

Rehabilitation of Patients with Chronic Pain Conditions

A Systematic Review

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Summary and Conclusions of the SBU Report:
**Rehabilitation of Patients
with Chronic Pain Conditions**

A Systematic Review

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SBU's Conclusions

Multimodal rehabilitation denotes a combination of psychological measures and physical activity/exercise, manual or physical methods. Health care personnel work in a team, of which the patient is also a member. The measures need to be coordinated and continued over a lengthy period of time. Multimodal rehabilitation is usually carried out at a hospital, in special clinics.

- Compared with less extensive treatment or no treatment at all, multimodal rehabilitation improves the potential for a patient to return to work. Other benefits include a reduction in sick leave and also the patients' own perception of increased ability to work. With respect to these benefits, however, the scientific basis is inadequate to determine which type of multimodal rehabilitation gives the best results.
- Since the previous SBU report "Methods of treating chronic pain" in 2006, a number of high quality studies have been published on the effects of multimodal rehabilitation. With respect to the effect on pain relief, the overall scientific evidence has therefore changed, from supporting an effect, to showing no greater benefit than with less comprehensive treatment measures. This applies to chronic pain from the neck, shoulders and lower back.

Behavioural medicine is based on the concept that the patient's thoughts, behaviour and environment are of importance for rehabilitation. Treatment strategies intended to change behaviour are combined with physical activity/ exercise. Together, the therapist, usually a physiotherapist and the patient share responsibility for carrying out the treatment. The treatment can be carried out in the primary care setting.

- This approach to treatment results in improved levels of activity compared with other treatment regimes that do not include a behavioural medicine approach. The effect persists for 2–5 years after completion of treatment. The long-term effects of physical activity/exercise, manual and physical methods and combinations of these cannot be differentiated. The scientific evidence is insufficient to determine the cost-effectiveness of these methods.

Acupuncture stimulates using needles which penetrate the skin or the mucous membrane. The method is applied both within orthodox health care and in alternative and complementary medicine.

- Compared with control methods involving some form of stimulation, acupuncture shows no difference with respect to either pain intensity or levels of activity three months after completion of treatment.



SBU's Summary

Background and aim

The SBU report “Methods of treating chronic pain” was published in 2006. Further relevant research results have since been published. SBU has therefore undertaken an update with respect to rehabilitation in the broad sense, for chronic pain from the neck, shoulders and lower back and also for generalized pain, including fibromyalgia.

Limitations

Description of patient groups included

In the treatment setting, there is a tendency to classify pain conditions on the basis of anatomical location. This approach has probably relatively little relationship to the origin and persistence of the pain. The current state of knowledge indicates that instead, it may be more relevant to classify patients and regard the chronic pain from a biopsychosocial aspect, ie a state in which biological, psychological and environmental factors interact in a complex way to contribute to the initiation and persistence of pain. The report has focused on treatment methods which have been tested scientifically on individuals suffering from pain from the back, neck, or most of the body, which has persisted for more than 3 months. Studies on pain associated with cancer or diabetes have not been included. Assessment of working ability has been central to the evaluation: hence only studies of subjects aged between 18 and 65 years have been included.

Description of methods included in the report

Multimodal rehabilitation is based on the so-called biopsychosocial model, which proposes that successful treatment must include consideration of somatic, psychological, environmental and personality aspects of the condition. Programmes for multimodal rehabilitation usually use an approach based on behavioural psychology, in combination with – for example – relaxation, ergonomic measures, different methods for coping with pain and education about the topic. Multimodal rehabilitation is a process of well-planned and coordinated measures, involving several different professions, with a common goal, over a lengthy but defined period. The therapists work in a team, of which the patient is also a member. In order to determine the long-term results of such a comprehensive treatment as multimodal rehabilitation, the minimal follow-up period was set at 1 year.

The report also scrutinizes treatment methods commonly applied by physiotherapists: physical training, counselling, massage, manipulation and physical modalities. Training can be integrated with behavioural medicine strategies, which are based on the principles of the psychology of learning. Behavioural medicine includes eg exercises in problem solving strategies, positive reinforcement, progressive goal formulation and an activity diary. Follow-up of treatment results should be conducted at the earliest 3 months after completion of treatment.

Evaluation of psychological treatment methods applies to treatment by a single therapist, such as a psychologist or a behavioural scientist. This particular delineation is made in order to differentiate effects attributable to the psychological method from the effect achieved by a multimodal rehabilitation treatment programme which includes behavioural modification. A follow-up period of at least three months was required.

Acupuncture is defined as mechanical, thermal or electrical stimulation via needles which penetrate the skin or the mucosa. Transcutaneous electrical nerve stimulation (TENS) is a non-invasive form of treatment in which the nerve fibers are electrically stimulated via electrodes on the skin. For acupuncture studies, the minimal follow-up time of treatment effects was set at three months. As TENS is often used as a complement to or as an alternative to medication, there was no requirement that this treatment should exhibit long-term effects. The evaluation therefore includes studies which present results directly after treatment.

Description of the outcomes which were evaluated

In this report we have chosen to assess treatment results which are encompassed by the different domains in the ICF (classification of function/ functional impairment and health). ICF is a model which has been accepted by clinicians and researchers as a structured and uniform means of evaluating the results of treatment methods targeting people with chronic pain. The domains of the model address the effect of treatment on pain, physical and emotional function, including the patient's own perception of change, satisfaction with treatment, other symptoms and side effects and the level of patient participation. A common outcome measure is disability, which describes a patient's ability to manage activities of daily living, to move around normally and to enjoy a functional social life without being affected by pain.

Also accepted as results in the report are measures as to what extent the treatment has allowed a person with chronic pain to return to work or studies, or to what extent the patient perceives that this would be possible.

The report presents the results of the various rehabilitation measures in terms of both local effects, eg less discomfort from the lower back, or as a more general effect, eg improved functional ability, depending on how these effects are reported in the scrutinized studies.

It was also a requirement for inclusion in the report that studies on health economic aspects of treatment should include evaluation of both costs and effects, should be relevant to Swedish conditions and contain a comparison with the best alternative.

Content of the report

The report presents the results of systematic reviews of the scientific evidence of benefits and risks associated with new methods being applied to treat people with chronic pain. Chapter 2 describes the methodology applied in the systematic review of the literature. The results of the evaluation of the treatment methods identified for treatment are presented in Chapter 3, which is the central and most extensive chapter in the report. Chapter 4 presents a discussion of ethical and social aspects of rehabilitation of people suffering from chronic pain. In the context of the literature review, Chapter 5 comprises a discussion of factors which may be of importance in implementing evidence-based knowledge in the field of rehabilitation and some proposals for changes to established practice. Chapter 6 concludes the report, with a presentation of gaps in current knowledge and important topics of future research.

Questions

The general issues to be addressed were:

- Which methods are effective for treatment of patients suffering from chronic pain?
- What information is available about the cost-effectiveness of these methods?

Method for review of literature

SBU has established a thorough and systematic method by which available databases are searched, to identify all literature relevant to the issues to be addressed in a project. For the present report, this involved an update of previous searches prior to the year 2004. The original search strategy from the previous report was used, as well as a search strategy based on index words (key words) found in the systematic overviews which were identified and tabulated. Each study included in the evaluation has been assessed for quality and tabulated according to a specially developed method. Quality assessment of the health economics articles was carried out as a collaborative effort between medical experts and health economists.

Facts 1 Study quality and strength of the evidence.

Study quality refers to the scientific quality of an individual study and its ability to provide a valid answer to a specific question.

Strength of the evidence refers to a judgment of the total strength of all scientific evidence and its ability to provide a valid answer to a specific question. SBU uses GRADE, an international grading system for scientific evidence. Study design is a key element in the overall judgment of each outcome measure. Other factors that can weaken or strengthen the power of the evidence are study quality, relevance, consistency, transferability, effect size, data precision, risk of publication bias, and other aspects, eg, the dose-response relationship.

Grading the strength of the evidence – four levels:

Strong scientific evidence (⊕⊕⊕⊕). Based on high-quality studies containing no factors that weaken the overall judgment.

Moderately strong scientific evidence (⊕⊕⊕○). Based on high-quality studies containing isolated factors that weaken the overall judgment.

Limited scientific evidence (⊕⊕○○). Based on high- or medium-quality studies containing factors that weaken the overall judgment.

Insufficient scientific evidence (⊕○○○). The evidence base is insufficient when scientific evidence is lacking, quality of available studies is poor, or studies of similar quality are contradictory.

The stronger the evidence, the less likely it is that the results presented will be affected by new research findings within the foreseeable future.

Conclusions

SBU's conclusions represent our overall judgment of benefits, risks, and cost-effectiveness.

Results

Multimodal rehabilitation

In most of the included studies, women comprised the majority of patients. However, it is unusual for the results for men and women patients to be presented separately. In studies which describe the treatment setting, it is stated that treatment was conducted at specialist level, usually a rehabilitation centre at a hospital, with the subjects as outpatients. The implication is that in contrast to patients undergoing treatment within the primary care section, these patients have had a more complex pain problem, eg with respect to pain intensity, depressive state, catastrophic thoughts and a history of sick leave. Variations in complexity among patients may also contribute to the fact that not all have experienced similar benefits from a multimodal rehabilitation programme. Usually, two to four therapists, from different professional disciplines, have participated in the treatment team.

The overall outcomes with respect to the effects of multimodal rehabilitation comprise a synthesis of the results of the previous review of the literature in the SBU report from 2006 and the results from more recently published literature. The effects have been analyzed partly by a general evaluation of the outcome measures presented and partly per single outcome measure.

General evaluation

- In cases of back pain, multimodal rehabilitation, which usually comprises a combination of psychological measures and physical activity/exercise, manual or physical modalities, leads to an overall better result than less comprehensive treatment or no treatment at all. This evaluation is in agreement with the conclusions of the SBU report from 2006, which applied to all chronic pain, regardless of which part of the body was affected.

- The scientific evidence is inadequate for any definite conclusions to be drawn about the cost-effectiveness of multimodal rehabilitation. (⊕○○○).

Results per effect measure

- Multimodal rehabilitation for treatment of chronic back pain leads to a reduction in sick leave and increased return to work rate than less intensive treatment or no treatment at all (moderately strong scientific evidence ⊕⊕⊕○).
- Multimodal rehabilitation for treatment of chronic back pain does not reduce the pain intensity, activity levels, or other symptoms compared with much less intensive treatment or no treatment at all (moderately strong scientific evidence ⊕⊕⊕○).
- The scrutinized studies show no differences between different types of multimodal rehabilitation programmes for chronic back pain with respect to pain intensity or other symptoms, disability or sick leave/return to work (moderately strong scientific evidence ⊕⊕⊕○).

Physical activity/exercise, manual and physical modalities and behavioural medicine treatment

The studies published since the 2006 SBU report differ in several respects from the earlier studies. It has become more common to compare different combinations of physical activity/exercise, manual and physical methods with one another. This development may reflect an attempt by researchers in this field to reduce the gap between research and established clinical practice. Problems arise, however, in attempting to determine which of the different measures are effective on their own and which combination of methods is necessary and adequate to achieve long-term benefits in cases of chronic pain.

Also, information about the qualifications/competence of the therapists and to what extent they complied with the treatment protocols has not been disclosed in studies investigating the effect of applying the principles of behavioural medicine to treatment.

Except where stated otherwise, the results presented below concern pain intensity and disability, ie the patient's ability to carry out activities of daily living, to move about normally and enjoy a fully functional social life without being hindered by pain.

- Behavioural medicine treatment results in a greater improvement in disability after 2–5 years than physical activity/exercise or combinations of treatment by physical activity/exercise, manual and physical modalities (strong scientific evidence ⊕⊕⊕⊕).
- The treatment modalities physical activity/exercise, manual and physical modalities and behavioural medicine each show statistically significant beneficial effects over time compared to pre-treatment status.
- The studies evaluated have not disclosed any differences in effect between simple counselling on self-care and the treatment modalities physical activity/exercise, manual and physical modalities, or combinations of these (limited scientific evidence ⊕⊕○○).
- No definite conclusions can be drawn with respect to the cost-effectiveness of the methods evaluated in the studies (insufficient scientific evidence ⊕○○○).



Psychological treatment methods

Psychological treatment is often provided as a separate clinical measure by a solo therapist, usually a psychologist or specialist in behavioural medicine. Even when a person with chronic pain is treated by a team, it is common practice for him or her to be referred for behavioural medicine. It is therefore important to evaluate the effects to be expected of psychological treatment provided by a solo therapist. In the evaluated studies such treatment has been carried out by a psychologist or specialist in behavioural medicine.

With respect to the following psychological treatment methods for people with chronic pain, this systematic review of the literature was unable to find adequate scientific evidence for overall results and conclusions:

- Social support
- Lifestyle changes
- Motivational measures (motivational interviews)
- Problem solving
- "Mindfulness"
- "Guided imagery"
- Hypnosis
- Structured writing exercises with emphasis on sensitive expressiveness
- Client-centered therapy
- In vivo exposure
- Cognitive behavioural therapy (CBT).
- Acceptance and commitment therapy (ACT).

Acupuncture, TENS (transcutaneous electrical nerve stimulation) and trigger point treatment

In the 2006 SBU report, acupuncture for treatment of chronic pain was evaluated in terms of effects directly after completion of treatment. In general, the studies of the application of acupunc-

ture for treatment of chronic pain published since the earlier report are of better quality than the earlier studies. However, there are still few studies which follow up the effects of treatment for some time after completion of the actual treatment. In the present report, the minimal interval for follow-up of effects of acupuncture was set at three months.

- Three months post-treatment, the effect of acupuncture for pain relief for chronic pain back pain is comparable with that of control treatment using sham-acupuncture (moderately strong scientific evidence ⊕⊕⊕○).
- Three months post-treatment, functional improvement after acupuncture treatment of chronic back pain is comparable with the effect of control treatment with sham-acupuncture (moderately strong scientific evidence ⊕⊕⊕○).
- As a complement to other treatment measures, acupuncture can result in better pain relief (limited scientific evidence ⊕⊕○○).
- Relief of pain from fibromyalgia following acupuncture is comparable with that of control treatment with sham-acupuncture (limited scientific evidence ⊕⊕○○).
- In the short term, relief of chronic back pain following treatment with either high- or low-frequent TENS is greater than that of control treatment with sham-TENS (limited scientific evidence ⊕⊕○○).
- There is insufficient scientific evidence on which to evaluate the effect of TENS on function or to assess the long term effect ⊕○○○).

Ethical and social aspects

A person undergoing rehabilitation is expected to comply by making major lifestyle changes and changing his/her coping with pain. Lifestyle changes can include starting to exercise, changing attitudes in order to achieve greater control over the pain and various strategies to return to work after (in some cases) a protracted period of sick leaves.

It is debatable as to whether medical personnel should persist with the aim of “doing good” for the individual patient with chronic pain. It is, for example, not clear to what extent the medical profession should interfere in a patient’s lifestyle or demand compliance as a condition of treatment.

Despite the fact that the positive sequel of treatment seem to dominate; ethical problems arise, primarily with respect to autonomy and justice. It is unclear how much consideration is given to the patients’ preferences compared with those of the medical professional/therapist. It is questionable whether it is possible to reconcile freedom of choice with the requirement that the patient really makes an effort to achieve a positive treatment result. In this context, another important issue is the degree to which the pain is associated with underlying unresolved social problems.

A condition for fulfilling the ethical principles is that people with chronic pain are well-informed about possible treatment alternatives and possible sequel. Moreover they should be given the opportunity to participate in decisions about the form of rehabilitation. Patients with chronic pain can in many cases find it difficult to assert themselves. For the sake of equity, it is therefore important to ensure that these patients receive the treatment they are entitled to.

Consequence analysis and possible changes to established practice

Certain changes to established practice would probably contribute to more evidence-based treatment of people with chronic pain, eg:

- Increased use of multimodal rehabilitation for patients with complex symptoms.
- Treatment based on the principles of behavioural medicine, including physical activity/exercise, should be used more frequently in primary care treatment of people with chronic pain.
- Methods based on nerve stimulation eg acupuncture and TENS, may be developed.

It is difficult to predict the combined health, ethical, social and economic consequences of these proposed changes to established practice. More qualified and individually tailored care should lead to obvious improvements for the patients in question.

The evaluation indicates that patients with chronic pain who participate in rehabilitation based on multimodal methods have a greater potential to improve their condition in the long-term. However, this relatively expensive treatment form is not appropriate for all patients with chronic pain. Those patients with less complex problems can instead undergo rehabilitation in the primary care setting.

This report considers several treatment methods which are commonly used in the primary care setting. Many of these are provided by physiotherapists who work within the established health and medical care system. Physical training achieves positive

effects on activity levels and self-reported pain. As no clear differences can be discerned in effect, the most cost-effective means is to select the least expensive method.

One explanation of the long-term effect of treatment according to behavioural medicine principles is that such treatment reinforces the patients' confidence in their own ability to manage activities of daily living and to be physically active. Increased use of behavioural medicine treatment which includes physical activity/exercise can result in improvement in the patients' ability to manage the pain themselves. A prerequisite is the development of competence within the primary care sector in this relatively new field of knowledge. In this context, there can be however, a risk for conflict between various ethical principles.

The report shows that TENS gives pain relief directly after stimulation. Otherwise healthy people with chronic pain can therefore be offered the opportunity to try TENS as a safe alternative without serious side-effects.

Knowledge gaps and the direction of future research

The systematic review of the literature has exposed lack of knowledge in certain fields with respect to non-pharmacological treatment of chronic pain. It has therefore not been possible to address all the issues originally raised for evaluation.

The available studies seldom include a description of the content of the various sections of the treatment programme, how comprehensive these sections are or the profession and level of competence of the therapists responsible for delivering treatment in the different parts of the programme. In order to improve clarity, there is a need for a standardized, concise means of describing

the content of the programme. One reference point for improving the potential for comparison between different studies can be to start with topics which are important in evaluation of treatment studies. One example can be the proposal for systematization by the international expert group IMMFACT. To encourage researchers to use the same point of reference when measuring the effects of treatment can provide a good basis for future research. There is also a need for a standardized description of patients with chronic pain. Using a database constructed on such a system would enable a research group to compare their patient group with those of other studies.

Treatment of chronic pain can result in side effects or complications. Because this aspect of treatment is seldom reported in studies, there is little information available on how commonly these arise.

There are hardly any studies at all which disclose how the organization of health care or health care routines influences the outcome of various treatment strategies for people with chronic pain.

There are only limited health economic studies in this field. There is a need for health economic studies of costs and effectiveness of various non-pharmacological methods for treating chronic pain. Future studies should be designed in order to allow conclusions to be drawn with respect to generalizability of treatment effects to the heterogeneous group comprising patients with chronic pain. Studies that can provide clearer guidance as to where in the health care system patients with different types of pain should be treated, what intervention is most appropriate and at what stage of treatment are needed. The potential to assess, in broad terms, the relationship between cost-effectiveness and health care organization would thus also be improved.

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SBU Evaluates Health Care Technology

Below is a brief summary of the mission assigned to SBU by the Swedish Government:

- SBU shall assess healthcare methods by systematically and critically reviewing the underlying scientific evidence.
- SBU shall assess new methods as well as those that are already part of established clinical practice.
- SBU's assessments shall include medical, ethical, social and economic aspects, as well as a description of the potential impact of disseminating the assessed health technologies in clinical practice.
- SBU shall compile, present and disseminate its assessment results such that all parties concerned have the opportunity to take part of them.
- SBU shall conduct informational and educational efforts to promote the application of its assessments to the rational use of available resources in clinical practice, including dental care.
- SBU shall contribute to the development of international co-operation in the field of health technology assessment and serve as a national knowledge centre for the assessment of health technologies.

Rehabilitation of Patients with Chronic Pain Conditions

SBU's report on rehabilitation of patients with chronic pain conditions builds on a systematic, critical review of the scientific literature in the field.

The report is one in a series of reports published by SBU (Swedish Council on Health Technology Assessment).

This document presents the summary and conclusions of the full report, which has been approved by SBU's Board of Directors and Scientific Advisory Council.