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Effects of Passive Movement Therapy in Patients with Stroke, Spinal Cord Injury, or Need of Intensive Care

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VÄSTRA GÖTALANDSREGIONEN
SAHLGRENSKA UNIVERSITETSSJUKHUSET

Effects of Passive Movement Therapy in Patients with Stroke, Spinal Cord Injury, or Need of Intensive Care

[Effekter av passivt rörelseuttag hos patienter med stroke, ryggmärgsskada eller behov av intensivvård]

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Table of contents

1. Abstract 4
2. Svensk sammanfattning – Swedish summary 5
3. Summary of Findings 7
4. Background 8
5. Objective 10
6. Methods 10
7. Results 11
8. Ethical issues 12
9. Organisational aspects 13
10. Economic aspects 13
11. Discussion 14
12. Future perspectives 15
13. Participants in the project 16

Appendix 1 Search strategy, study selection and references
Appendix 2 Included studies – design and patient characteristics
Appendix 3 Excluded articles
Appendix 4 Outcome tables

1. Abstract

Background
Therapy with passive movements is a widely used treatment in which the limbs of a patient are passively moved by another person, or by the person itself with the assistance of a loop, gravity, or by a healthy extremity. It is used in patients at risk of developing contractures, oedema and pain. These patient categories include patients with stroke, spinal cord injury, severe burns, orthopaedic injuries, or for any reason in need of intensive care treatment.

Objective
To assess whether passive movement therapy leads to better function, increased activity, greater range of motion of affected joints, reduced pain, or improved health-related quality of life in hospitalised adult patients with either a stroke, a spinal cord injury, or in need of intensive care compared with no passive movement therapy.

Methods
A systematic literature search was conducted in Medline, Embase, the Cochrane Library, Amed and HTA databases. The certainty of evidence was graded according to the GRADE system.

Main results
Only two studies, one randomised controlled trial (RCT) and one cohort study, fulfilled the criteria for inclusion. Both studies included patients with stroke, and the stroke patients in the RCT were also in need of intensive care. No controlled study was identified that evaluated passive treatments in patients with spinal cord injury. Moreover, no controlled study was identified that evaluated the effects on contractures, health-related quality of life, cerebral blood flow or cortical activation.

Function and activity was evaluated in the RCT by a self-care score. It was significantly higher after four weeks of treatments in the intervention group compared with the control group. Conclusion: Treatment with passive movement therapy may slightly improve function and activity in patients with stroke (low certainty of evidence, GRADE ⊕⊕○○) but it is uncertain whether there is any difference after treatment with passive movement therapy in patients in intensive care (very low certainty of evidence, GRADE ⊕○○○).

Range of motion in the upper extremities was evaluated in the RCT and found to be significantly increased at four weeks compared with the control group. Conclusion: Treatment with passive movement therapy may slightly improve ROM in patients with stroke (low certainty of evidence (GRADE ⊕⊕○○) but it is uncertain whether there is any difference after treatment with passive movement therapy in patients in intensive care (very low certainty of evidence (GRADE ⊕○○○).

Pain was not specifically addressed in the studies. However, since it is a major symptom of the Shoulder-Hand-Syndrome (SHS) the incidence of SHS was used as a surrogate variable for pain. The cohort study found that restricted use of passive movement therapy according to a strict protocol resulted in a lower incidence of SHS than if such a protocol was not used.
Conclusion: It is uncertain whether passive movement therapy has any beneficial effects on pain in patients with stroke (very low certainty of evidence, GRADE ⊕○○○).

Concluding remarks
There is limited scientific documentation with regard to the effects of passive movement therapy in patients with stroke, spinal cord injury or need of intensive care. Nevertheless, the clinical experience and perceived benefits make it an ethical dilemma whether to withdraw or continue use of passive movement therapy.

2. Svensk sammanfattning – Swedish summary

Bakgrund
Behandling med passivt rörelseuttag är en vanlig behandlingsform som innebär att en patients extremitet rörs passivt av en annan person eller av patienten själv med hjälp av en frisk extremitet eller tyngdkraften. Det används för patienter med risk att utveckla kontrakturer, ödem eller smärta. Patientkategorier där behandlingen är vanlig inkluderar patienter med stroke, ryggmärgsskada, allvarliga brännskador, ortopediska skador samt de som av andra orsaker är i behov av vård på intensivavdelning.

Syfte
Att utvärdera huruvida passivt rörelseuttag på vuxna patienter inlagda på sjukhus för stroke, ryggmärgsskada eller intensivvård leder till bättre funktion, ökad aktivitetsnivå, större rörelseomfång i den påverkade leden, minskad smärta eller förbättrad hälsorelaterad livskvalitet, jämfört med inget passivt rörelseuttag.

Metod
En systematisk litteratursökning gjordes i Medline, Embase, Cochrane Library, Amed och HTA-databaser. Tillförlitligheten till det vetenskapliga underlaget graderades enligt GRADE-systemet.

Huvudresultat
Endast två studier, en randomiserad kontrollerad studie (RCT) och en kohortstudie, uppfyllde inklusionskriterierna enligt PICO. Båda studier avsåg patienter med stroke och patienterna med stroke i RCT:n var även i behov av intensivvård. Ingen kontrollerad studie identifierades som utvärderade passivt rörelseuttag på patienter med ryggmärgsskada. Inga kontrollerade studier identifierades som utvärderade effekter på andra utfall än nedanstående.

Funktion och aktivitet mättes i RCT:n med ett ”self-care score” och var signifikant förbättrad efter 4 veckors behandling med passivt rörelseuttag jämfört med kontrollgrupp.
<u>Slutsats:</u> Behandling med passivt rörelseuttag kan förbättra funktion och aktivitet något hos patienter med stroke (begränsat vetenskapligt underlag, GRADE ⊕⊕◯◯) men det är osäkert huruvida det finns någon skillnad jämfört med kontrollgrupp hos patienter som vårdas på intensivavdelning (otillräckligt vetenskapligt underlag, GRADE ⊕◯◯◯).

Rörelseomfång mättes i RCT:n och ökade signifikant efter 4 veckor jämfört med kontrollgrupp.
<u>Slutsats:</u> Behandling med passivt rörelseuttag kan förbättra rörelseomfång något hos patienter med stroke (begränsat vetenskapligt underlag, GRADE ⊕⊕◯◯) men det är osäkert huruvida det finns någon skillnad jämfört med kontrollgrupp hos patienter som vårdas på intensivavdelning (otillräckligt vetenskapligt underlag, GRADE ⊕◯◯◯).

Smärta mättes inte i någon av studierna men eftersom det är ett huvudsymtom i Skuldra-Hand-Syndrom (SHS) användes SHS som ett surrogatmått för smärta i kohortstudien. Studien visade att begränsad användning av passivt rörelseuttag enligt ett strikt protokoll resulterade i lägre incidens av SHS än om ett strikt protokoll inte användes.
<u>Slutsats:</u> Det är osäkert huruvida passivt rörelseuttag har någon effekt på smärta hos patienter med stroke (otillräckligt vetenskapligt underlag, GRADE ⊕◯◯◯).

Sammanfattande kommentarer
Den vetenskapliga dokumentationen är begränsad avseende effekterna av passivt rörelseuttag hos patienter med stroke, ryggmärgsskada eller behov av intensivvård. Klinisk erfarenhet av positiva effekter gör det till ett etiskt dilemma huruvida man bör fortsätta eller upphöra med denna behandling.

The above summaries were written by representatives from the HTA-centrum. The HTA report was approved by the Regional board for quality assurance of activity-based HTA. The abstract is a concise summary of the results of the systematic review. The Swedish summary is a brief summary of the systematic review intended for decision makers, and is ended with a concluding summary.

Christina Bergh, Professor, MD
Head of HTA-centrum of Region Västra Götaland, Sweden, 2018-05-30

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DDS Doctor of dental surgery
MD Medical doctor
PhD Doctor of Philosophy
PT Physiotherapist
RN Registered Nurse

3. Summary of Findings

Patients with stroke and in need of intensive care

Outcomes	Study design Number of studies	Absolute effect	Certainty of evidence GRADE[1]
Function and activity	RCT 1	Self-Care Score (7-42) 18.2 vs 12.7 Δ + 5.5	⊕⊕◯◯[1] ⊕◯◯◯[2]
Range of Motion	RCT 1	Shoulder flexion Difference: + 7.9° Elbow supination Difference: + 0.4° Wrist extension Difference: + 2.1°	⊕⊕◯◯[1] ⊕◯◯◯[2]
Pain	Non-randomised controlled study 1	Incidence SHS 18.5 % vs 32.4 %	⊕◯◯◯[3]

Abbreviations: SHS = Shoulder-Hand Syndrome

Footnotes: [1.] GRADE with regard to Stroke: Some study limitations, some indirectness, and uncertain precision.
[2.] GRADE with regard to need of intensive care. Some study limitations, serious indirectness, and uncertain precision.
[3.] Serious study limitations, some uncertainty with regard to directness, uncertain precision.

Certainty of evidence

High certainty ⊕⊕⊕⊕	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty ⊕⊕⊕◯	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty ⊕⊕◯◯	Confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low certainty ⊕◯◯◯	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

4. Background

The disorders of interest and the degree of severity

Neurological diseases and injuries, trauma, severe burns, severe infectious diseases, rheumatoid arthritis, orthopaedic injuries, and long-term postoperative care are conditions that could lead to contractures (shortened muscles), oedema and pain. This may lead to permanent damage, reduced quality of life, and a risk of disability (Yarkony et al. 1985, Deng et al. 2016, Andrade et al. 2016, Fergusson et al. 2007). Passive movement therapy is widely used in physiotherapy and occupational therapy (Chang et al. 2002, Weber et al. 2015, Vér et al. 2016) in order to prevent these complications in patients who are unable, or not allowed, to perform active movements. Since passive movement therapy is a commonly used intervention, perceived as beneficial by both patients and healthcare providers, it is important to clarify its effects.

Prevalence and incidence of contractures and pain

In an Australian study half of all patients developed at least one contracture within six months after a stroke. In the patients with moderate to severe strokes the incidence of contracture was even higher (Kwah et al. 2012). Many patients with stroke often develop pain in the affected shoulder (Fergusson et al. 2007).

Contractures are also common in patients with tetraplegia with over half of the joints affected in the upper extremities (Hardwick et al. 2018).

More than a third of all patients who are treated in an intensive care unit develop a functional major joint contracture after a prolonged stay (Clavet et al. 2008). Furthermore, it has been reported that nearly 40% of the patients who were admitted to a specialized burn unit had at least one contracture in a major joint at hospital discharge (Schneider et al. 2006).

Present use of passive movement therapy

Passive movement therapy is a treatment in which the limbs of a patient are passively moved by another person, or by the person itself with the assistance by a loop, the gravitation or by a healthy extremity. In the literature different names are used for this therapy such as passive movements, passive limb/joint movements, contracture prophylaxis and passive mobilization. The definition of range of motion (ROM) is "range of rotation or translation through which a joint is actively or passively moved between two extreme positions in a certain direction", and it is quantified in degrees or millimetres (de Groot et al. 2005).

The main reasons (Stockley et al. 2012) for the use of passive movements are:

- assessment of range of motion, muscle tone and pain.
- prevention of contractures, shoulder problems, stiffness and oedema.
- maintenance and restoration of range of motion, muscle length, as well as soft tissue extensibility and circulation.

Passive movement therapy can be administered by physiotherapists, occupational therapists, nurses, assistant nurses and other care givers in hospitals as well as in primary or home-based care.

There is a wide variety in the duration of the separate treatment sessions and the total treatment period depends on the number of joints that are treated, and whether the patient has spasticity, oedema or pain.

At the Sahlgrenska University Hospital (SU) treatment with passive movements is widely used. Mostly it is given by physiotherapists and occupational therapists, but it could also be performed by nurses and assistant nurses. Since almost every ward in Swedish hospitals has a physiotherapist affiliated to its staff, the treatment of the patient often starts on the same day the need of this treatment has been recognized. After discharge from the hospital care givers and staff in the community health care system are trained to perform the passive movements.

Number of patients per year treated with passive movement therapy

There are no reliable statistics on how many patients annually receive passive movement therapy. However, it is a common treatment which is performed every weekday by physiotherapists and occupational therapists at SU.

Present recommendations from medical societies or health authorities

Passive movement therapy is recommended in several SU local physiotherapy/occupational therapy guidelines as well as international medical guidelines for both patients with neurological and non-neurological conditions (Sahlgrenska Universitetssjukhuset 2016a-c, Sommers et al. 2015, Wiles et al. 2010, Kamolz et al. 2009, Gosselink et al. 2008) at risk of developing contractures, or when oedema and pain complicate the underlying disorder.

Health technology at issue: Passive movement therapy

Treatment with passive movements is rarely used as a single intervention but is most commonly combined with other treatments as one part of a rehabilitation program.
Passive movement therapy aims for:

- prevention and treatment of pain, to give the patient a feeling of his/her bodily boundaries, and to provide a feeling of wellbeing
- rehabilitation after neurological conditions, such as stroke and neurological trauma, to evaluate or facilitate movements, to enhance blood flow in the associated brain area, to stimulate the recognition of an extremity in order to reduce neglect and spasticity, and to prevent and treat contractures and oedema
- prevention of contractures after spinal cord injuries
- evaluation of a patient in intensive care of his/her ability to perform own movements as well as the consciousness, and to screen for contractures or other joint or muscle disorders or undiagnosed fractures
- mobilisation of a joint in an orthopaedic patient who is not allowed, or capable, to do movements on his/her own with the purpose to prevent and treat oedema and contractures
- prevention of contractures after severe burns due to development of scar tissues
- prevention and treatment of oedema and contractures after fractures and neurological deficits in the hand and wrist

5. Objective

The question at issue

Does passive movement therapy lead to better function, increased activity, reduced contracture, greater range of motion of affected joints, reduced pain, or improved health-related quality of life in hospitalised adult patients with either a stroke, a spinal cord injury, or in need of intensive care compared with no passive movement therapy?

PICO: P= Patients, I= Intervention, C= Comparison, O=Outcome

P	Hospitalised adult patients with stroke, or spinal cord injury, or in an intensive care unit (ICU)
I	Passive movement therapy*
C	No passive movement therapy
O	Critical for decision making Function/activity level (validated scales) Important for decision making Contracture Range of motion (ROM) Pain Health Related Quality of Life (HRQoL) Not important for decision making Cerebral blood flow Cortical activation Adverse events/ complications

*) Passive movement therapy is defined as the treatment in which limbs of a patient are dynamically moved by another person, with less than 20 seconds' hold in the end position. No devices were allowed.

6. Methods

Systematic literature search (Appendix 1)

During November 2017 two authors (KF, ELD) performed systematic database searches in Ovid/Medline, OVID/Embase, the Cochrane Library, and Amed. The web-sites of SBU, Folkehelseinstituttet and Sundhedsstyrelsen were also searched. Reference lists of relevant articles were scrutinised for additional references. Search strategies, eligibility criteria, and a graphic presentation of the selection process are presented in Appendix 1.

All participants of the project group assessed the obtained abstracts and made a first selection of articles to be obtained in full text. A selection of articles in full text was done by two of the authors (KF, ELD), and the remaining articles were sent to all the participants of the project group. All authors read the articles independently, and decided in a consensus meeting which articles should be included in the assessment. Any disagreements were resolved in consensus.

Critical appraisal and certainty of evidence

The included studies, study designs, and patient characteristics are presented in Appendix 2. The excluded studies and the reasons for exclusion are presented in Appendix 3. The included studies were critically appraised using checklists from SBU (Swedish Council on Health Technology Assessment) and a checklist for assessment of case series, modified from Guo et al. (2013) by HTA-centrum. The results and the assessed quality of each article were summarised per outcome in Appendix 4. A summary of results and the certainties of evidence were presented in a Summary-of-findings table (page 7). The certainty of evidence was graded according to the Grade system (Atkins et al. 2004; GRADE Working group).

Ongoing research

Searches in Clinicaltrials.gov using the search terms (Stroke* OR Hemipleg* OR Hemipar* OR Spinal Cord AND (Injur* OR lesion* OR trauma* OR transection* OR laceration* OR contusion*) OR Traumatic Myelopath* OR Intensive Care Units OR Critical care* OR Intensive care* OR ICU OR NICU) AND ((Passive OR manual) AND (movement* OR exercise* OR motion OR therap* OR training OR stretch OR stretching OR mobilisation OR mobilization OR elongation) identified 45 trials.

7. Results

The literature search identified 1,815 articles after removal of duplicates. After reading the abstracts 1,725 articles were excluded. Another 63 articles were excluded after reading the articles in full text. The remaining 28 articles were read by all participants of the project group, whereafter two articles (one RCT and one non-randomised controlled study) were finally included in the assessment (Appendix 2).

No controlled study was identified that reported on any of the outcome variables of interest (see PICO) in patients with a spinal cord injury.

No controlled study was identified that reported on the effects on contractures, health-related quality of life, cerebral blood flow or cortical activation, or adverse events/complications in patients with stroke or in need of intensive care.

The RCT that reported effects of passive movements in patients with stroke was also separately assessed for patients admitted to an ICU.

OUTCOMES CRITICAL FOR DECISION MAKING

Function and activity (Appendix 4.1)

Function and activity was reported in one RCT (Kim et al. 2014). It was assessed in patients with acute stroke. They were evaluated by a "self-care score" (Granger et al. 1990, Granger et al. 1993). The study included a specific subgroup of acute stroke patients in need of intensive care (i.e. some indirectness) and also had some study limitations and the precision was uncertain. Regarding generalisability for patients in need of intensive care the study was considered to have serious indirectness.
The RCT reported a significantly greater change in self-care score at four weeks in the patients who were treated with passive movement therapy already from the time of admission compared to the control group who started treatment with passive movement therapy two weeks after admission to the ICU.

Conclusion for patients with stroke:
Treatment with passive movement therapy may slightly improve function and activity in patients with stroke. Low certainty of evidence (GRADE ⊕⊕◯◯).

Conclusion for patients in need of intensive care:
It is uncertain whether there is little or no difference in function and activity after treatment with passive movement therapy in ICU patients. Very low certainty of evidence (GRADE ⊕◯◯◯).

OUTCOMES IMPORTANT FOR DECISION MAKING

Range of motion (Appendix 4.2)
The effects of passive movement therapy on passive ROM was reported in the same RCT that evaluated function and activity (Kim et al. 2014). There were significant increases at four weeks in passive ROM in the upper extremities compared with the control group in which treatment with passive movement therapy was started two weeks after admission.

Conclusion for patients with stroke:
Treatment with passive movement therapy may slightly improve ROM in patients with acute stroke. Low certainty of evidence (GRADE ⊕⊕◯◯).

Conclusion for patients in need of intensive care:
It is uncertain whether there is any difference in ROM after treatment with passive movement therapy in ICU patients. Very low certainty of evidence (GRADE ⊕◯◯◯).

Pain (Appendix 4.3)
The effect of treatment with passive movement therapy on pain was not reported specifically in any of the identified controlled studies. However, pain is one of the characteristic symptoms of the Shoulder-Hand syndrome (SHS) that may develop following a stroke. The incidence of SHS was reported in one cohort study of stroke patients (Kondo et al. 2001). This study had some study limitations and problems with regard to directness and precision.

The study reported a significantly lower 4-month incidence of SHS with the use of a set protocol for controlled passive movement therapy by trained therapists, including the restriction of incautious movements, compared with a historical control group. The patients in the control group were not instructed to restrict their passive movements in the shoulder, i.e. risked performing incautious movements.

Conclusion: It is uncertain whether passive movement therapy has any beneficial effect on pain in patients with stroke. Very low certainty of evidence (GRADE ⊕◯◯◯).

8. Ethical issues

Based on very few studies with limited populations and low quality of evidence, but perceived good clinical experience, it may constitute an ethical dilemma whether to continue or withdraw a treatment that is perceived as beneficial by both patients and healthcare providers.

9. Organisational aspects

Present use of the technology in other hospitals in Region Västra Götaland

Passive movement therapy is widely used in patients with a variety of diagnoses, at SU and in other hospitals in Region Västra Götaland, as well as elsewhere in Sweden and worldwide (see section 4).

Consequences of passive movement therapy for personnel and organization

Passive movement therapy is presently performed by physiotherapists and occupational therapists at SU. The treatment is taught at undergraduate level and there are therefore no needs for information or training, whether the method remains in use or not. If the treatment is continued, there are no consequences for personnel and organization. If the treatment were to be discontinued or reduced in volume, work time will be made free for other tasks.

10. Economic aspects

Estimated present costs of currently used treatment strategy with passive movement therapy at Sahlgrenska university hospital (SU)

There are no reliable statistics on how many patients that annually are treated with passive movement therapy. Thus, some of the wards in which passive movement therapy is used at SU have made an estimation of the number of treated patients per week, the number of weekly treatments per patient, and the duration in minutes of each treatment session (Table 1).

The average hourly cost for a physiotherapist and an occupational therapist at SU is 350 SEK. This includes social security contribution, holiday allowance and overhead costs of 20%.

According to the estimation, 52 to 57 patients per week are treated with passive movement therapy either once or twice peer weekday (Monday to Friday). This corresponds to an estimated 260 to 300 hours per month at SU. The annual cost is then estimated to 1 010 000 to 1 500 000 SEK.

Table. 1. Estimated cost for treatment with passive movement therapy at Sahlgrenska University hospital.

Ward/Unit	Patients per week	Treatments per patient per week	Minutes per treatment	Monthly hours of treatment	Estimated monthly costs (SEK)
Spinal cord unit OT	4	10	20	57	20 130
Spinal cord unit PT	4	5	20	30	10 100
Intensive care unit	24-30	3	20	100-130	36 200 – 45 300
Stroke unit and Neurosurgery unit	20-27	5	10-15	70-140	25 200 – 50 000

Expected decrease in costs if the volume of passive movement therapy is reduced

This economic analysis is based on a scenario to estimate the cost savings with a reduction the volume of passive movement therapy. However, it is difficult to state to what extent treatment with passive movement therapy may decrease over time. Thus, for strictly economic aspects in this report, two scenarios are presented based on a reduction by:
1) 25%
2) 50%

In the first scenario, a 25% reduction in volume will yield a reduction of 65-75 treatment hours per month. This corresponds to an annual cost saving of 280 000 to 555 000 SEK. The corresponding figures in the second scenario are 130-150 treatment hours, yielding a cost saving of 550 000 to 870 000 SEK.

Available economic evaluations

No economic evaluations or cost-effectiveness analyses have been identified.

11. Discussion

In this HTA report, passive movement therapy was defined as the treatment in which limbs of a patient are dynamically moved by another person with less than 20 seconds' hold in the end position. Thus, passive stretch, self-treatment, use of gravity, or devices were not included.

The literature search identified only two studies conducted in specific patient categories that fulfilled the criteria defined in the focused question (PICO). This clearly shows that there is a substantial gap of knowledge concerning the effects of passive movement therapy. Furthermore, this systematic review showed that many clinically relevant outcome variables have not been studied at all in controlled trials.

Although some effects were reported in the two included studies, the effect sizes were generally small and it is uncertain whether those effects are clinically relevant. None of the studies defined any minimal clinical important difference. Moreover, the study limitations make it difficult to draw any certain conclusions, underscoring the need for more and better designed studies on the effects of passive movement therapy.

If passive movements are performed improperly, they may harm the patient. The non-randomised controlled study actually showed that passive movements performed in an excessive manner not following a strict protocol could increase the risk of shoulder pain (Kondo et al. 2001). However, we did not find any evidence that passive movements performed by therapists according to a strict protocol could harm the patients.

A common reason for using passive movements in the clinical setting is to facilitate active movements. Fu et al. (2015) suggested that passive movement induces cortical reorganization in patients with cerebral infarction, and that passive movements are beneficial for recovery of motor function in these patients. However, this has not been confirmed in controlled studies. Proprioceptive dysfunction is strongly associated with difficulties in postural control and activities of daily living. Baek et al. (2009) demonstrated the clinical feasibility of passive movements as a rehabilitation method for improving proprioception in patients with stroke. The results of the RCT by Kim et al. (2014) support that passive movements in the early stage of acute stroke can improve the function of upper extremities and ADL (Kim et al. 2014).

Clavet et al. (2008) found that already after two weeks of stay in the ICU with prolonged immobility 39 % of the patients developed functionally significant joint contractures. The contractures became more frequent the longer the patients stayed in the ICU. After discharge from ICU to home 50 of 147 patients (34%) had one or more joint contractures which influenced their ability to perform personal care, for example eating, showering, dressing. This lack of independence also imposed a burden on family members and healthcare providers. Clavet et al. (2015) argued that prevention of joint contractures should be considered critical for ICU patients. Delayed start of treatment of joint contractures might lead to increased length of stay, increased need of rehabilitation, and a higher cost for health care and society. Our own professional experiences are in agreement with this. Therefore, passive movement therapy is currently performed on a regular basis at SU.

We conclude that very little research has been performed on the effects of passive movement therapy in patients with stroke, spinal cord injury, or in need of intensive care, and the certainty of evidence for effect is low or very low. Nevertheless, the effects reported in the included studies, together with clinical experience and perceived benefits by both patients and healthcare providers, make it an ethical dilemma whether to withdraw or continue use of passive movement therapy for these patient groups.

12. Future perspectives

Scientific knowledge gaps

There is a substantial lack of knowledge on both short and long-term effects of passive movement therapy in the populations assessed in this HTA. Hence, a great need for high quality studies has been identified. Furthermore, there are other patient categories that have not been assessed in this HTA, and there are other types of passive movement therapy, i.e. using devices, stretch exercises, self-care or gravity, that have not been evaluated in this HTA.

Ongoing research

None of the 45 ongoing clinical trials identified in clinicaltrials.gov addressed the question at issue in this HTA.

13. Participants in the project

The question at issue was nominated by
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Declaration of interest
No conflicts of interest were declared.

Project time
The HTA was accomplished during the period of 2017-09-06 – 2018-05-30.

Appendix 1: PICO, study selection, search strategies and references

The question at issue

Does passive movement therapy lead to better function, increased activity, reduced contracture/ greater range of motion of affected joints, reduced pain, or improve health-related quality of life in hospitalised adult patients with either a stroke, a spinal cord injury, or in need of intensive care compared with no passive movement therapy?

P	Hospitalised adult patients with stroke, spinal cord injury, or in an intensive care unit (ICU)
I	Passive movement therapy*
C	No passive movement therapy
O	Critical for decision making Function/activity level (validated scales) Important for decision making Contracture Range of motion (ROM) Pain Health-related quality of life (HRQoL) Not important for decision making Cerebral blood flow Cortical activation Adverse events/complications

*) Passive movement therapy is defined as the treatment in which limbs of a patient are dynamically moved by another person, with less than 20 seconds' hold in the end position. No devices were allowed.

Eligibility criteria

Study design:
Systematic reviews
Randomised controlled trials
Non-randomised controlled studies
Case series etc. if ≥ 100 patients regarding complications

Language:
English, Swedish, Danish, Norwegian

Selection process – flow diagram

Identification

Records identified through database searching (n = 3076)

Additional records identified through other sources (n = 32)

Screening

Records after duplicates removed (n = 1815)

Records screened by HTA librarians and project group (n = 1815)

Records excluded by HTA librarians and project group. Did not fulfil PICO or other eligibility criteria (n = 1725)

Eligibility

Full-text articles assessed for eligibility by HTA librarians (n = 91)

Full-text articles excluded by HTA librarians, with reasons (n = 63)
8 = wrong patient/population
31 = wrong intervention
10 = wrong study design
14 = other

Included

Full-text articles assessed for eligibility by project group (n = 28)

Full-text articles excluded by project group, with reasons (n = 26)

See Appendix 3

Studies included in analysis (n = 2)

See Appendix 2

Search strategies

Database: Ovid **MEDLINE(**R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present
Date: 2017-11-28
No. of results: 984

#	Searches	Results
1	exp Motion Therapy, Continuous Passive/	684
2	((Passive or manual) adj5 (movement$ or exercise$ or motion or therap$ or training or stretch or stretching or mobilisation or mobilization or elongation)).ab,ti.	14514
3	1 or 2	14829
4	exp stroke/ or (Stroke* or Hemipleg* or Hemipar*).ab,ti.	269192
5	3 and 4	798
6	exp Spinal Cord Injuries/	46463
7	(Spinal cord adj2 (injur* or lesion* or trauma* or transection* or laceration* or contusion*)).ab,ti.	39898
8	Traumatic Myelopath*.ab,ti.	69
9	6 or 7 or 8	59926
10	3 and 9	281
11	exp Intensive Care Units/	76298
12	(Critical care* or Intensive care* or ICU or NICU).ab,ti.	164193
13	11 or 12	187247
14	3 and 13	116
15	5 or 10 or 14	1161
16	(Child$ or pediatric or paediatric or rat or mice or soccer or dermal matrix or primate or player$ or athlete$ or sport or sports).ti.	1686817
17	(animals not (animals and humans)).sh.	4708497
18	(comment or editorial or letter).pt.	1693372
19	16 or 17 or 18	7299468
20	15 not 19	1036
21	**limit 20 to (danish or english or norwegian or swedish)**	**984**

Database: Embase 1974 to 2017 November 27 (OVID SP)
Date: 2017-11-28
No. of results: 1485

#	Searches	Results
1	exp passive movement/	3223
2	Motion Therapy, Continuous Passive/	2039
3	exp movement therapy/	2039
4	((Passive or manual) adj5 (movement$ or exercise$ or motion or therap$ or training or stretch or stretching or mobilisation or mobilization or elongation)).ab,ti.	17604
5	1 or 2 or 3 or 4	20804
6	exp cerebrovascular accident/	161548
7	(Stroke* or Post-stroke* or Hemipleg* or Hemipar*).ab,ti.	337468
8	exp stroke patient/	23199

9	6 or 7 or 8	385386
10	5 and 9	1895
11	exp spinal cord injury/	67820
12	(Spinal cord adj2 (injur* or lesion* or trauma* or transection* or laceration* or contusion*)).ab,ti.	48792
13	(Traumatic Myelopath* or Post-traumatic myelopath*).ab,ti.	75
14	11 or 12 or 13	77640
15	5 and 14	431
16	exp intensive care unit/	145886
17	(Critical care* or Intensive care* or ICU or NICU).ab,ti.	241183
18	16 or 17	287066
19	5 and 18	256
20	10 or 15 or 19	2488
21	(Child$ or pediatric or paediatric or rat or mice or soccer or dermal matrix or primate or player$ or athlete$ or sport or sports).ti.	1870851
22	(animal not (animal and human)).sh.	1385636
23	21 or 22	3132446
24	20 not 23	2226
25	**limit 24 to ((danish or english or norwegian or swedish) and (article or conference paper or note or "review"))**	**1485**

Database: Cochrane library (Wiley)
Date: 2017-11-28
No. of results: 437
Cochrane reviews 37
Other reviews 4
Trials 390
Technology assessments 1
Economic evaluations 4
Method Studies 1

ID	Search	Hits
#1	(Passive or manual) near/5 (movement* or exercise* or motion or therap* or training or mobilisation or mobilization or stretch or stretching or elongation):ti,ab,kw (Word variations have been searched)	3345
#2	MeSH descriptor: [Motion Therapy, Continuous Passive] explode all trees	135
#3	#1 or #2	3345
#4	MeSH descriptor: [Stroke] explode all trees	7179
#5	Post-stroke or Stroke* or Hemipleg* or Hemipar*	51113
#6	#4 or #5	51361
#7	#3 and #6	300
#8	MeSH descriptor: [Spinal Cord Injuries] explode all trees	1121
#9	((Spinal cord) near/2 (injur* or lesion* or trauma* or transection* or laceration* or contusion*))	2306
#10	#8 or #9	2420
#11	#3 and #10	36
#12	MeSH descriptor: [Intensive Care Units] explode all trees	3462
#13	Critical care* or Intensive care* or ICU or NICU	54487
#14	#12 or #13	54699
#15	#3 and #14	131
#16	**#7 or #11 or #15**	**437**

Database: AMED (EBSCOhost)
Date: 2017-11-28
No. of results: 170

Söknings-ID nr	Söktermer	Åtgärder
S17	**S15 AND S16** Avgränsare - Dokumenttyp: Journal Article, Notes, Position-Paper, Report, Review Utökning - Tillämpa relaterade ord **Sökinställningar - Hitta alla mina söktermer**	**Visa resultat (170)**
S16	LA Danish OR English OR Norwegian OR Swedish	Visa resultat (274,695) Visa detaljer Redigera
S15	S13 NOT S14	Visa resultat (209) Visa detaljer Redigera
S14	TI Child* or pediatric or paediatric or rat or mice or soccer or dermal matrix or primate or player* or athlete* or sport or sports	Visa resultat (39,522) Visa detaljer Redigera
S13	S5 OR S10 OR S12	Visa resultat (226) Visa detaljer Redigera
S12	S1 AND S11	Visa resultat (19) Visa detaljer Redigera
S11	TI (Critical care* or Intensive care* or ICU or NICU) OR AB (Critical care* or Intensive care* or ICU or NICU)	Visa resultat (1,997) Visa detaljer Redigera
S10	S1 AND S9	Visa resultat (55) Visa detaljer Redigera
S9	S6 OR S7 OR S8	Visa resultat (4,876) Visa detaljer Redigera
S8	TI (Traumatic Myelopath* or Post-traumatic myelopath*) OR AB (Traumatic Myelopath* or Post-traumatic myelopath*)	Visa resultat (8) Visa detaljer Redigera
S7	TI (((Spinal cord N2 (injur* or lesion* or trauma* or transection* or laceration* or contusion*))) OR AB (((Spinal cord N2 (injur* or lesion* or trauma* or transection* or laceration* or contusion*)))	Visa resultat (4,126) Visa detaljer Redigera
S6	(DE "SPINAL CORD COMPRESSION") OR (DE "SPINAL CORD DIS") OR (DE "SPINAL CORD INJURIES")	Visa resultat (4,367) Visa detaljer Redigera
S5	S1 AND S4	Visa resultat (158) Visa detaljer Redigera
S4	S2 OR S3	Visa resultat (8,493) Visa detaljer Redigera
S3	TI (Stroke* or Post-stroke* or Hemipleg* or Hemipar*) OR AB (Stroke* or Post-stroke* or Hemipleg* or Hemipar*)	Visa resultat (8,375) Visa detaljer Redigera
S2	(DE "STROKE")	Visa resultat (2,249) Visa detaljer Redigera
S1	TI (((Passive or manual)N5(movement* or exercise* or motion or therap* or training or stretch OR stretching OR mobilization OR mobilization OR elongation))) OR AB (((Passive or manual)N5(movement* or exercise* or motion or therap* or training or stretch OR stretching OR mobilization OR mobilization OR elongation)))	Visa resultat (2,119) Visa detaljer Redigera

The web-sites of SBU, Folkehelseinstituttet and Sundhedsstyrelsen were visited 2018-02-07
Nothing relevant to the question at issue was found.

Reference lists
A comprehensive review of reference lists brought 32 new records

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Appendix 2 – Characteristics of included studies

Author Year Country	Study Design	Length of Follow-Up	Study Groups; Intervention vs control	Patients (n)	Mean Age (years)	Men (%)	Outcome variables
Kim 2014 Republic of Korea	RCT	4 weeks	Passive treatments vs No Passive treatments	37	61	59	Function and activity Range of motion
Kondo 2001 Japan	Non-randomised controlled study	4 months	Restricted passive treatments vs Free passive treatments	152	62	54	Shoulder-Hand-Syndrome

Appendix 3.
Excluded articles

Author, year	Reason for exclusion
Achugbue FS, 2009	Wrong outcome
Baek JH, 2009	No control group
Bai YL, 2014	Wrong intervention
Chang A, 2002	Wrong outcome
Crawford CM,1986	Wrong intervention, population, outcome
Crowe J, 2000	Wrong intervention
Fu Y, 2015	No control group
Harvey LA, 2016	Wrong intervention
Koch SM, 1996	Case series: too few patients
Kumar R, 1990	Wrong comparison
Lee J, 2017	Wrong intervention
Lee J, 2015	Wrong intervention
Morris PE, 2016	Wrong intervention
Nelles G, 2001	Wrong intervention
Norrenberg M, 1999	Wrong outcome
Prabhu Rk, 2013	Wrong population
Richard R, 1994	Wrong intervention
Rodgers H, 2003	Wrong intervention
Salinet AS, 2014	Wrong comparison, Case serie: too few patients
Salinet AS, 2013	Wrong comparison, Case serie: too few patients
Salinet AS, 2015	Wrong comparison, Case serie: too few patients
Svensson M, 1995	Case series: too few patients
Thelandersson A, 2010	Case series: too few patients
Thelandersson A, 2012	Wrong outcome; Case series: too few patients
Tyson SF, 2002	Wrong intervention
Wattchow KA, 2018	SR: no new original articles

*	+	No or minor problems
	?	Some problems
	-	Major problems

Appendix 4.1

Outcome variable: Function and activity, according to a Self-care score

Author year country	Study design	Number of patients n=	With-drawals - dropouts	Results: Intervention	Results: Control	Comments	Directness*	Study limitations*	Precision*
Kim, 2014	Randomised controlled	I= 25 C=26	I=6 C=8	**Self-care score** After 2 weeks: 16.8 (sd 9.6) After 4 weeks: 18.2 (sd 10.1) p= 0.001 between groups	**Self-care score** After 2 weeks: 12.5 (sd 5.5) After 4 weeks: 12.7 (sd 5.8)	Patients with acute stroke in NSICUs[1]. Patients were immobilized at admission. Functional capacity evaluated by a score developed by Granger et al. (1990) and modified by Park & Sohng (2005). It includes "eating, personal hygiene, bathing, dressing oneself, using the toilet". The score ranges from 7 to 42. The higher the better.	?	+	?

[1]NSICUs= Neuroscience Intensive Care Units

*	+ No or minor problems
	? Some problems
	- Major problems

Appendix 4.2
Outcome variable: PROM, passive range of motion

Author year country	Study design	Number of patients n=	With-drawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention	Control				
Kim, 2014	Randomised controlled	I= 25 C=26	I=6 C=8	**PROM shoulder flexion** After 2 weeks: 116.7° (sd 12.8) After 4 weeks: 119.0° (sd 12.6) p= 0.001 between groups **PROM elbow supination** After 2 weeks: 48.5° (sd 28.7) After 4 weeks: 50.2° (sd 28.5) p= 0.001 between groups **PROM wrist extension** After 2 weeks: 38.6° (sd 6.6) After 4 weeks: 40.1° (sd 6.6) p= 0.001 between groups	**PROM shoulder flexion** After 2 weeks: 109.8° (sd 20.7) After 4 weeks: 111.1° (sd 21.1) **PROM elbow supination** After 2 weeks: 49.5° (sd 19.1) After 4 weeks: 49.8° (sd 19.0) **PROM wrist extension** After 2 weeks: 37.5° (sd 7.1) After 4 weeks: 38.0° (sd 7.3)	Patients with acute stroke in NSICUs[1]. Patients were immobilized at admission. For measuring PROM a plastic goniometer was used. PROM (shoulder extension, abduction, internal and external rotation), p= 0.001 between groups PROM (elbow flexion and pronation), p= 0.001 between groups PROM (wrist flexion, ulnar and radial deviation), p= 0.001 between groups	?	+	?

[1]NSICUs= Neuroscience Intensive Care Units

* + No or minor problems
? Some problems
- Major problems

Appendix 4.3
Outcome variable: Pain as reflected in the development of a Shoulder-Hand Syndrome (SHS)

Author year country	Study design	Number of patients n=	With-drawals - dropouts	Results		Comments	Directness*	Study limitations*	Precision*
				Intervention	Control				
Kondo, 2001	Cohort	I= 81 C=71	Not reported	**Incidence of Shoulder-Hand Syndrome** 18.5% (n=15) $p<0.05$ between groups	**Incidence of Shoulder-Hand Syndrome** 32.4% (n=23)	Patients in the intervention group were referred to a Rehabilitation department from July 1994 to June 1996. Patients in the control group were referred to the same rehabilitation department from July 1991 to June 1994. Pain is defined as the presence of SHS. Assessment of SHS was performed weekly for 4 months.	?	+	?

Region Västra Götaland, HTA-centrum

Health Technology Assessment
Regional activity-based HTA

HTA

Health technology assessment (HTA) is the systematic evaluation of properties, effects, and/or impacts of health care technologies, i.e. interventions that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care.

To evaluate the quality of evidence the Centre of Health Technology Assessment in Region Västra Götaland is currently using the GRADE system, which has been developed by a widely representative group of international guideline developers. According to GRADE the level of evidence is graded in four categories:

High quality of evidence	= (GRADE⊕⊕⊕⊕)
Moderate quality of evidence	= (GRADE ⊕⊕⊕O)
Low quality of evidence	= (GRADE ⊕⊕OO)
Very low quality of evidence	= (GRADE ⊕OOO)

In GRADE there is also a system to rate the strength of recommendation of a technology as either “strong” or “weak”. This is presently not used by the Centre of Health Technology Assessment in Region Västra Götaland. However, the assessments still offer some guidance to decision makers in the health care system. If the level of evidence of a positive effect of a technology is of high or moderate quality it most probably qualifies to be used in routine medical care. If the level of evidence is of low quality the use of the technology may be motivated provided there is an acceptable balance between benefits and risks, cost-effectiveness and ethical considerations. Promising technologies, but a very low quality of evidence, motivate further research but should not be used in everyday routine clinical work.

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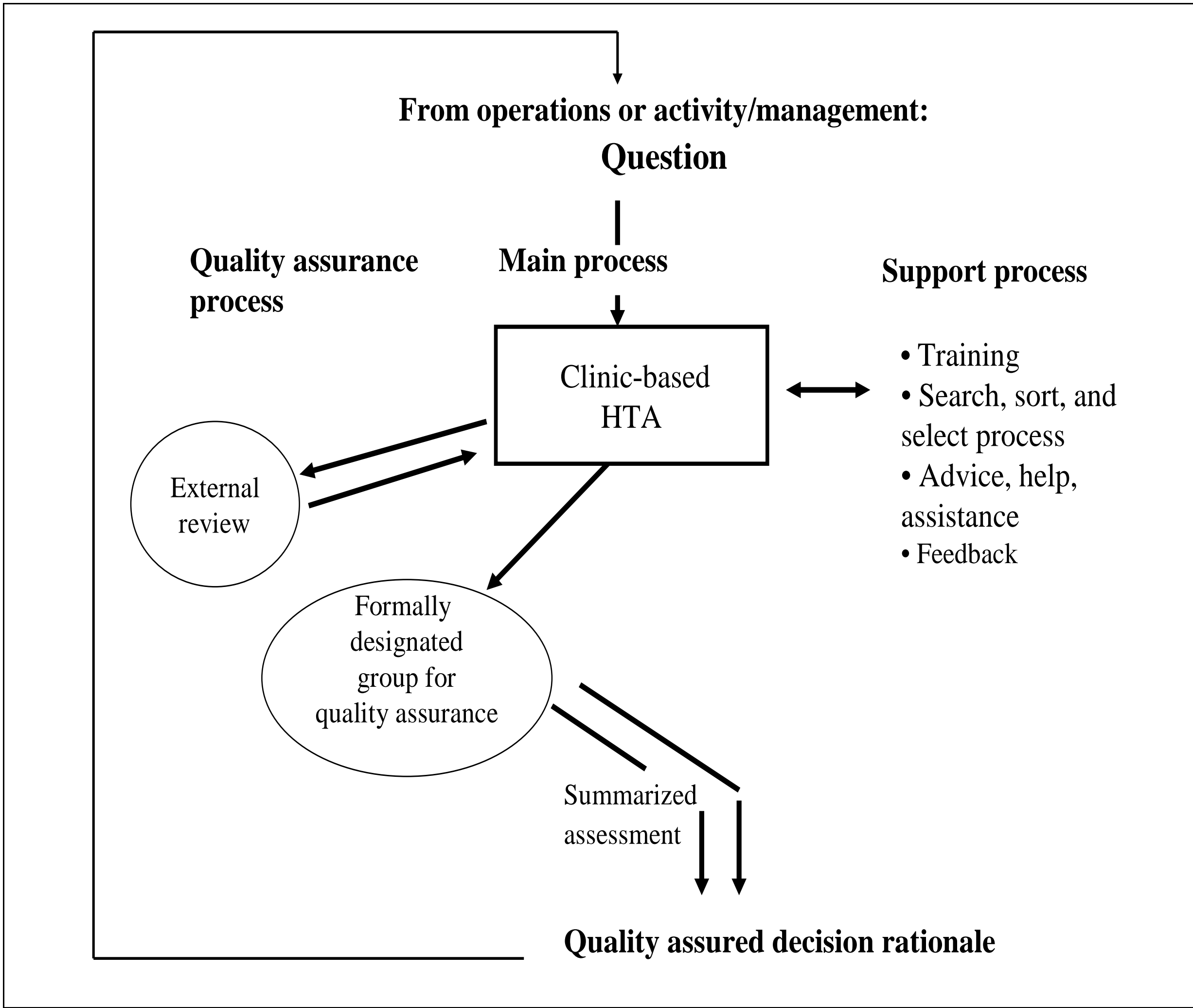
From operations or activity/management:
Question
Quality assurance process
Main process
Support process
Clinic-based HTA
• Training
• Search, sort, and select process
• Advice, help, assistance
• Feedback
External review
Formally designated group for quality assurance
Summarized assessment
Quality assured decision rationale

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