are several disadvantages to crossovers that restrict their application. They are particularly vulnerable to the effects of subject withdrawal, since individuals that withdraw after the first period cannot be included in the analysis because they do not receive the other intervention (Altman, 1991). They are also less appropriate when the efficacy of the first intervention continues for a prolonged interval (Rothman and Greenland, 1998). If this is likely to occur, the trial may incorporate a 'washout' period between the intervention periods. Crossover studies are ideally suited for long-term conditions for which treatment only provides short-term relief (Woodward, 1999). Compared to parallel group studies, crossover studies are more complex to analyse.

The main advantage of crossover studies is that by accounting for between-subject variability in the outcome, they may be more efficient than a parallel group trial (Kirkwood and Sterne, 2006; Rothman and Greenland, 1998). Depending on the specific research question, a crossover study is potentially good for assessing an intervention to prevent MSDs.

3.3.8 Quasi-experimental studies

Quasi-experiments are a variety of experimental design where a quasi (*almost*)-experiment is done instead of a full experiment. Typically they are controlled studies in which exposure is assigned, but not according to a randomised experimental protocol (Cook and Campbell, 1979; Rothman and Greenland, 1998). They are frequently used by ergonomists to investigate research questions (Goldenhar and Schulte, 1996; Zwerling *et al.*, 1997). Recent examples include studies of participatory interventions (Laing *et al.*, 2005; Rivilis *et al.*, 2006) and a comparison of two groups with different exposures to biomechanical load (Bonfiglioli *et al.*, 2007). They are suitable for "found" experiments or observational studies but are not as powerful as a true randomised experiment.

One of their purposes is to capture longer time-periods and a sufficient number of different events to control for various threats to reliability and validity. Instead of investigating cause, they tend to report trends and instead of randomisation they tend to match subjects or worksites. Zwerling *et al.* (1997) describe them as being appropriate in circumstances where it is neither necessary nor ethical to carry out a randomised controlled trial. The comparison group serves to provide an estimate of what the injury incidence would be without the intervention. If selection or matching of subjects is not possible confounding can be controlled either by multivariate analysis or by stratification.

3.4 DATA COLLECTION

3.4.1 Data quality

In order for any study to be successful, consideration must be given to a number of issues regarding the data collected because the quality of any study is determined by the quality of the resulting data. This depends on the types of information to be collected and the methods used to obtain them and to ensure their accuracy. Moreover, the chosen data collection method will affect response rate, bias and costs. As well as outcome data, epidemiological studies of MSDs usually involve measurements of the workplace and the physical exposures experienced there. Some studies rely on data from records, although self-administered questionnaires and interview methods are very common means of data collection (Bowling, 2002). If an interview method is preferred, the issue of structured, semi-structured or in-depth needs to be addressed as well as whether the interview is to be personal or by telephone. Each method has its advantages and disadvantages, and each has implications for bias.

In an intervention study, it is important that the intervention should not evolve over time according to the experience of those providing it (Medical Research Council, 2000). This is to ensure that the same changes are implemented and that comparable data are collected. Therefore, quality checks and monitoring of the status of the implementation will need to be planned into the study. However, once an intervention has been shown to be effective and is being widely implemented, it is desirable that it should be allowed to evolve to reflect local conditions.

Whichever data collection method is chosen, it should be validated internally and externally. Failure to validate can introduce bias.

3.4.2 Variable definition and selection

Exposures for MSDs are complicated to measure because very large numbers of factors have been implicated as risk factors. The problem with many measurement methods is that they measure instantaneous exposure, not ongoing or historical exposure and are time-consuming to use. The methods that have been used for exposure assessment include (Hernberg, 1992):

- Static biomechanical models
- Dynamic biomechanical models
- Measurements of energy consumption
- Questionnaires
- Ergonomics assessments
- Registration of work load
- Posture measurement

Moreover, there is a need to understand better the specific effects of a number of factors (Punnett and Wegman, 2004):

- Dynamic forceful motions
- Prolonged low-effort exertions
- Extreme postures
- Repetitive motion close to the centre of the normal range
- Non-cyclical work

Finally, the measures chosen should satisfy the following criteria (Lipsey, 1996):

- Valid measurement of the variables of interest;
- Reliability of measurements over irrelevant variation in the occasion and circumstances of measurement;
- Practicality of measurement in the circumstances of the study;
- Sufficient sensitivity to respond to changes in/distinguish levels of the variable;
- Multivariate measures of outcomes to capture the range of aspects of the outcomes.

3.4.3 Baseline data

Data will be required that are sufficient to adequately characterise the differences between the intervention group and the control group before the start of intervention (Friedman *et al.*, 1998). These baseline data are likely to be of a range of types, both parametric and non-parametric. They are also likely to include both objective measures and subjective responses from participants, such as:

- Basic demographic and anthropometric data on individual participants;
- Contact details;
- Job details;
- Details of the employer;
- Details about the employer;
- Health status details, especially history of MSDs, measured with a tool such as the Nordic Musculoskeletal Questionnaire (NMQ);
- Relevant medical history;
- Results of a clinical examination;
- Psychosocial measures;
- Safety management systems in place;
- Safety climate measures;
- Details of exposure to the risk factors being studied, including measures of posture, activity and biomechanical loading;
- History of previous exposure;
- Measures of confounders and covariates.

Measurements of exposure to risk factors are likely to include photographic or video evidence. Although they have been widely used, (e.g., Bergstrom *et al.* (2007)), there are concerns about the lack of precision of questionnaire methods for obtaining physical exposure data, especially if a measure of cumulative load is being sought (Waters *et al.*, 2006). In fact, Waters *et al.* (2006) note the pressing need for a valid, reliable and practical method for estimating cumulative spinal loading.

Assessing physical exposure using surrogate measures such as job title, is an unacceptable method as the variability of exposures to individuals within job titles is very great (Punnett and Wegman, 2004; Gardner *et al.*, 2000). This is especially so where generic job titles, such as "production worker", are used to indicate position within a hierarchy, not the specific demands and activities of the job.

Baseline data need to be collected before and immediately after the implementation of the interventions. Data will also need to be collected on the process of implementing the intervention and on how well the final status of the intervention reflected the target. In other words, was the intervention implemented as planned? This will permit the measurement of the precise dose of the intervention as initially applied and an assessment of whether the intervention as implemented led to the intended change in exposure.

3.4.4 Outcome measures/case definitions

The target outcomes of the intervention need to be clearly specified at the outset, as do case definitions. This is fundamental to any intervention study to reduce the risk of reading previously accepted findings/conclusions into the data. In the context of MSDs it is necessary because there is a progression of health outcomes of increasing severity, and different interventions may have different effects on symptoms, symptom reports, 'injuries', sickness absences or the incidence of long-term disability (Waddell and Burton, 2001).

Careful selection of outcome measures/case definitions will enable the efficient capture of the information needed to test the intervention by focusing data collection on the outcomes of interest and avoiding the collection of unnecessary data. Outcome measures must be chosen carefully to maximise response rates at follow-up. It is strongly recommended that a hierarchy of case definitions be used to capture the range of possible outcomes. These can range from temporary discomfort, through acute injury, to long-term disabling work loss. Where possible, they should use accepted definitions in order to facilitate comparison with other studies. Indeed, standardisation of definitions is particularly important where clinical outcomes are being used and in other situations where data collection is to be carried out by a range of individuals.

The lack of data on latency periods mean that intervention studies can appear to fail if dose and response measurements are taken at the wrong times (Karsh, 2006). There are difficulties in measuring doses in a practical and economical manner and of measuring apparent cascading doses and responses. As a result, multiple outcomes should be measured, both short and long-term.

3.4.5 Follow-up data

The purpose of a follow-up phase of a longitudinal study is to collect data marking the transition of an individual to becoming a case of the outcome of interest. This can be done by measuring status at fixed time intervals and/or by recording when the change of state/event of interest occurs. Once time-to-event data or incident status data are available, they can be related to the exposure status of the individual. However, in a longitudinal study, there is always the risk that the exposure of the individual will change over the duration of the study because of various factors, including:

- Changes in the workplace, such as job redesign;
- Changes in working patterns;
- Changes of job;
- Changes in the individual, such as injury or health problems;
- Changes in the psychosocial context at work, such as changes in management or staffing in a work team;
- Changes in personal circumstances altering the amount of social support received.

It cannot be assumed, therefore, that measurements at baseline will adequately characterise the exposure throughout the follow-up period and appropriate monitoring or re-measurement of exposure will be needed. Possible methods for such monitoring include:

- Repeat of baseline questionnaires at follow-up;
- Questions about changes in the job at follow-up;
- Repeat of physical exposure measurements at follow-up.

A system for immediate reporting of incidents alongside a regular follow-up system is recommended in order to increase the probability of capturing incident events. An incident reporting system would probably attempt to capture:

- Date of data report;
- Date of incident;
- Nature of incident;
- Severity of incident;
- Results of a clinical examination and any first aid/medical treatment given;
- Repeat measures of the status of the intervention and its precise dose;
- Repeat measurements of health status and psychosocial status;
- Repeat measures of confounders and covariates;
- Any changes in employment and hence exposure status;
- Changes in health status that affect the ability to continue in the study (e.g. pregnancy);
- Changes in contact details.

A programme of regular follow-ups would collect data on a sub-set of these , i.e.,

- Date of data report;
- Dates of any incidents in the previous period;
- Nature of incident;
- Severity of incident, including amount of time off work;
- Repeat measures of the status of the intervention and its precise dose;
- Repeat measurements of health status and psychosocial status;
- Repeat measures of confounders and covariates;
- Any changes in employment and hence exposure status;
- Changes in health status that affect the ability to continue in the study (e.g., pregnancy);
- Changes in contact details.

3.4.6 Project management data

Finally, project management data will also need to be collected, including:

- Informed consent from participating firms and individuals;
- Contact details for firms and individuals;
- Evidence of validation and calibration of data collection methods;

- Participation rates;
- Response to follow-up rates.

3.5 DATA ANALYSIS AND INTERPRETATION

This section will discuss issues related to the analysis of the data. The analyses undertaken will depend on the original research question, the study design used and the types of variables measured.

Specific to occupational epidemiology, analyses will need to take into consideration worker turnover, job redesigns, exposure stability and consistency, non-work-related exposures (concurrent exposures) and the healthy worker effect. Moreover, analyses should consider missing data, non-compliance with the study protocol, and subject drop-out (Pearl, 2000b). Analysis of the effect of non-compliance with the protocol needs to consider the effect on exposure to risk factors, as well as health outcomes (Silverstein and Clark, 2004).

During many randomised controlled trials, participants are lost to follow-up, which can result in bias if the characteristics of these individuals differ between the randomised groups. Such differential attrition prevents a full intention-to-treat analysis being carried out and can introduce bias (Tierney and Stewart, 2005; Hollis and Campbell, 1999). It is therefore important to describe the missing data and take appropriate steps in the analysis (Omar *et al.*, 2004; Peng *et al.*, 2004; Collins *et al.*, 2001; Schafer and Graham, 2002; Carpenter *et al.*, 2002). Model developers should clearly state the extent of missing observations in their data and how these were dealt with in the modelling process. Before fitting the model, it is important to determine if there are systematic differences in the characteristics of subjects with missing risk factors as this could introduce bias. Furthermore, if the extent of missing data is large, appropriate methods should be used to substitute missing values and the results examined to see if the results remain consistent. Many methods are available such for substitution and, before fitting the model, a preferred approach should be selected in the light of the objectives of the study (Roberts *et al.*, 2002).

Analysis of intervention trials can be complex and should examine the size of the effect of the intervention, both before and after adjustment for baseline variables. Analysis of subgroups may also be needed. Analyses will need to be more specialised for cluster randomised trials or crossover trials (Kirkwood and Sterne, 2006) since clustered data are treated as repeated measurements in longitudinal studies. When analysing clustered data, summary measures for each cluster with robust standard errors should be reported and random effects models and Generalized Estimating Equations (GEE) should be used. Analyses of crossover trials take the design into account by using methods for paired data; for numerical outcomes, the mean difference between each subject's results on the first and second intervention is analysed and the standard deviation of the mean differences reported.

As mentioned previously, the ability to assess causation and association between exposure and outcome depends on the study design, which will in turn affect the type of analysis undertaken. Table 6 summarises the measures used to test association and the impact of an exposure (Kirkwood and Sterne, 2006).

Table 6. Measures of association and impact

Measures of association	
Risk ratios	Assess the strength of association between an exposure and an outcome
Odd ratios	
Rate ratios (or hazard ratios)	
Comparisons of the Risk, Odds and Rate ratios	Used for rare outcomes
Measures of the impact of an exposure	
Attributable risk	Gives the magnitude of the excess risk in absolute terms (sometimes a percentage: proportional attributable risk)
Comparing attributable and relative measures	Gives the measure of strength of an association compared to the excess risk.
Population attributable risk	The impact at the population level is assessed by the excess overall risk (or rate) in the population, as compared with the risk among the unexposed.
Potential impact of reducing exposure	Measure of impact that would be achieved by a completely successful intervention, which managed to eliminate the exposure.
Measures of the impact of an intervention	
Efficacy	The efficacy of an intervention is measured using the risk ratio to determine how many cases it prevents.
Number needed to treat	The number of individuals who must be treated to prevent one adverse event.

3.6 PRESENTATION OF RESULTS

Systematic reviews of ergonomics intervention studies have typically assessed them as having poor to marginal methodological quality (Tuncel *et al.*, 2006a; 2006b), mainly due to incomplete reporting of methods and findings. It is recommended that attention is paid to reporting in order to ensure that the results are presented as comprehensively as required, which will aid interpretation, application and future meta-analysis. Results should be presented in at least two stages; firstly with an initial report describing and summarising the data, and secondly presenting the results from all statistical analyses. The CONSORT statement (Moher *et al.*, 2001) includes a checklist and flow diagram recommended for use by authors reporting an RCT (see Section 5.2).

4 EXAMPLE PROJECT PLAN

4.1 INTRODUCTION

This section of the report gives an example of a possible project plan and illustrates the implications in terms of staffing, and duration, and hence cost.

It cannot be stressed too strongly that this example is hypothetical and has many untested assumptions included. All estimates of time required are crude. The estimates of costs are based on typical rates at HSL so should be seen as merely indicative of the scale of costs required for such a study. The detail of the interventions to be implemented is deliberately not specified, but it is assumed that engineering interventions are included.

As a result, any attempt to take the time or cost indications and to use them as a basis for a tender specification or as a benchmark to evaluate submitted tenders against would be a gross misuse of the example.

4.2 ASSUMPTIONS UNDERLYING THE HYPOTHETICAL PROJECT PLAN

The hypothetical project is based round a longitudinal clustered randomised study design where randomisation is done at the workplace level. The time estimates are based on the recruitment of five substantial groupings of clusters. Timings in the project plan are estimates in three-month blocks so it is assumed that each cluster grouping could be recruited within one three month period. This assumption may be untestable until the recruitment process is started. Each cluster grouping could relate to a particular type of intervention or to a particular industry sector. It is assumed that each cluster grouping would have at least 1000 participants, equally split between an intervention group and a control group. A follow-up period of one year is used.

Staffing descriptions are based on roles within the project. Staff time estimates for each role in each three-month block or phase are of the proportion of time required from a full-time team member. Full-time equivalent (FTE) numbers of staff are calculated by multiplying percentage time by duration and summing. The FTE estimates show that multiple individuals would be required at some stages of the study for some roles. At other stages, these roles are not required.

4.3 POSSIBLE GANTT CHART FOR THE PROJECT WITH CRUDE ESTIMATES OF STAFFING, TIME AND COSTS

A large scale, complex intervention study must inevitably have a significant duration. There are therefore complex logistical issues that must be managed effectively for it to be successful. An illustrative Gantt chart for the example project is shown in Figure 4. It assumes no overlap between project phases/stages, except in Phase 3, Data collection. Table 7 shows possible timings for the stages of the example project. Table 8 shows a breakdown by role of the possible staffing requirements of the hypothetical project. It includes reviews of the viability of the project at a number of break points and identifies the point of no return after which cancellation would be unwise. It also indicates the stakeholders that will need to be consulted at the different stages. Table 9 shows a breakdown of time estimates for the hypothetical project by phase and by job role.

The full timescale shown includes two years for publication of the results at scientific conferences and in peer-reviewed journals. The assumption is that the results of the study would be presented to HSE at the start of this period, in a report format but would then be submitted for peer-reviewed publication. While publishers are increasingly using electronic

submission and review, which are helping to reduce the period from submission to publication, the vagaries of the peer-review process and publication schedules mean that a substantial period must be allowed before final publication occurs. Because there would be little activity during this period, the staff time involved and associated costs would be relatively small.

On the basis of the example timings given, and assuming no rescheduling, HSE could expect to have final results that could inform its policy decisions 5.75 years after the project planning began. If a longer follow-up period was used this would increase the project duration directly. If recruiting clusters were to take, say, an average of 3 months longer than the assumed 3 months, this would increase the project duration by that amount.

The time estimates have been used to calculate estimates of cost. This involved using HSL charge out rates for appropriate grades of staff. As almost all the work would occur within the first six years of the project plan, total costs were adjusted by making an allowance for inflation. This was done by first allowing approximately a year for HSE to decide to fund the project and then averaging the costs to the mid point in the project. This resulted in making an adjustment for inflation over four years. An allowance of 25% was then added to cover project specific expenditure such as travel and equipment costs. Because of the very great uncertainty in such estimates at this stage, many of which would remain even at the end of Phase 1, a 100% contingency was then added.

The estimated total cost of this project, given the assumptions stated above, is approximately £11.5 million. This figure must be seen as only indicative. No breakdown of costs is provided, as one would be misleading. When comparing tenders received, HSE will want to take into account the different charging regimes that different organisations have. It is therefore recommended that in such a situation HSE compares the amount of staff time allocated in the submitted tenders. It is anticipated that such tenders would provide more detail of how staff time would be allocated to the various phases of the project.

The final plan for any project funded by HSE should be similar in outline. Any tenders received should be compared with this outline to ensure that all necessary activities are included. It should be borne in mind that tenders could differ in detail from this outline, particularly in relation to sequencing or overlapping of project activities.

Figure 4. Gantt chart for the hypothetical project

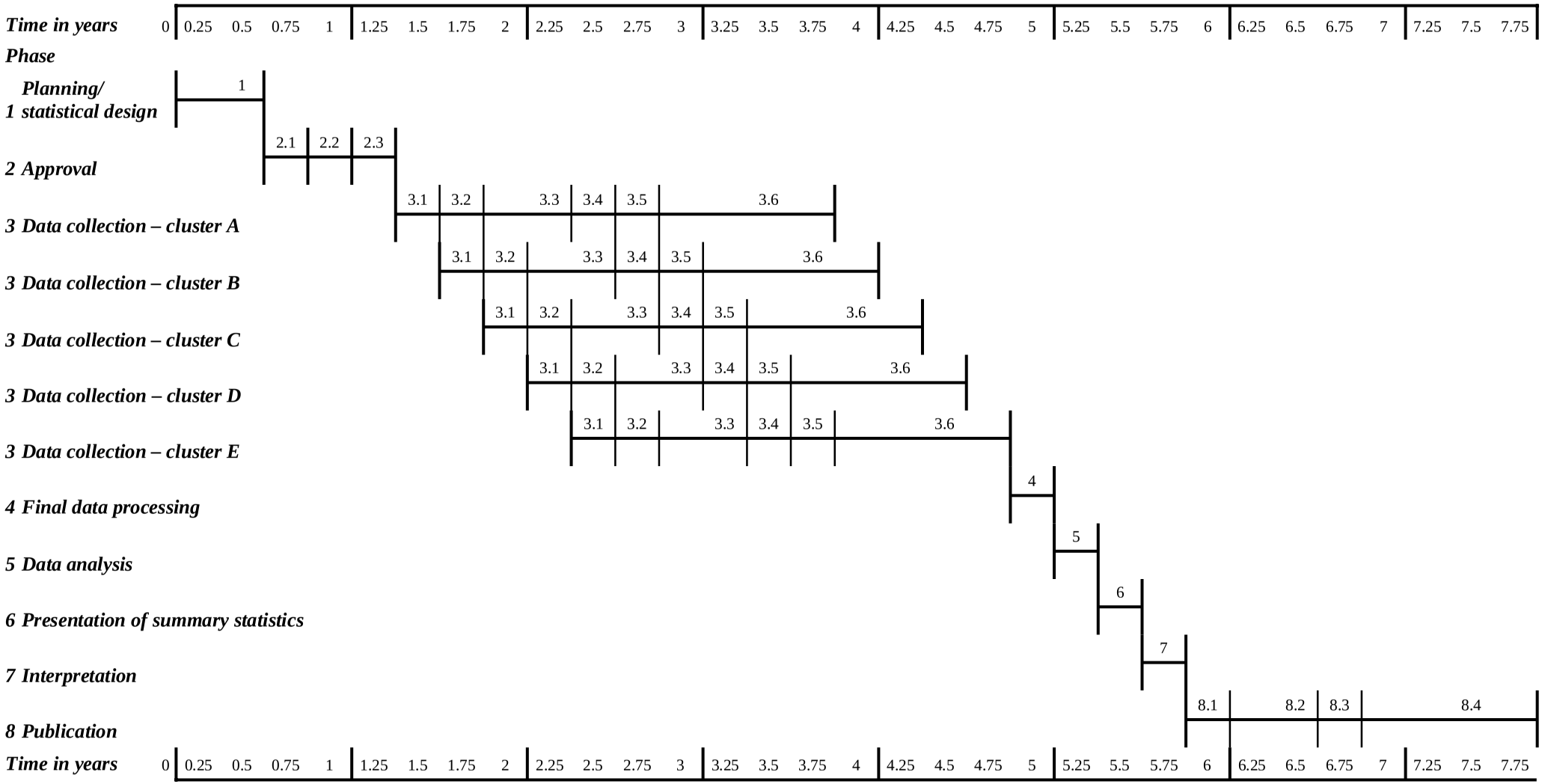


Table 7. Possible timings for the example project

	Phase/stage	*Stage duration*	*Time elapsed during phase*	*Total time elapsed*
1	***Planning/statistical design***	6 months	6 months	6 months
2	***Approval***			
2.1	Gaining ethical approval	3 months	3 months	9 months
2.2	Engagement of stakeholders	3 months	6 months	1 year 0 months
2.3	Staff training	3 months	9 months	1 year 3 months
3	***Data collection***			
3.1	Recruitment of firms in first cluster	3 months	3 months	1 year 6 months
3.2	Identification of suitable jobs and locations in first cluster	3 months	6 months	1 year 9 months
3.3	Designing, piloting and economic evaluation of interventions in first cluster	6 months	1 year 0 months	2 years 3 months
3.4	Recruitment of individuals, collection and processing of pre-intervention baseline measures for first cluster	3 months	1 year 3 months	2 years 6 months
3.5	Implementation of interventions, collection and processing of post-intervention baseline measures for first cluster	3 months	1 year 6 months	2 years 9 months
3.6	Collection and processing of follow-up measures for first cluster	1 year	2 years 6 months	3 years 9 months
3.6	Collection and processing of follow-up measures for final cluster	1 year	3 years 6 months	4 years 9 months
4	***Final data processing***	3 months	3 months	5 years 0 months
5	***Data analysis***	3 months	3 months	5 years 3 months
6	***Presentation of summary statistics***	3 months	3 months	5 years 6 months
7	***Interpretation***	3 months	3 months	5 years 9 months
8	***Publication***	2 years	2 months	7 years 9 months
8.1	Preparation of scientific papers and submission to conferences/journals	3 months	3 months	6 years 0 months
8.2	Wait for results of peer review	6 months	9 months	6 years 6 months
8.3	Revision of papers and resubmission	3 months	1 year 0 months	6 years 9 months
8.4	Making conference presentations/waiting for journal publication	1 year	2 years 0 months	7 years 9 months

Table 8. Possible staffing of the example project

	Stage	*Project staff directly involved*	*Other project staff involved*	*External stakeholders*
1	***Planning/statistical design***	Project manager MSD specialist Epidemiologist Psychologist Trials manager		Funding body; Collaborating organisations
2	***Approval***			
2.1	Gaining ethical approval	Project manager	Epidemiologist MSD specialist Psychologist	Ethics committee
PBP1	Project break point	Project manager Epidemiologist	MSD specialist Psychologist	Funding body; Collaborating organisations
2.2	Engagement of stakeholders	Project manager Trials manager	Facilities team	Employer organisations; Chief Executives; Trade Unions; Royal Colleges; Other professional bodies
PBP2	Project break point	Project manager Epidemiologist	MSD specialist Psychologist	Funding body; Collaborating organisations
2.3	Staff training	Project manager MSD specialist Epidemiologist Psychologist Trials manager Call centre Field ergonomists Clinicians Clerical team Facilities team Intervention topic specialists/engineers Economist		
3	***Data collection***			
3.1	Recruitment of firms	Project manager Trials manager Call centre	Clerical team Facilities team	Boards and safety advisors of companies
3.2	Identification of suitable jobs and locations	Trials manager Field ergonomists Intervention topic specialists/engineers	Project manager MSD specialist Facilities team	Local managers/safety officers; Trade Unions; Safety reps
3.3	Designing, piloting and economic evaluation of interventions	MSD specialist Psychologist Trials manager Field ergonomists Intervention topic specialists/engineers Economist	Project manager Facilities team	Local managers, engineers and safety officers; Trade Unions; Safety reps; Intervention providers (e.g. equipment, processes or training)

PBP3	Project break point	Project manager Epidemiologist	MSD specialist Psychologist	Funding body; Collaborating organisations
3.4	Recruitment of individuals, collection and processing of pre-intervention baseline measures	MSD specialist Epidemiologist Psychologist Trials manager Field ergonomists Clinicians Clerical team	Project manager Facilities team	Local managers and safety officers; Trade Unions; Safety reps
3.5	Implementation of interventions, collection and processing of post-intervention baseline measures.	MSD specialist Epidemiologist Psychologist Trials manager Field ergonomists Intervention topic specialists/engineers Clerical team	Project manager Facilities team	Local managers, engineers and safety officers; Trade Unions; Safety reps; Intervention providers (e.g. equipment, processes or training)
PBP4	Project break point	Project manager Epidemiologist Trials manager	MSD specialist Psychologist	Funding body; Collaborating organisations
3.6	Collection and processing of follow-up measures	Trials manager Call centre Field ergonomists Clinicians Clerical team	Project manager Facilities team	
PBP5	Project break point — point of no return	Project manager MSD specialist Epidemiologist Psychologist Trials manager		Funding body; Collaborating organisations
4	***Final data processing***	MSD specialist Epidemiologist Psychologist Clerical team	Project manager	
5	***Data analysis***	Epidemiologist MSD specialist Psychologist Economist	Project manager	
6	***Presentation of summary statistics***	MSD specialist Epidemiologist Psychologist Economist	Project manager Clerical team	
7	***Interpretation***	MSD specialist Epidemiologist Psychologist Economist	Project manager	
8	***Publication***			
8.1	Preparation of scientific papers and submission to conferences/journals	MSD specialist Epidemiologist Psychologist Economist	Project manager Clerical team	Funding body
8.2	Wait for results of peer review	None	Project manager MSD specialist	Journal editors/reviewers

			Epidemiologist Psychologist Economist	
8.3	Revision of papers and resubmission	MSD specialist Epidemiologist Psychologist Economist	Project manager Clerical team	
8.4	Making conference presentations/waiting for journal publication	MSD specialist Epidemiologist Psychologist	Project manager Economist	Conference organisers; Journal editors; Scientific community

Table 9. Time estimates (FTE years) for the hypothetical project

	Phase								
Role	***1***	***2***	***3***	***4***	***5***	***6***	***7***	***8***	***Total***
Project manager	0.250	0.525	1.250	0.025	0.025	0.025	0.025	0.050	2.175
MSD specialist	0.250	0.250	1.125	0.250	0.175	0.250	0.250	0.325	2.875
Epidemiologist	0.250	0.250	1.000	0.250	0.250	0.250	0.250	0.325	2.825
Psychologist	0.250	0.250	1.000	0.250	0.175	0.250	0.250	0.325	2.750
Trials manager	0.250	0.500	3.313						4.063
Call centre		0.100	1.125						1.225
Field ergonomists		0.250	4.875						5.125
Clinicians		0.250	1.750						2.000
Clerical team		0.250	2.375	0.250					2.875
Facilities team		0.025	1.250						1.275
Topic specialists			1.875						1.875
Economist			0.250		0.050	0.050	0.050	0.075	0.475
Total	1.250	2.650	21.188	1.025	0.675	0.825	0.825	1.100	29.538

4.4 STUDY IMPLEMENTATION ISSUES

4.4.1 Staffing

Suitably qualified and experienced staff will be required to manage and implement the study over its duration. Skills will be required in project management and specifically in trials coordination, in addition to the need for technical skills in musculoskeletal ergonomics and in epidemiology. If, as suggested in this report, clinical examinations of participants are proposed, suitably medically qualified, experienced and trained staff will be required to carry them out. In addition, administrative requirements such as contacting participants for follow-up purposes will need to be allowed for. The staff and skill mix required will vary over the duration of the project. While some roles will be required throughout the project, some will only be required at specific stages. While there will be clear advantages in senior staff being involved for the duration of the project, this cannot be guaranteed and the possible need to find replacements must be considered. In some roles, individuals will be more easily replaced, especially where multiple individuals are required. Planning will need to ensure that suitable individuals are

available at the necessary stages of the project for the duration of the study and that replacements can be brought in, possibly at short notice, when that proves necessary.

4.4.2 Finance

A commitment to providing sufficient finance to fund the whole study will be required before the project is started. This should be made contingent upon the project being shown to be viable at each of the break points/review stages proposed in the flow chart in Table 8. An adequate contingency allowance will need to be available to take account of both foreseeable problems such as staff turnover or difficulties recruiting subjects and other unforeseen circumstances. Such a complex study will almost certainly be carried out at multiple sites and there will be significant amounts of travel involved as a result. Sufficient time and funding will be needed to allow proper reporting of the results of the study in the appropriate scientific fora and journals.

Because of the potential scale and duration of such a project, one single funding body, such as HSE, may feel that its budget is not sufficient to cover the entirety of the project. If this is the case, the possibilities of collaborative funding from suitable partners will need to be explored. It is beyond the scope of this work to consider who such partners might be.

One approach to funding that could be used to help manage the risks of the project would be to allocate money in budgets for the full proposed life of the project but to only commit money to future stages in the light of the on-going monitoring of the progress of the project.

A specific funding issue that will need addressing at the project design phase is how the actual implementation of interventions will be funded. The possible interventions vary in cost implications and in potential payback to the employer. Thus, a training intervention would have costs associated with the provision of the trainer and training materials, and the lost opportunity/lost production costs of the staff being trained. Even with on-going training or refresher training, such costs could easily be one or two orders of magnitude smaller than the costs of an engineering intervention where processes and equipment were modified.

If an employer can see a clear financial case for the intervention and has sufficient resources then they are likely to be willing to fund it themselves, especially if they can introduce associated changes that also reduce costs. Thus, a training course that claims to be able to significantly reduce lost-time and associated compensation claims, or an engineering change that also increases productivity, reduces labour costs or improves quality will tend to be viewed favourably.

However, if an employer is presented with a suggested intervention that has benefits that are not clear cut, or if they are in financial difficulties, or are financially risk averse, then they are unlikely to be willing to allow the intervention to happen, even if the costs to them are relatively minor.

If an employer is funding an intervention, they will have a financial interest in its success. This will have beneficial effects in creating pressure to implement it successfully, possibly leading to ad hoc modifications intended to improve it. It may also lead to attempts to portray the intervention as more successful than it was in reality. However, if there is a perception that an intervention is failing, then whether or not the perception is justified, there may be a business decision to terminate it before the study has run its course. This last situation is likely to occur whether or not the employer is funding the intervention. Decisions will therefore need to be made before ethics approval is sought as to when and how the outcome of an intervention will be communicated to the employer and employees concerned.

The net effect of this will be to add another potential confounder to the study design. HSE might therefore wish to explore the possibility of part-funding selected interventions, possibly on a match-funding basis, with the employer providing the rest of the funding. Further consideration of this approach, particularly its policy implications, is also beyond the scope of this work.

4.4.3 Monitoring of project progress

An intervention study is likely to be a project of very significant scale and duration. The funding bodies will want to monitor progress and spending. It will be impossible to produce estimates of duration and cost for the whole project before the planning phase is complete. Therefore, the planning phase should be funded before a firm decision is made about proceeding with the whole project. It is possible that the project proposal will need to be revised in the light of concerns raised by the ethics committee that considers it, and therefore commitment to the full project should be delayed until the proposal has been cleared ethically.

Because of the inevitable, and probably significant uncertainties that there will be at the start of the project, initial estimates of cost and duration are likely to need revising in the light of the progress achieved. Rigid limits on expenditure and timing that cannot be adjusted in the light of the progress of the project are likely to cause problems. If it becomes clear at a project break point that the project cannot meet its scientific goals then the project should be terminated early.

4.4.4 Identification of intervention sites

One of the most demanding parts of an intervention study is likely to be the logistic one of recruiting sufficient suitable workplaces, jobs and individuals. A number of criteria will need to be met:

- Management and workforce are willing to cooperate with the study.
- Sufficient jobs and potential participants are available within the workplace to form a cluster within the study and to justify implementation of the intervention. Recruiting very small numbers in each cluster will increase project costs significantly.
- A suitable control cluster can be identified for each participating cluster.
- Comprehensive job analysis shows that the job is suitable for intervention.
- The sector, workplace and workforce are sufficiently stable to allow a reasonable expectation of low drop out during the follow-up period. Contrasting annual drop out rates of approximately 43% (Dempsey *et al.*, 2002) and 16% (Lavender *et al.*, 2007) have been reported. A high turnover may itself be an indication that the job is high risk for MSDs. Conversely, a successful intervention may result in turnover diminishing significantly.

Tuncel *et al.* (2006a) recommended that interventions should be designed and implemented in accordance with the specific needs of the workplaces where they are happening. This is consistent with the findings of a study that sought to identify key issues requiring intervention in the printing industry (Brown *et al.*, 2006). That study argued for an in-depth exploration of "the working practices, beliefs, and attitudes within a workforce" before the interventions to be tested are selected.

Given the trend towards automation and to overseas manufacturing, attempting to find UK workplaces in manufacturing where a common intervention can be implemented across large numbers of workers doing identical jobs is likely to be very difficult. Other economic sectors will have larger numbers of workers with similar exposures, particularly in office-based

environments. However, if physical risk factors are the target of the intervention, then such sectors are likely to create problems with a lack of variability of exposure between exposed individuals. While some specialised workforces, such as emergency services, will have high exposures, there is also a distinct possibility that there would be very high variability of the exposures that an individual experiences, and this would also create problems with measurement and analysis.

It is therefore likely that the only practical solution would be to identify a class of intervention and implement it appropriately in a range of workplaces. If the intervention were to be an engineering intervention to, say, optimise the biomechanics of a workstation, then given that workstations will be of variable quality before the intervention, the target standard of the intervention would have to be specified so that all workstations in the intervention group were brought up to the same standard. In this case, the magnitude of the change made would need to be included in the analysis.

This approach would at least ensure constant post-intervention exposure among the recipients of the intervention, which would simplify analysis. However, it is inevitable that there would be considerable variability of the exposure among any control group that did not receive an intervention. There would also be significant variability in the exposure history of the intervention group. These confounding factors will need to be taken into consideration at the design stage.

4.4.5 Identifying suitable interventions

A clear conceptual basis is required for interventions and as mentioned previously (Section 1.5) the model proposed by Karsh (2006) is a suitable framework. However, defining the intervention is likely to be difficult, especially if the decision is made to tailor the intervention to the circumstances in the workplace. Griffiths (1999) gives the example of "Control" as a psychosocial factor that might be targeted and points out that perceived lack of control is likely to be the result of a set of factors that are unique to the organisation and also to the moment in time . She also points out that it is important to seek to establish how change in a variable causes a change in the response variable.

For an intervention to be accepted in a workplace it has to be one that the management and workforce are willing to at least try. Therefore, the intervention sites are likely to be ones that have not recently had similar interventions and perceive problems that a suitable intervention might address. This is a selection effect and it will need to be taken into account in the design and analysis. It is therefore possible that such a study would have to be carried out on a pragmatic "as found" basis.

Another factor that has been identified as relevant to the success of interventions is the role of "gatekeepers" with access to and control over resources (Stephens *et al.,* 2004). If such stakeholders are not fully engaged with a project, it is highly likely that it will not be implemented successfully in their organisations, even if it has been approved or endorsed by senior managers.

Related to the last point is the cost-benefit balance to the organisation that is a potential location for the intervention. If significant costs, either direct or indirect, are involved in an intervention then it will be harder to gain approval for it to be implemented. There will therefore be pressure to choose interventions that are "low-cost" and "easy" to implement. This may result in "behavioural" interventions such as training being preferred by employers over engineering changes. Moreover, there may be costs to the individual employee. If either the employer or the employees do not see benefits that outweigh the costs, then the intervention may simply not happen or may be fatally compromised.

4.4.6 Recruitment of individual participants

The biggest threat to the study, once approved, is likely to be a problem in recruiting sufficient participants to give adequate statistical power. The recent CRT by IJzelenberg *et al.* (2007) reported that power calculations showed that an initial sample of 350 workers would be required in nine intervention clusters. With an equal control group, this implies that they were seeking to ask 700 to participate. In fact, they were only able to invite 590 to participate. There is every indication that this was a well-planned study. It is therefore demonstrates the difficulties of such studies that they were unable to ask more than 85% of their relatively modest target to participate. It is therefore essential that at the planning stage detailed consideration is given to recruitment and contingency plans put in place should recruitment prove more difficult than anticipated. In a clustered trial, this is likely to include the inclusion of additional clusters. Allowance must be made in the power calculations for the likely refusal rates in clusters.

Consideration should be given to the possibility of a multi-centre study, possibly an international one, which would allow access to much greater populations for recruitment. Such an approach would create additional management and communication problems, particularly if subjects are recruited from multiple language groups.

4.4.7 Problems implementing interventions

Workplace interventions are often not straightforward, with weak, inconsistent, or even non-existent implementation of intervention plans occurring in practical settings (Lipsey, 1996; McCluskey *et al.,* 2006; Griffiths, 1999). "A pressing problem that has plagued ergonomic intervention research is the lack of understanding as to why seemingly identical interventions work in some instances and not in others." (Karsh *et al.,* 2001) This observation led to the recommendation that research should pay special attention to the effect of a variety of implementation approaches to ergonomic interventions to determine the effect that implementing the intervention in different ways has on the outcomes. In other words, studies of the implementation process are needed.

4.4.8 Barriers to change and "unforeseen organisational obstacles" to interventions

"Successful implementation, where the key players are onside and organisational obstacles are overcome, is difficult to achieve" (McCluskey *et al.,* 2006). Barriers can be cognitive, behavioural, organisational, socio-cultural or financial (Campbell *et al.,* 2007). The following factors have recently been reported (Whysall *et al.,* 2006):

- Inability to generate behaviour change among employees due to resistance by employees or failure by managers to promote behaviour change;
- Getting managerial authorisation and/or commitment, which can involve multiple levels of approval;
- Managerial perceptions of the importance of tackling MSD, that may result in them seeing managing or cooperating with an intervention as merely another task to be fitted into an already overcrowded schedule;
- Management failure to appreciate the value of taking preventative action resulting in action only happening in response to specific problems;
- Perceptions by management that health and safety initiatives originating from higher up the management chain reflect badly on their competence;
- Lack of resources, particularly staff time and appropriate skills;

- Conflicting priorities of production and health and safety resulting in the potential long-term benefits of the intervention being sidelined by the immediate need to maintain production at the target rate;
- Problems finding appropriate equipment to implement the intervention;
- Industrial relations issues leading to opposition to the change from the workforce.

These authors also reported a number of other factors that were seen as facilitating the change process:

- Supportive managers
- Changes in management
- Good awareness of health and safety and/or communication
- Local control of budgets simplifying the approval process

IJzelenberg *et al.* (2007) found problems in implementing later stages of their intervention. The initial intervention of training was delivered to 258 individuals. The second stage intervention of rapid access to physical therapy was used by only 10 of this group and 66 used external therapists. Of the seven workers that consulted the in-company physical therapist about LBP, only three used the further option of a workplace examination and consequent ergonomic adaptation. While IJzelenberg *et al.* offered a possible explanation in terms of difficulties of implementation, it is apparent that the failure of the workers to use the in-company provision was the key difficulty limiting the power of this stage of their study.

There is a danger of changes in workplaces occurring that are unexpected by the researchers and beyond their control and that can overwhelm a study. These changes may be driven by commercial or even safety concerns and if driven by a level of an organisation that is not actively supporting the study, are likely to ignore the needs of the study and hence to cause major problems.

4.5 DISCUSSION

The example project plan gives an indication of the possible scale, duration, staffing and costs of a well-planned intervention study. It cannot be emphasised strongly enough that the estimates are crude and would need significant refining in any tender submission as all of them would depend on the precise details of the project specification. The nature of the proposed intervention, its theoretical basis and likely incidence rates will need to be examined in detail. In particular, the basis on which the follow-up duration is determined in any tender submitted to HSE should be examined very carefully.

As noted earlier, it is easier to enhance statistical power in a CRT by increasing the number of clusters, rather than increasing the size of each cluster. However, once a cluster has been identified then recruiting extra individuals within that cluster is less labour intensive than identifying another suitable cluster. There is therefore a trade-off between cluster number and cluster size. The relative advantages of a narrow study of a few large clusters and a broad study of many small clusters are set out in Table 10. The ultimate balance to be obtained is impossible to predict at this stage so it will be up to the study designers to specify, in the light of their power calculations and their knowledge of the likely availability of clusters, the target number and size of clusters to be sought.

Table 10. Cluster size/number trade-off

Narrow study	*Broad study*
Target sample size N = 4000	Target sample size N = 4000
Few very large firms, e.g. F=4	Many large firms, e.g. F = 40
8 clusters in matched pairs	80 clusters in matched pairs
Cluster size = 500	Cluster size = 50
Limited range of exposures	Wide range of exposures
Easy to design interventions	Extensive work to design suitable interventions
Inherent variability within clusters so hard to characterise jobs accurately	Less variability within clusters so easier to characterise jobs accurately
Limited number of stakeholders	Many stakeholders
Relatively few contact people at intervention sites	Much more management of contacts with intervention sites and stakeholders

Increasing the follow-up period would be an efficient way of increasing the power of the study. However, drop-outs would increase with time so sample size would need adjusting to account for that. Lengthening the follow-up phase would have relatively small impact on the amount of staff time required to run the project as it would increase the numbers of follow-up contacts which are relatively low effort. It would also have an impact on the amount of follow-up data acquired and the consequent effort required to manage, process and interpret it. Therefore, a trade-off will exist between the sample size and the need to control the duration of the project.

It must be borne in mind that there is no simple relationship between the sample size desired to give the target power and the cost of implementing the project. While approximately 72% of the time is allocated to the Data collection phase, a significant proportion of this is assigned to preparations that would be necessary before an intervention could be implemented. As noted above, it would be relatively cheap to increase the number of individuals within a cluster or to extend the duration of the follow-up phase. Therefore increasing or decreasing subject numbers would have a noticeable effect on effort required at some stages of the project but would have little or no effect at other stages,

For the suggested design, pairs of matched workplaces would be required for a comparison between an intervention group and a control group. Blinding would be very difficult in these circumstances. If matched triplets were available, then comparisons could be made between a control group, a sham intervention group and an intervention group. Blinding of the sham and intervention groups would be less difficult than blinding a single intervention group.

It is possible that the staffing of the roles could be adjusted so that team members fulfilled more than one role or fulfilled different roles as the study progressed. Time estimates are made on the basis that when a particular role is not required the individual staff concerned would be occupied on other work so would not expect funding from this project. This would also allow part-time staff to be involved in the project.

In the example plan, a twelve-month period is allocated to Stages 3.1 to 3.4, which involve preparation for implementation of the actual intervention at Stage 3.5. Such a lengthy period is provided because of the need to negotiate access to suitable sites and to ensure that if the aim is to make engineering changes to the job or the workplace, then the planned interventions are properly designed and piloted. This period could almost certainly be reduced if it was decided to implement interventions requiring less preparation, such as organisational or psychosocial interventions.

5 CHECKLISTS FOR INTERVENTION STUDIES

5.1 METHODOLOGICAL CRITERIA FOR EVALUATING OCCUPATIONAL SAFETY INTERVENTION RESEARCH

Shannon *et al.* (1999) listed methodological criteria suitable for evaluating occupational safety intervention research. These have been added to by Karsh *et al* (2001) who took into consideration other recommendations. Based on earlier work (Silverstein and Clark, 2004), Genaidy *et al.* (2007) have developed the EAI, an "Epidemiological Appraisal Instrument", which can be used to evaluate the methodological quality of proposed ergonomic epidemiological studies. It is designed for evaluating both observational epidemiological studies and intervention studies. It consists of 43 items forming five measurement scales:

- Reporting (17 items)
- Subject/record selection (7 items)
- Measurement quality (10 items)
- Data analysis (7 items)
- Generalization of results (2 items)

The existence of these checklists provides methods by which a proposed study can be evaluated. The EAI has been developed by a team with expertise in research in both MSDs and epidemiology and is more comprehensive than the list compiled by Karsh *et al.* (2001) though they provide additional material criteria that will be valuable in evaluating any proposal for an intervention study. Moreover, the EAI team has sought to provide rigorously tested criteria with detailed specifications for levels of answers for each question. It is therefore recommended that the EAI is used, with the indicated additions from Karsh *et al.* (2001), to evaluate any proposed study in response to a tender by HSE. In order for this to happen, detailed criteria, similar to those already in the EAI, will need to be developed for the additional questions.

Table 11 summarises the methodological criteria originally specified by Shannon *et al.* (1999) (*) and added to by Karsh *et al.* (2001) (**). The criteria are cross-referenced to the criteria of the EAI. Similarly, the detail of the questions to be answered when using the EAI is set out in Table 12 and cross-referenced to the criteria from Karsh *et al.* (2001). Inevitably, the criteria in the two lists cannot be matched precisely due to overlaps, gaps and the use of different phraseology. The less precise identifications are indicated by question marks. Questions given by Karsh *et al.* (2001) that are not in the EAI are indicated by dashes.

In Table 11, for one question (Q 24) under "Statistical analysis", there is a significant difference between the wording of Shannon *et al.* (1999) and Karsh *et al*. (2001) who rightly remove the restriction that power and confidence intervals should be calculated only if findings are non-significant. One question in the EAI (Question 10) is specific to intervention studies. The detailed criteria describe some questions as not applicable to intervention studies; these are indicted by an asterisk against the question number and by Strikethrough of the question text. This is also done where equivalent criteria are included in the list provided by Karsh *et al.* (2001). As the EAI list has been through a much more detailed and rigorous development process than the list from Karsh *et al.* (2001), the judgement of the creators of the EAI (Genaidy *et al.,* 2007) should be accepted.

When using the EAI question set it is essential to consult the full paper (Genaidy *et al.*, 2007) which sets out detailed criteria for assessing each response as "Yes", "Partial", "No", "Not applicable" or "Unable to determine".

An example of the detailed criteria is as follows:

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1. Is the hypothesis/aim/objective of the study clearly described?

Yes — clearly described

The objective is clearly stated in one or two statements in the introduction.

The relationship to be examined between the exposure/intervention and outcome variables is clearly stated.

Partial — somewhat described

There is sufficient information to be able to infer the objective in the introduction.

The relationship to be examined between the exposure/intervention and outcome variables has to be inferred.

No — Not described

The study objective is not described in the introduction, and there is insufficient information provided to even 'infer'.

5.2 CRITERIA FOR REPORTING RANDOMISED TRIALS – THE CONSORT STATEMENT

Assessment of the quality of the intervention relies on sufficient detail in trial reports, but many reports provide only superficial descriptions of complex interventions. This poor level of reporting underlies the conclusions of systematic reviews that the methodological quality of existing studies is poor. In fact, it is possible that good quality studies have been inadequately reported, resulting in their evidence being discounted.

In order to improve the quality of reporting, the CONSORT statement (Moher *et al.*, 2001) on reporting of clinical trials recommends that reports of clinical trials include "precise details of the interventions intended for each group and how and when they were actually administered." Interventions should be described in sufficient detail to enable readers to assess if the intervention was administered well (Genaidy *et al.*, 2007). The CONSORT checklist and flowchart are reproduced in Table 13 and Figure 5. It is recommended that the CONSORT statement be used alongside the EAI to evaluate any tender received by HSE. It is further recommended that it be specified by HSE that the EAI and CONSORT statement and flowchart will be used to evaluate the progress and final reporting of any intervention project funded or part-funded by HSE.

In order to provide practical solutions and to be able to interpret the results from ergonomics intervention studies, efforts should be made to provide dose-response and time-response relationships as the bases for creating threshold limit values for prevention of MSDs.

Table 11. Intervention evaluation criteria proposed by Karsh *et al.* (2001)

Karsh et al. (2001) criterion	*Source*	*Program objectives and conceptual basis*	*EAI criteria*
1	*	Were the program objectives stated?	1
2	**	Does the study identify a gap in the existing literature?	—
3	*	Was the conceptual basis of the program explained and sound?	1,4
		Study design	
4	*	Was an experimental or quasi-experimental design employed instead of a non-experimental design?	4
5	**	Did the interventions appear to be long enough to find the desired effect?	38
6	**	Did the subjects have a reasonable amount of exposure to the intervention?	38?
7	**	Was the intervention powerful enough to cause change?	17?
8	**	Were the subjects randomly selected or volunteers?	23
9	**	Was the outcome assessment blind to the intervention status?	29,30
		External validity	
10	*	Were program participants/study population fully described?	8
11	*	Was the intervention explicitly described?	2
12	*	Were contextual factors described?	11,12
13	**	Could the reader repeat the study based on the description in the methods section?	2,4,6,13
14	**	Is the study population representative of the end-user population?	42,43
15	**	Is the study setting representative of the workplace to which the results will be applied?	42,43
		Outcome measurement	
16	*	Were all relevant outcomes measured?	—
17	*	~~Was the outcome measurement standardised by exposure?~~	40
18	*	~~Were the measurement methods shown to be valid and reliable?~~	25,26
19	**	Were baseline measures of the outcome collected?	35
		Qualitative data	
20	*	Were qualitative methods used to supplement quantitative data?	—
		Threats to internal validity	
21	*	Were the major threats to internal validity addressed in the study?	23,24,31,32, 36, 37
22	**	Were confounding factors controlled for?	36,37
		Statistical analysis	
23	*	Were the appropriate statistical analyses conducted?	36,37,39
24	*	~~If study results were negative,~~ were statistical power or confidence intervals calculated?	13,17
25	**	Was survivor bias avoided?	9,21
26	**	Were response or recruitment rates adequate?	19
27	**	Was attrition a problem?	—

		Conclusions	
28	*	Did conclusions address program objectives?	—
29	*	Were the limitations of the study addressed?	—
30	*	Were the conclusions supported by the analysis?	—
31	*	Was the practical significance of the results discussed?	42,43
32	**	Are recommendations for workers discussed?	—
33	**	Are areas of further research discussed?	—

*Source = ** *Criterion originally specified by Shannon et al. (1999)*
*Source = *** *Additional criterion specified by Karsh et al. (2001)*

Table 12. The EAI question set with additions from Karsh *et al.* (2001)

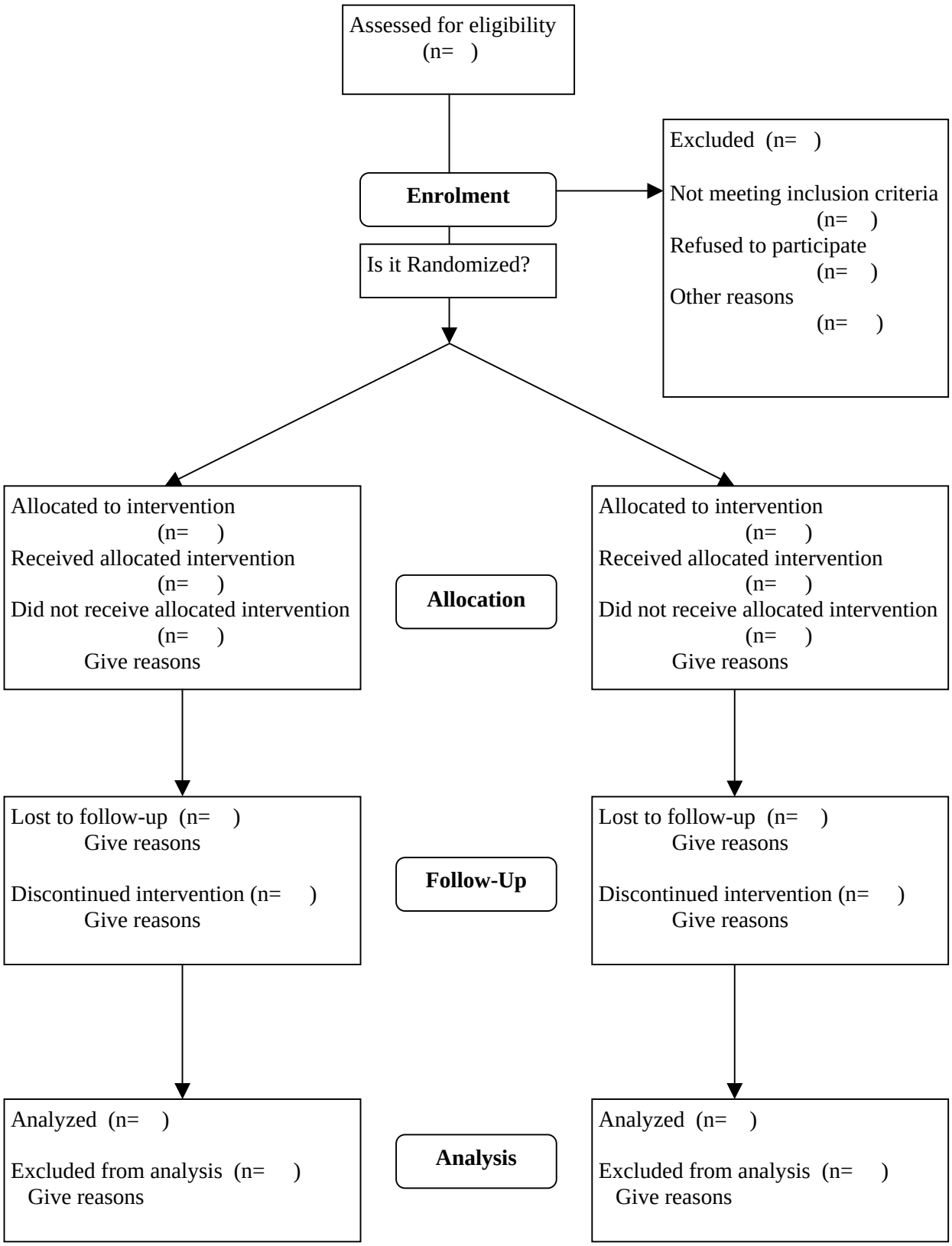
EAI criterion	*Study description*	*Karsh et al. (2001) criteria*
1	Is the hypothesis/aim/objective of the study clearly described?	1,2
—	Does the study identify a gap in the existing literature?	20
2	Are all the exposure variables/intervention(s) clearly described?	5,21
3	Are the main outcomes clearly described?	—
4	Is the study design clearly described?	2,3,21
5	Is the source of subject population (including sampling frame) clearly described?	—
6	Are the eligibility criteria for subject selection clearly described?	21
7	Are the participation rate(s) reported? Are ascertainments of record availability described?	—
8	Are the characteristics of study participants described?	4
9	Have the characteristics of subjects lost after entry into the study or subjects not participating from among the eligible population been described? Have the details of unavailable records been described?	30
10+	Have all important adverse effects been reported that may be consequences of the intervention(s)?	—
11	Are the important covariates and confounders described in terms of individual variables?	6
12	Are the important covariates and confounders in terms of environment variables described?	6
13	Are the statistical methods clearly described?	21
14	Are the main findings of the study clearly described?	—
15	Does the study provide estimates of the random variability in the data for the main outcomes or exposures (i.e. confidence intervals, standard deviations)?	13
16	Does the study provide estimates of the statistical parameters (e.g. regression coefficients or parameter estimates such as odds ratio)?	—
—	Did the conclusions address programme objectives?	14
—	Were limitations addressed?	15
—	Were the conclusions supported by the results?	16
17	Are sample size calculations performed and reported?	13,28
—	Are recommendations for workers discussed?	24
—	Are areas of further research discussed?	25
	Methodological quality	
18	Is the comparison/reference group comparable to the exposed/intervention/case group?	—
19	Is the participation rate adequate? Is the ascertainment of record availability adequate?	31
—	Were all relevant outcomes measured?	8
—	Were qualitative methods used to supplement quantitative data?	10
20	Are the study subjects from different groups recruited over the same period of time?	—
21	Are subject losses or unavailable records after entry into the study taken into account?	30
22*	~~Are newly incident cases taken into account?~~	—

23	Are the study subjects randomized to groups?	11,29
24	Is the randomized assignment to groups concealed from both subjects and observers until recruitment is complete and irrevocable?	11
	Measurement quality	
25*	~~Are the exposure variables reliable?~~	9
26*	~~Are the exposure variables valid?~~	9
27*	~~Are the methods of assessing the exposure variables similar for each group?~~	—
28*	~~Is exposure conducted at a time prior to the occurrence of disease or symptoms?~~	—
29	Are the observers blinded to: subject groupings when the exposure/intervention assessment was made or the disease status of subjects when conducting exposure assessment?	33
30	Are the subjects blinded to their grouping when the exposure/intervention assessment was made?	33
31	Are the main outcome measures reliable?	11
32	Are the main outcome measures valid?	11
33	Are the methods of assessing the outcome variables standard across all groups?	—
34	Are the observations taken over the same time for all groups?	—
	Data analysis	
35	Is prior history of disease and/or symptoms collected and included in the analysis?	18
—	Was attrition a problem?	32
36	Is there adequate adjustment for covariates and confounders in terms of individual variables in the analyses?	11,12,19
37	Is there adequate adjustment for covariates and confounders in terms of environment variables (other than exposure) in the analyses?	11,12,19
38	Is the minimum follow-up time since initial exposure sufficient enough to detect a relationship between exposure/intervention and outcome?	26,27?
39	Do the analyses adjust for different lengths of follow-up of subjects in cohort/interventions studies; is the time period between the exposure and the outcome the same for cases and controls?	12
40*	~~Are outcome data reported by levels of exposure?~~	7
41	Are the outcome/exposure data reported by subgroups of subjects?	—
	Generalization of results	
42	Can the study results be applied to the eligible population?	17,22,23
43	Can the study results be applied to other relevant populations?	17,22,23

Table 13. The CONSORT checklist for reporting a randomised trial

Paper section & topic	*Item*	*Description*
Title & Abstract	1	How participants were allocated to interventions (e.g., "random allocation", "randomised", or "randomly assigned").
Introduction	2	Scientific background and explanation of rationale.
Methods Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.
Objectives	5	Specific objectives and hypotheses.
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.
Randomisation -- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (e.g., blocking, stratification)
Randomisation -- Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.
Randomisation -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups?
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. When relevant, how the success of blinding was evaluated.
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.
Results Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.
Recruitment	14	Dates defining the periods of recruitment and follow-up.
Baseline data	15	Baseline demographic and clinical characteristics of each group.
Numbers analysed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (e.g., 10/20, not 50%).
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval).
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.
Adverse events	19	All important adverse events or side effects in each intervention group.
Discussion Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.
Generalisability	21	Generalisability (external validity) of the trial findings.
Overall evidence	22	General interpretation of the results in the context of current evidence.

Figure 5. The CONSORT flowchart Aug. 2005



5.3 EXAMPLES OF POSSIBLE STUDY PROPOSALS

5.3.1 Introduction

This section gives some examples of possible study designs. It starts by listing inclusion/exclusion criteria that can be used to select the MSDs that are to be studied. It then lists the types of workplace interventions available for reducing workplace exposure to MSD risk factors.

Table 14 lists details of possible primary intervention types and gives specific examples of each type. It also gives example measurement methods and specific objectives that could be used to evaluate the effectiveness of each intervention component.

The focus of the possible tender will be on primary workplace interventions aimed at preventing musculoskeletal pain, injury and disability. Interventions aimed at not only the primary level but also at secondary and/or tertiary levels are also within scope. Interventions only targeted at the secondary (return to work) or tertiary (treatment) levels should be excluded.

Before any specific intervention is selected for implementation, the existing literature and other evidence about its effectiveness should be considered.

Tables 15, 16 and 17 give three examples of possible specific protocols that could be implemented. Table 16 is a mixed secondary and primary prevention study. Table 18 gives details of features that would be common to all three protocols.

5.3.2 Inclusion/exclusion criteria for MSDs

Possible work-related musculoskeletal disorders that could be studied are:

- Low back pain, including disk prolapses, sciatica and other forms of nerve root pain, and simple mechanical low back pain;
- Upper limb disorders, such as Carpel Tunnel Syndrome, Epicondylitis, Rotator Cuff Syndrome and Non-Specific Arm Pain;
- Lower limb problems such as bursitis;
- Problems associated with seated postures;
- Problems associated with whole-body vibration.

The following musculoskeletal disorders should be excluded from any studies:

- Back problems due to non-work related causes/pre-existing medical conditions such as arthritis, ankylosing spondylitis, spondylisthesis, traumatic impacts or pregnancy.
- Hand-arm vibration syndrome;
- Whiplash and other impact injuries to the neck;
- Traumatic tendon/ligament injuries in the lower limb such as sports injuries to the anterior cruciate ligaments.

5.3.3 Type of interventions under consideration

The types of ergonomics interventions that have been carried out in the past to reduce the exposure in the workplace to risk factors for MSDs have been categorised into six groups (Tuncel *et al.,* 2006a; Karsh *et al.,* 2001; Volinn, 1999). A multiple component intervention would combine two or more interventions or types of intervention.

- Organisational environment changes, including psychosocial interventions, changes to work organisation/methods and participatory approaches;
- Job design (ergonomics) including engineering redesigns and providing assistive devices;
- Job placement/worker selection;
- Education/training (including providing advice on ergonomics);
- Physical exercise (including work hardening);
- Back supports.

Table 14. Possible primary interventions to reduce the incidence of episodes of MSDs

Intervention type	*Intervention details/examples*	*Example baseline and post intervention measurements, (implementation, follow-up or prospective event data)*	*Specific outcome (measurable aim) = Objective of intervention*
All interventions	• Agreement between labour and management on best interests of employees	• Effectiveness of intervention implementation • Pain scales/diagrams • Reports of musculoskeletal trouble • Clinical examination • MSD injury rates • Time to injury • Injury severity • MSD absence rates • Absence duration • Staff turnover	• Intervention implemented according to plan • Reduced exposure to MSD hazards • Reduced incidence of clinical diagnoses • Reduced pain intensity/duration • Reduced prevalence of musculoskeletal trouble • Reduced injury rates • Reduced recurrence rates • Increased survival time • Decreased injury severity • Reduced absence rates • Reduced days lost • Reduced disability • Reduced medical care costs • Reduced compensation claims • Reduced staff turnover
Training/education	• Understanding of body posture, anatomy and biomechanics • Training in ergonomic risk analysis • Correcting erroneous beliefs • Training in lifting, job and work techniques	• Posture • Understanding of risk factors • Quality of risk assessments • Techniques in normal use	• Improved posture • Increased knowledge • Improved risk assessments • Altered attitudes to and beliefs about pain • Increased job-specific skills
PPE	• Back belts • Wrist supports	• Understanding of correct use of PPE	• Acceptability of PPE to users • Ongoing use of PPE
Engineering redesigns	• Reduce load moment • Mechanise handling • Reduce frequency • Decrease unit load and increase frequency • Reduce vertical movement • Reduce force requirements • Improve postures – move force requirements to stronger muscle groups • Replace carrying with pushing/pulling	• Posture • Repetitive movements • Number of manual handling operations • Lifting index or similar metrics • Joint loading/percent capable • MAC red scores	• Improved body posture • Elimination of some handling operations • Reduced repetition & forces • Reduced manual handling operations • Reduced daily physical workload

Changes in work organisation	• Eliminate "job and finish" • Rebalance machine paced tasks • Rotate employees among tasks with different exposures • Alter patterns of rest breaks • Introduce work pauses: passive, active, diverted	• Repetitiveness of tasks • Time spent on each task and number of tasks • Total exposure • Actual working patterns	• Increased variation in jobs • Ongoing implementation of job rotation • Ongoing use of rest breaks and compliance with changes
Psychosocial	• Improve management commitment to health and safety • Improve communication about health and safety • Improve reporting mechanisms for health and safety problems, particularly MSDs • Reduce excessive demands • Increase worker control • Improve worker support	• Perceptions of management commitment • Use made of reporting mechanisms • General Health Questionnaire (GHQ) • Psychosocial factor questionnaires • Other psychological scales	• Improved perceptions of management commitment to health and safety • Reporting mechanisms in place and seen to be effective. • Improved psychological/ psychosocial status • Increased job satisfaction
Exercise	• Implement coordination, strength, & aerobic fitness programme • Provide progressive resistance exercise programme • Encourage active micro-breaks with stretching exercises	• Muscle strength • Joint flexibility • Resting heart rate • Estimated maximal oxygen consumption • Percent body fat • Body mass index	• Increased strength • Improved flexibility • Decreased resting heart rate • Increased estimated maximal oxygen consumption • Decreased percent body fat • Decreased body mass index
Health advice/care to prevent recurrence	• Teach pain management techniques • Spread "remain active" message • Encourage return to normal activities as quickly as possible • Provide mini back schools • Provide easy access to health care providers.	• Worker expectations of interventions and beliefs about MSD prognosis • Immediacy of care-seeking	• Reduced levels of fear, pain & pain-related disability/fear • Improved understanding of keep active message • Reduced catastrophic thinking and depression • Improved functional status • Uptake of mini back schools • Increased use of health care providers

Table 15. Preventing ULD problems in newly employed workers

Objective:	To reduce the incidence of musculoskeletal disorders affecting the upper limb (ULDs) amongst workers in the first 6 months of employment
Study design	Longitudinal experimental prospective case cross-over design with randomisation Follow-up for 12 months (each individual) Individuals can enter at any time (dynamic) Target recruitment period: 1-2 years Length of study: 3-4 years? (Depending on sample size and rate of new jobs)
Intervention type	Multi-component PPE Engineering redesigns Administrative tools Psychosocial interventions
Measurement/ outcome	Clinical examination and diagnoses Incident rate of injuries Pain scores Amount of lost/restricted time
Subject selection/ entry criteria	Exclude subjects with musculoskeletal trouble in the previous week Exclude subjects with musculoskeletal trouble lasting longer than 24 hours in the previous month Exclude subjects with 'disability' due to musculoskeletal trouble in the previous three months No previous exposure to similar types of work (preferable) Upper age limit Exclude those returning to the job or those with experience in similar jobs
Control group selection/entry criteria	Subjects who did the same or a similar job within the previous 12 months (> two years of work-experience?) Or case-crossover (subject acts as own control in second half of study)
Possible target employment sectors	Army, fire-fighters Newly opened workplaces Keyboard workers – call centres or large offices
Study strengths	Reduced likelihood of subjects having a history of MSD problems Using clinical diagnoses (as opposed to relying on subjective measurements) Subjects act as own controls (reduces confounding)
Study weaknesses	Sites with large numbers of new recruits are likely to have high staff turnover A study involving clinical diagnoses will be more expensive than one relying on self-reports It is difficult to compare working environment and jobs for new recruits (except at new sites) as companies rarely do mass new recruiting
Relevant references	(Breslin and Smith, 2006; Hakkanen *et al.*, 2001a; 2001b; Harkness *et al.*, 2003a; 2003b; Heuer *et al.*, 1996; Jones *et al.*, 2006; Macfarlane *et al.*, 1997; Melhorn *et al.*, 1999; 2001; Nahit *et al.*, 2001a; 2001b; Parenmark *et al.*, 1988; Park *et al.*, 1994; 1996; Thompson *et al.*, 1951; Waersted and Westgaard, 1991; Westgaard and Aaras, 1984)

Table 16. Preventing disability through return to work interventions

Objectives:	To prevent disability through return to work (RTW) intervention To reduce the severity and frequency of episodic lower back pain (LBP) To reduce the incidence of LBP re-occurrence To prevent a progression from an acute condition to chronic disability) To reduce pain and disability and decrease period before return to work.
Study design	Cohort (experimental longitudinal) or RCT (single blind) Follow-up for 3-5 years (each subject) Subjects can enter at any time (dynamic) – but when they go off work with LBP or within a fixed period (i.e. 2 weeks) of going on sick leave.
Intervention type	Clinical intervention: Cognitive-behavioural interventions during rehabilitation (within 2 months of reporting sick) until worker makes full return to regular work. Occupational (ergonomics) intervention: Provide tailored workplace redesign interventions
Measurement/ outcome	Baseline clinical diagnoses and quarterly clinical assessments Industrial records/Days off work (sick leave) Questionnaires (self-assessment) Return to Work perception survey Pain (intensity), discomfort and disability Psychosocial factors Health care utilization Physical function
Subject selection/ entry criteria	Exclude subjects with constant pain at baseline Include subjects with recent history of low back disorders (≥2 episodes within last 12 months) with diagnosed occupational back pain Subject enters study when absent from work for ≥24 weeks due to LBP
Control group selection/entry criteria	Subjects with occupational low back pain without intervention
Possible target employment sectors	Airline industry Police force
Study strengths	Using clinical diagnoses (as opposed to relying on subjective measurements) Long duration follow-up: few studies have looked at effects beyond 1 year The minority of LBP patients with long-duration work absenteeism account for a large proportion of socio-economic burden of LBP. RTW is a complex social phenomenon, not well characterized by measures collected at a single point in time. Few studies have addressed the impact of interventions targeting outside individual psychosocial risk factors.
Study weaknesses	More expensive involving clinical diagnoses Difficulties in comparing/matching different industries Need to recruit psychologists to provide cognitive-behavioural interventions
Relevant references	(Anderson, 1987; Elders *et al.*, 2000; Franche *et al.*, 2005a; 2005b; Lagerstrom *et al.*, 1998; Loisel, 2005; Loisel *et al.*, 2005; Mahmud *et al.*, 2000; Martocchio *et al.*, 2000; Mayer *et al.*, 2001; Ostelo *et al.*, 2003; Pransky *et al.*, 2005; Scheer *et al.*, 1997; Snook, 2004; Staal *et al.*, 2002; 2005; Sullivan *et al.*, 2005; Troup and Videman, 1989; van den Heuvel *et al.*, 2005; Von Korff and Saunders, 1996; Wasiak *et al.*, 2003)

Table 17. Prevention of LBP among high mileage drivers

Objectives:	Primary prevention of episodes of LBP among individuals driving high mileages as part of their work
Study design	Cluster randomised trial Follow-up for two years Subjects recruited as part of clusters Target recruitment period: 3-6 months Length of study 2-3 years (depending on sample size and number of clusters)
Intervention type	Provision of customised specialist seats Provision of anti-vibration seating Postural advice/training Advice on rest breaks Advice on manual handling Provision of manual handling aids for delivery drivers
Measurement/ outcome	Clinical examination/diagnosis
Subject selection/entry criteria	Exclude drivers with existing LBP Exclude drivers with LBP within the previous 12 months Exclude drivers commuting more than 50 miles per week between home and work Drivers of work vehicles travelling more than 500 miles per week or for more than 12 hours per week Include drivers of a range of vehicles from cars to HGVs
Control group selection/entry criteria	Drivers in matched occupational clusters
Possible target employment sectors	Businessmen Taxi/private hire drivers Light goods van drivers HGV and PSV drivers
Study strengths	Using clinical diagnosis
Study weaknesses	Clinical examinations are a more costly measurement method
Relevant references	(Chen *et al.*, 2005; Gyi and Porter, 1998; Magnusson *et al.*, 1996; Pope *et al.*, 2002; Porter and Gyi, 1995; 2002; Okunribido *et al.*, 2006; Skov *et al.*, 1996; van der Beek *et al.*, 1994)

Table 18. Common features of the three example proposals

Measuring tools	Self-reported frequency of symptoms Self-reported work restriction/loss Company books (days off work) Clinical visits Baseline clinical examination Medical history Physicians diagnosis of MSDs
Main outcome measure	• Measured in comparison with baseline clinical diagnoses • Questionnaires (self-assessment) • Incident cases of MSDs • Psychosocial factors
Secondary outcomes	Assess effectiveness /accuracy of subjective questionnaires
Confounders	Age Gender Anthropometry Cigarette smoking Non-occupational physical activities Healthy worker effect
Main risk factors to study	Failure to recruit Failure to implement interventions Loss to follow-up; Study contamination,
Sample size (90% power and 5% significance level)	Standard deviation Mean difference N (considering response rate)
Analysis	Survival analysis

6 DISCUSSION/RECOMMENDATIONS

6.1 INTRODUCTION

There is a view that primary interventions to prevent initial onset of MSDs are not likely to be effective because of the very high lifetime prevalence of MSDs. On this view, the concentration should be on secondary interventions to return injured individuals to work as quickly as possible, despite them still suffering pain, particularly with the aim of preventing long-term work loss and disability (Burton *et al.*, 2004; 2005).

However, this worldview has a number of inherent difficulties. Firstly, it is counterintuitive to tell people that the pain they are feeling doesn't really matter, especially when the associated guidance is very vague as to the use of pain-relief to control the pain and when first-aid advice on dealing with new episodes of MSDs is effectively non-existent. Secondly, it is perfectly rational for an individual suffering pain to avoid situations or activities that they think could exacerbate or cause a new episode of the pain. The whole system of risk assessment and control of manual handling risks is based on the premise that MSD causing situations can often be eliminated or at least ameliorated. The third problem with the early return to work message is that it denies by implication the value of workplace modification in prevention but then explicitly calls for workplace modification to ease reintegration of injured workers. Such a gloomy prognosis of the possibility of prevention is not universal, with, for example, Volinn (1999) noting that rapid progress in medicine has been associated with explanatory studies. He therefore argued that despite most previous studies of workplace MSD risk factors having been pragmatically oriented (i.e. observational), "explanatory workplace intervention studies may come to prevail and, assuming they do, rapid progress in preventing low back disorders may be expected".

Evidence from such a study or studies would add to the body of knowledge about the prevention of episodes of MSDs. It could then be integrated with the other knowledge via meta-analysis and systematic reviews and then influence guidance and standards for the prevention of MSDs.

Burdorf has been calling for some time for a shift towards intervention research and is involved in carrying it out (Burdorf, 2007; Burdorf *et al.*, 1997a; 1997b; IJzelenberg *et al.*, 2007). An article by Dempsey (2007) to which Burdorf (2007) refers is more circumspect, pointing out the practical difficulties involved. Dempsey's experience in attempting an epidemiological evaluation of the NIOSH lifting equation (Dempsey *et al*., 2002; Dempsey, 2002) clearly has influenced his thinking. Despite this understandable caution, there is a demand within the ergonomics scientific community for such trials. However, the individuals who are calling for such studies are, with the exception of Burdorf, approaching the issue from a technical ergonomics end rather than as epidemiologists. If Burdorf, who is an epidemiologist/statistician with considerable experience in the MSD field, was not calling for intervention studies, the inclination would be to highlight comments betraying limited knowledge of the epidemiological methods required and to argue that the practical difficulties are so large as to make the success of an intervention study very doubtful.

However, there are worldwide efforts to carry out these studies. Moreover, it is the nature of science that when a previously unaddressed area becomes topical or potentially solvable, then multiple research groups will be working on it at the same time. It is also unlikely that one single intervention study will prove to be definitive, however large and comprehensive it is.

6.2 STUDY DESIGN

In principle, it would be possible to carry out a cohort study of initial onset of MSDs by following a cohort from birth to early adulthood but this would be a very long-term project. Given a pragmatic acceptance that back pain is episodic (Eisen, 1999; Burdorf and van der Beek, 1999b; Cassidy *et al.*, 2005) and that the majority of cases resolve with conservative treatment in a relatively short time frame, then a credible aim would be the prevention of new episodes in individuals who have been symptom free for a period long enough to demonstrate complete recovery from any previous episodes. (This may require close examination of the value of a previous episode of back pain as a predictor of a subsequent one to see if the relationship weakens with time). Such an approach would require a careful back pain history to be taken from each individual that might conveniently be combined with a detailed clinical examination.

Any robust intervention study needs careful design and thorough planning. Implementation will require dedication and relevant experience from the study managers in order to overcome the significant logistic and organisational challenges that it will face. The ethical issues must be addressed to the satisfaction of an ethical committee that will include lay members representing the public as well as scientists and topic experts.

In order to allow criteria for assessing causality to be met, it is necessary to use an experimental, as opposed to observational, study design to look at interventions to prevent MSDs. This means that studies must be prospective and longitudinal, not cross-sectional or retrospective. Interventions are most easily implemented at group level (e.g., work team, factory or company level) and so the best study design would be a clustered randomised trial.

There are so many variables to be considered that it would be counterproductive to specify at this stage a precise study design listing target MSDs, industry sectors to be involved, intervention characteristics, follow-up periods, or subject numbers. Instead, it is recommended that HSE write any tender document in such a way as to ensure that potential contractors have to demonstrate that their proposals are scientifically sound while giving them sufficient flexibility to produce innovative proposals that will overcome the practical problems. The example project plan in Section 5 and the three outline protocols in Section 5.3 are written from this viewpoint.

6.3 MAIN RECOMMENDATION

The conclusion of this feasibility study is that there are very significant practical obstacles to the successful execution of a scientifically robust study to demonstrate the effectiveness of an ergonomics intervention to prevent the onset of episodes of musculoskeletal disorders. However, because of the scale of the MSD problem, there are important calls for such studies to be done despite the difficulties.

1. It is therefore recommended that HSE should consider funding or part funding a longitudinal study designed to test the effectiveness of interventions designed to prevent the onset of new episodes of MSDs, and that consideration be given to making it a multi-centre, possibly international, study.

2. It is also recommended that HSE write any tender document in such a way as to ensure that potential contractors have to demonstrate that their proposals are scientifically sound while giving them sufficient flexibility to produce innovative proposals that will overcome the practical problems.

A hard-headed approach is needed to the carrying out of such a study to maximise the chances of it being successful. A study that demonstrates either the effectiveness or ineffectiveness of

such interventions will have succeeded. A study that fails to produce clear results due to methodological limitations or insufficient power would have been better unattempted.

3. It is recommended that any study that HSE funds have an integrated management team to lead the project throughout its life. At the minimum, this would need to consist of an epidemiologist experienced in intervention studies, an ergonomist with significant understanding of MSDs, and an experienced project manager. No single individual is likely to be able to fill all of these roles in any large-scale project. It is also recommended that an occupational psychologist or similar person familiar with the psychosocial and biopsychosocial aspects of MSDs be involved throughout the study.

4. It is recommended that the viability of any project should be rigorously reviewed, particularly at the design stage, and throughout the subject recruitment phase. If it becomes clear at any of these stages that the project has a low probability of success then it should be terminated.

5. The recommended study design is a longitudinal cluster randomised trial because it is a natural design to implement in workplaces. This design will require control clusters to which the intervention is not implemented. Case-control and cross-sectional studies cannot demonstrate causality and are completely inappropriate. Analysis methods will need to be selected at the study design stage.

6.4 DETAILED RECOMMENDATIONS

1. Any tender specification should use the integrated model proposed by Karsh (2006) as a basis for identifying potential intervention points that should be explored.

2. Proposals in response to the tender should be evaluated against their ability to test the effectiveness of interventions at these points. At this stage, use should be made of methods for mapping causal relationships.

3. Any tender specification should require that any proposal is written against the criteria of the Epidemiological Assessment Instrument (EAI) (Genaidy *et al.,* 2007) augmented by the additional material in the Karsh *et al.* (2001) checklist. In order for this to happen, detailed criteria, similar to those already in the EAI, will need to be developed for these additional questions. Tenders will need to demonstrate awareness of the requirements of the CONSORT statement on the reporting of RCTs (Moher *et al.,* 2001).

4. When comparing tenders received, HSE should compare the amount of staff time allocated in order to form a judgement on the ability of the project team to deliver the specified project.

5. Any tenders received should be compared with the outline project plan in Section 5 to ensure that all necessary activities are included. It should be borne in mind that tenders could differ in detail from the example outline, particularly in relation to sequencing or overlapping of project activities.

6. Multi-component/multi-factorial study designs that attempt to intervene in several ways should be favoured.

7. Known risk factors should be the targets of the intervention research and doses, responses and capacity factors should be measured to the extent possible. Possible interactions between risk factors need to be considered.

8. All study design decisions and power calculations will need to involve a statistician and must be documented. The PASS 2005 software package can be recommended for performing power calculations.

9. Except where completely impossible, any intervention should be piloted to check that it can be implemented successfully.

10. The study will need to measure not only lost-time due to MSDs, but will also need a hierarchy of case definitions to capture the range of possible adverse outcomes that do not lead to lost-time. A system for immediate reporting of incidents alongside a regular follow-up system is recommended in order to increase the probability of capturing incident events.

11. The study will need to control for different workplace cultures, and different absence management expectations and milieus. If a multi-national study is chosen then cultural differences will need to be considered at the design stage.

12. It is recommended that economic evaluations are carried out when choosing the interventions to be attempted and in the final analysis of the results of the study. While a variety of methods are available (Korthals-de Bos *et al.,* 2006), it is likely that cost-utility analysis and cost-benefit analysis would be suitable. Both broad societal perspectives and the narrow perspective of the employer would need to be considered.

13. Once the study is complete, careful attention must be paid to proper reporting of the study. This will aid interpretation, application and future meta-analysis. Results should be presented in at least two stages; firstly with an initial report describing and summarising the data, and secondly presenting the results from all statistical analyses. It is recommended that any tender specification state that the CONSORT checklist and flow diagram (Moher *et al.,* 2001) will be used alongside the augmented EAI (Genaidy *et al.,* 2007; Karsh *et al.,* 2001) to evaluate not only the initial tenders but also the progress and final reporting of the project.

7 GLOSSARY

Term	*Definition*
Aetiology	The factors that cause a disease or health problem
Attributable Fraction (AF)	The proportion of incident cases that can be attributed to a particular exposure or risk factor.
Association	A relationship between two variables so that a change in one is linked to a change in the second.
Bias	The effect of external or uncontrolled factors on the conclusions of a study.
Blinding	Allocation of subjects to a treatment condition so that they, or they experimenter, or both, are unaware of whether the treatment is the active intervention or the placebo.
Causality	The determination if a change in one variable causes a change in a second variable.
Confounding	A confusion of effects so that the apparent effect of an exposure is distorted by an extraneous factor.
Differential attrition	A difference in drop-out rates between intervention and control groups due to factors extraneous to the study.
Ecological study	A study that compares results from groups rather than individuals.
Ecological fallacy	Assuming that the results of an ecological study apply to all individuals within the group
Effect size	The size of a difference in outcome measures, e.g., between an intervention group and a control group.
Healthy worker effect	The tendency for a workforce to consist of “survivors” who can cope with the exposures in the workplaces. They remain after other individuals have left the workforce due to morbidity or mortality.
Incidence rate	The frequency of new cases of the outcome of interest.
Intention to treat analysis	Analysis of outcomes based on how subjects were assigned to intervention or control groups, rather than on the basis of the actual intervention received.
Intervention study	A study where the exposure to a risk factor is manipulated to examine its effect.
Matching	Allocation of subjects to groups so that individuals or groups are matched for certain variables, such as age and gender.
Non-specific low back pain	Low back pain that cannot be attributed to a specific pathology or lesion.
Non-specific arm pain	Arm pain that cannot be attributed to a specific pathology or lesion.
Nocebo effect	A negative health outcome associated with negative beliefs about the effects of an inactive treatment.
Placebo	An inactive or ineffective treatment or intervention given to a control group.
Placebo effect	A positive health outcome associated with positive beliefs about the effects of an inactive treatment.
Power	The ability of a statistical test to detect a genuine difference or effect
Prevalence rate	The frequency of existing cases of the outcome of interest
Randomisation	Allocation of subjects to study conditions so that the probability that each subject is allocated to a particular condition is known.

Randomised controlled trial	A longitudinal study where subjects are randomised to control and intervention groups.
Statistical significance	An observed outcome being less probable than a pre-determined level, typically 5%.
Stratification	Creating subject groups that fit into separate levels or categories on a particular variable, such as age.

8 ACRONYMS AND ABBREVIATIONS

Acronym/abbreviation	*Meaning*
CCT	Controlled Clinical Trial
CRT	Clustered Randomised Trial
CV	Coefficient Of Variation
DAG	Directed Acyclic Graph
DHHS	Department of Health and Human Services
EAI	Epidemiological Appraisal Instrument
FOM	Faculty of Occupational Medicine
GEE	Generalized Estimating Equations
HSE	Health and Safety Executive
HSL	Health and Safety Laboratory
ICC	Intra-cluster Correlation Coefficient
IOM	Institute of Occupational Medicine
LBD	Low back disorders
LBP	Low back pain
MRC	Medical Research Council
MSD	Musculoskeletal Disorder
NIOSH	National Institute for Occupational Safety and Health (U.S.)
NORA	National Occupational Research Agenda
NRC	National Research Council
NMQ	Nordic Musculoskeletal Questionnaire
OR	Odds Ratio
PHM	Proportional Hazards Model
RCT	Randomised Controlled Trial
WMA	World Medical Association
WMSD	Work-related Musculoskeletal Disorder
WRMSD	Work-Related Musculoskeletal Disorder

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Feasibility of carrying out an ergonomics intervention study to prevent the incidence of musculoskeletal disorders

This work examines the feasibility of assessing the effectiveness of workplace ergonomic interventions to prevent the onset of musculoskeletal disorders (MSDs). It reviews existing models of causation of MSDs and the scientific literature on interventions to prevent MSDs. It describes relevant epidemiological methods and research protocols.

Many previous studies of the risk factors for MSDs have not been able to assess causation and the need remains for intervention studies of high methodological quality to do this. A longitudinal Cluster Randomised Trial is the most appropriate study design for assessing MSD causation in an occupational setting. Measurement of injury rates generally requires very large samples and/or long follow-up times to provide adequate statistical power. It is likely that the study would need to be carried out across multiple employers.

Because of the scale of the MSD problem, it is recommended that HSE consider funding or part-funding a study designed to test the effectiveness of workplace ergonomics interventions to prevent the onset of episodes of musculoskeletal disorders. Consideration should be given to making the study a multi-centre, possibly international, collaborative study. Such a study would be high risk due to the scale and duration needed and the practical and organisational difficulties involved.

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