

# ThemenCheck Medizin



Extract of HTA report

## Movement disorders<sup>1</sup>

Is the Feldenkrais method effective?

Health technology assessment commissioned by IQWiG

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## Involvement of patients or other persons affected

Three patients or other persons affected were consulted during the preparation of the report.

IQWiG coordinated the project, conducted the literature search for the domains “Benefit assessment” and “Health economic evaluation”, and prepared the easily understandable summary “HTA compact”.

**Keywords:** Feldenkrais, Movement Disorders, Pain, Benefit Assessment, Systematic Review, Technology Assessment – Biomedical

According to §139b (3) No. 2 of Social Code Book (SGB) V, Statutory Health Insurance, external experts who are involved in the Institute's research commissions must disclose "all connections to interest groups and contract organizations, particularly in the pharmaceutical and medical devices industries, including details on the type and amount of any remuneration received". The Institute received the completed *Form for disclosure of potential conflicts of interest* from each external expert. The information provided was reviewed by a Committee of the Institute specifically established to assess conflicts of interests. The information on conflicts of interest provided by the external experts and external reviewers is presented in Chapter A11 of the full report. No conflicts of interest were detected that could endanger professional independence with regard to the work on the present commission.

## Publisher's comment

### **What is the background of the HTA report?**

Insured persons and other interested individuals are invited to propose topics for the assessment of medical procedures and technologies through “ThemenCheck Medizin” (Topic Check Medicine) to the Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG). The assessment is done in the form of a Health Technology Assessment (HTA) report. HTA reports include an assessment of medical benefit and health economics as well as an investigation of ethical, social, legal, and organizational aspects of a technology.

In a 2-step selection procedure, which also involves the public, up to 5 new topics are selected each year from among all submitted proposals. According to the legal mandate, these topics should be of particular relevance to patients [1]. IQWiG then commissions external teams of scientists to investigate the topics in accordance with IQWiG methods, and it publishes the HTA reports.

In August 2020, IQWiG commissioned a team of scientist from Hannover Medical School (MHH) to investigate the selected topic “HT20-05: Movement Disorders: Is the Feldenkrais Method effective?”. The team consisted of methodologists experienced in generating HTA reports, experts with knowledge and experience in health economic, ethical, social, legal, and organizational topics, a specialist for physical and rehabilitative medicine, orthopaedics, and trauma surgery as well as an occupational therapist.

### **Why is the HTA report important?**

Mobility impairment, i.e. reduced mobility, is experienced by virtually everyone at some point in their lives, either sporadically or permanently [2]. This impairment is often harmless and typically resolves within a few days or weeks [3]. Where further limitations such as pain develop and markedly reduce locomotor function, affected people are said to have a movement disorder. The latter can lead to reduced autonomy, lower quality of life as well as the need for help from others [4].

Medications and/or physiotherapy are often recommended for treating movement disorders. Where conservative interventions fail to achieve any improvements in mobility, surgical procedures may be an option as well. The Feldenkrais method represents another intervention for treating movement disorders. By training proprioception, the method is intended to improve functional movement patterns and reduce any pain and to thereby contribute to learning new body movements to improve the overall well-being. The method offers 2 formats: Feldenkrais group interventions in the “Awareness Through Movement”

format and one-on-one sessions in the “Functional Integration” format. The former consists of participants actively moving as verbally instructed, while the latter involves passive, guided movements, targeted touch, as well as soft pressure and pulling by teachers.

The commissioned team of experts therefore investigated the various perspectives of an HTA report to see whether Feldenkrais is a method from which people with movement disorders can benefit.

The HTA report is based on a topic suggested by a member of the public who wanted to know whether Feldenkrais was a method suitable for replacing drug or surgical therapy in people with back pain.

### **Which questions are answered – and which are not?**

#### ***Benefit assessment***

The assessment of this HTA report is based on randomized controlled trials (RCTs). In the assessment, the MHH authors included a total of 6 RCTs on 5 therapeutic indications. They comprise the disorders of Parkinson's disease, chronic low back pain, neck–shoulder pain, multiple sclerosis, and cognitive impairment.

An advantage of the Feldenkrais method was found for 2 of the 5 investigated therapeutic indications. For the therapeutic indication of Parkinson's disease, for instance, it was found that, compared to an education programme, the Feldenkrais method improves mobility and health-related quality of life. In the therapeutic indication of chronic low back pain, the Feldenkrais method improved mobility and health-related quality of life when compared with an education programme with trunk stabilization exercises. In the same therapeutic indication of chronic lower back pain, but comparing Feldenkrais versus Back School, no consistent picture emerged: There was an advantage of the Feldenkrais method for pain, but an advantage of Back School for health-related quality of life. In the therapeutic indications of multiple sclerosis and cognitive impairment, no advantage of the Feldenkrais method versus an educational programme or no intervention was found. In the therapeutic indication of shoulder-neck pain, insufficient data were available for determining whether the Feldenkrais method offers any advantages over physiotherapy.

Ultimately, all studies suffered from methodological limitations which rendered the observed results uncertain.

This HTA report investigated the Feldenkrais method only as a therapeutic intervention for people with confirmed movement disorders. Frequently, the Feldenkrais method is also used for preventive purposes, but this application was not the subject of the present HTA report.

The included studies provided information only on the Feldenkrais method as a group intervention in the “Awareness Through Movement” format. No usable data were available on the Feldenkrais method as a one-on-one intervention in the “Functional Integration” format. Therefore, it was impossible to draw any conclusions on the benefit of the Feldenkrais method in one-on-one sessions.

### **IQWiG perspective**

From the IQWiG perspective, the studies included in the benefit assessment do not allow drawing any conclusions on the benefit of Feldenkrais as a therapeutic intervention for treating movement disorders. This is, in part, explained by the fact that the studies do not provide the essential information needed for a ranking and, therefore, the relevance of the findings for the patients could not be assessed.

In addition, the included studies investigated a very heterogeneous number of Feldenkrais sessions, ranging from 8 to 50 “Awareness Through Movement” units. The long-term effects of the Feldenkrais intervention are difficult to assess due to (a) the substantial variation in the number of sessions and (b) only 1 study providing data on the follow-up observation period. None of the studies investigated adverse events, which made it impossible to fully weigh benefits versus harm.

The effectiveness of the Feldenkrais method was typically investigated in comparison with passive therapies (e.g. lectures or educational programmes). Due to the lack of appropriate comparisons, no conclusions can be drawn regarding the potential advantage of the Feldenkrais method over active therapies, which are common in routine care and are typically reimbursable (e.g. physiotherapy).

### ***Health economic assessment***

While the costs for back school or physiotherapy are typically reimbursed by statutory health insurance (SHI) funds after being medically prescribed (excluding a copayment of €10 plus 10% of the costs which patients pay out of pocket), this is not the case for the Feldenkrais method. SHI funds cover the cost only in exceptional cases or pay part of the cost, e.g. through bonus programmes. However, this particularly applies to Feldenkrais being used for preventive purposes, not as a therapeutic intervention in movement disorders, as was examined in the current HTA report. No studies on health economic evaluations were found.

### ***Further aspects***

On the basis of scoping literature searches as well as expert and patient interviews, some ethical, social, legal, and organizational aspects related to the disorder and the investigated interventions were additionally identified.

From an ethical perspective, MHH views the insufficient evidence as a challenge. For instance, no information is available on adverse events. Additionally, no studies are available comparing Feldenkrais with interventions typically used in routine care, such as physiotherapy. To make an informed decision, however, patients need information on all relevant aspects of treatment.

According to the authors, lack of standardization in Feldenkrais teacher training can also be viewed as ethically and organizationally relevant. While only people who have completed special training are allowed to call themselves “Feldenkrais teacher”, the contents of the training are not standardized.

### **What’s the next step?**

It was not possible to answer the general question whether Feldenkrais is a method from which people with movement disorders benefit. Drawing conclusions on the benefit of the Feldenkrais method as a therapy for movement disorders requires RCTs with sufficiently long follow-up observation and an assessment of patient relevance. The RCTs should also record adverse events so that the effectiveness of the Feldenkrais method can be more reliably evaluated as an intervention for treating movement disorders.

Assessing whether the Feldenkrais method offers an advantage over other active therapies requires comparisons with treatments which are common in German healthcare practice and are typically reimbursable, such as physiotherapy.

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## HTA key statements

### Research question of the HTA report

The aims of this investigation are to

- assess the benefit of treatment with the Feldenkrais method in comparison with treatment without the use of the Feldenkrais method in patients with movement disorders with regard to patient-relevant outcomes,
- determine the costs (intervention costs) and assess the cost effectiveness of treatment with the Feldenkrais method in comparison with treatment without the Feldenkrais method in patients with movement disorders as well as
- review ethical, social, legal, and organizational aspects associated with the use of the Feldenkrais method.

### Conclusion of the HTA report

The Feldenkrais method is presumably preferred by social groups who generally strive to use non-drug and non-surgical interventions for preventing and treating diseases. Since chronic pain is more common in advanced age, older people are likely to be more interested in this method. This health technology assessment (HTA) report investigates the use of the Feldenkrais method as a therapeutic intervention, i.e. only in people with movement disorders, rather than for preventive purposes or in persons with mobility impairments which are not defined in more detail. Demand is nurtured, in part, by the Feldenkrais method being expected to favourably affect private and social life due to greater self-perceived physical mobility. Since the Feldenkrais method's trademark protection is viewed positively, these groups may harbour erroneous assumptions with regard to the benefits to be expected. From an ethical perspective, this tends to be viewed critically because users who do not reap any benefit may have incurred costs to be paid out of pocket (the relevance of this aspect differs between social groups) and not utilized effective therapies.

A total of 6 randomized controlled trials (RCTs), all with a high risk of bias, were identified for 5 therapeutic indications, and hints of (greater) benefit were determined for 2 therapeutic indications.

For patients with Parkinson's disease, there is a hint of greater benefit of the Feldenkrais method in comparison with the passive strategy of an educational programme in the form of lectures. This benefit consists of improved mobility and health-related quality of life at the end of treatment.

In the comparison with active strategies, the available evidence for patients with chronic low back pain is inconsistent. Compared with an educational programme involving trunk stabilization exercises, there is a hint of greater benefit of the Feldenkrais method with regard to improved mobility and health-related quality of life at the end of the 5-week treatment period. In comparison with back school, there is a hint of greater benefit of the Feldenkrais method with regard to pain reduction, but also a hint of lesser benefit of this method with regard to health-related quality of life after 3 months. However, no differences in effects were found directly at the end of therapy.

There is no hint of either long-term benefit of the Feldenkrais method or for its benefit in other therapeutic indications. It was also impossible to derive any hint of harm from the Feldenkrais method, with the studies failing to provide data on deaths and adverse events. The question about the benefit of the Feldenkrais method in comparison with active strategies such as extensive physiotherapy generally remains open.

The determined evidence is based on group interventions in the “Awareness Through Movement” (ATM) format rather than one-on-one interventions in the “Functional Integration” format (only 4 sessions investigated in 1 study). The intervention costs equal €10 to €20 per person and group session or €60 to €90 per one-on-one session. These costs are typically to be paid out of pocket by patients, a fact which is of differing relevance for different social groups. No studies on health economic aspects are available.

If greater benefit were to be confirmed for certain therapeutic indications, some problematic issues might arise from an ethical or organizational perspective, particularly in view of limited access to the method. Since liability issues are conceivable in case of demonstrable physical injuries, the use of the Feldenkrais method as a therapeutic intervention would require corresponding basic medical qualifications of Feldenkrais teachers, possibly with state accreditation.

From a social and organizational perspective, use of the Feldenkrais method requires some patient collaboration (to ensure continuity of the intervention) and potentially leads to lower utilization of medically trained healthcare providers. If the costs of the Feldenkrais method were to be covered by statutory health insurance for therapeutic indications with established benefit, the service would need to be offered nationwide by appropriately trained personnel. Additional resources would likely be needed.

Overall, little evidence is available. From an ethical perspective, the absence of evidence from RCTs is problematic for informed decision making but does not constitute evidence of an absent benefit. Only 2 small, ongoing RCTs of questionable relevance were identified, and therefore, the availability of evidence is not expected to change in the short term. Due to the limited availability of data, further research is needed, particularly regarding long-term effects

of the Feldenkrais method, its application in various therapeutic indications, and in comparison with further active comparator therapies typically used in practice, e.g. physiotherapy.

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## List of abbreviations

<b>Abbreviation</b>	<b>Meaning</b>
ATM	Awareness Through Movement
EUnetHTA	European Network for Health Technology Assessment
FI	Functional Integration
HTA	health technology assessment
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
RCT	randomized controlled trial
SGB	Sozialgesetzbuch (Social Code Book)
SHI	statutory health insurance

# HTA overview

## 1 Background

### 1.1 Health policy background and commission

According to § 139b (5) of Social Code Book V, Statutory Health Insurance (SGB V), statutory health insurance members and other interested people may suggest topics for the scientific assessment of medical interventions and technologies to the Institute for Quality and Efficiency in Health Care (IQWiG). The topics for these health technology assessment (HTA) reports can be submitted on the ThemenCheck Medizin (“topic check medicine”) website.

ThemenCheck Medizin aims to promote the involvement of the public in evidence-based medicine and answer questions which are particularly relevant in patient care.

Once yearly, IQWiG, in collaboration with patient representatives and members of the public, selects up to 5 topics on which HTA reports are to be prepared. IQWiG then commissions external experts to investigate the research question. The results prepared by the external experts and a publisher’s comment by IQWiG are then published in the form of an HTA report.

IQWiG disseminates HTA reports to German institutions, for instance those deciding about health care services and structures. The HTA report will be made available to the professional community through the ThemenCheck Medizin website ([www.iqwig.de](http://www.iqwig.de)). In addition, a lay summary of the results of the HTA report will be published under the title “HTA compact: The most important points clearly explained”. This is done to ensure that the results of HTA reports will impact patient care.

### 1.2 Medical background

Information on medical background was summarized primarily based on Bühring and Essers “Die Methode nach Feldenkrais” (The Feldenkrais Method) [1], Wittels “Die Feldenkrais-Methode in der Schmerztherapie” (The Feldenkrais Method in Pain Management) [2] as well as information on the websites of [Medizininfo.de](http://Medizininfo.de) [3], [Schmerzgesellschaft.de](http://Schmerzgesellschaft.de) [4], and the German Feldenkrais Association [5]. Information from other sources has been identified as such.

### Movement disorders

The terms “movement disorder”, “limited range of motion”, and “mobility disorder” are often used interchangeably. These disorders can have a variety of root causes. The most common are disorders of the locomotor system (muscles and joints for implementing movement), the nervous system (control of movement, sense of balance) as well as the mind (initiation and



targeted nature of a movement). Movement disorders are therefore topics discussed particularly in the fields of traumatology, orthopaedics, and neurology. Clinical pictures associated with movement disorders include stroke, Parkinson's disease, multiple sclerosis, osteoarthritis, and spinal disorders. Movement disorders can affect both adults and children, but they are more common with increasing age. In general, minor reductions in mobility particularly due to ageing must be distinguished from the movement disorders discussed in this report. Movement disorders are not diagnosed until a marked reduction in the normal function of the locomotor system occurs due to other restrictions, e.g. pain. Part of the reason why movement disorders garner much attention is that they can lead to reduced autonomy, decreased quality of life, and the need for external help. Limited mobility can further increase the risk of secondary diseases such as pneumonia and osteoporosis as well as the risk of falls.

### **The Feldenkrais method**

Dr Moshé Feldenkrais (born 1904 in current-day Ukraine, died 1984 in Israel), a physicist, engineer, and Jiu-Jitsu/Judo trainer, developed the Feldenkrais method as a movement theory and learning method based on the self-treatment of his knee problems. The goal of this development-oriented learning method is to connect movement and thoughts and to thereby learn new body movements which improve overall well-being.

The method is taught by trained Feldenkrais teachers; depending on the initial situation, it is implemented either in the Awareness Through Movement (ATM) group format or in the Functional Integration (FI) one-on-one format. At the heart of the method are movement sequences which are performed either actively following verbal instructions or passively (through guided movement, targeted touch as well as by teachers applying gentle pressure and tension). The training lasts several weeks or months, with one or more sessions per week. Depending on the initial situation, one-on-one sessions can later be replaced by group sessions or be combined with them.

The method is explicitly intended not only for people with an illness, but for all people who want to develop physically and mentally. In patients with movement disorders, i.e. the population of interest in this HTA report, the method is used to detect individual harmful movement habits, to determine the causes for poor posture and wrong movement patterns, and to use exercises in order to achieve a new quality of movement. The goal is to reduce dysfunction and, depending on the degree of improvement of movement patterns, to alleviate pain.

Some authors view the Feldenkrais method as a body psychotherapy, a field which also includes Gestalt therapy as well as concentrative movement therapy. Aside from the body-mind connection, the two cited methods also primarily include elements geared towards active relaxation. These methods, like numerous other treatment concepts (e.g.

neurodevelopmental treatment according to Bobath; manual therapy, or massage therapy) are treatment alternatives to be differentiated from the Feldenkrais method.

### **1.3 Health services situation**

Unlike established treatment techniques (e.g. physiotherapy, manual therapy, and classic massage therapy), the Feldenkrais method is not listed in the remedies catalogue [6].

Health services involving the Feldenkrais method have been increasingly offered for decades, including in group courses for the prevention of disease. The method is to be applied only by specially trained teachers and was originally referred to as a learning method rather than a form of therapy. Nevertheless, the Feldenkrais method is also applied in rehabilitation medicine as a body-oriented therapeutic method implemented in physiotherapy and occupational therapy. According to the rules of the Feldenkrais Association, providers must have undergone training; therefore, some practices specialize exclusively in this method. Certified teachers are typically referred to as Feldenkrais teachers, Feldenkrais instructors, or Feldenkrais practitioners.

Since the Feldenkrais method has not yet been listed as a remedy (no determination of therapeutic benefit by the Federal Joint Committee [G-BA]), it technically cannot be prescribed. Currently, SHIs cover treatment costs only in exceptional cases. However, some SHIs pay part of the Feldenkrais courses, particularly via bonus programmes [3].

### **1.4 Concerns of those proposing the topic**

This HTA report is based on a suggestion by a member of the public. In her experience, back pain is often either treated with medications or surgery is recommended. With this in mind, she asks whether the Feldenkrais method is of benefit to patients and whether it may make drug or surgical therapy unnecessary. The HTA questions were developed from this suggestion.

## 2 Research questions

The aims of this investigation are to

- assess the benefit of treatment with the Feldenkrais method in comparison with treatment without the use of the Feldenkrais method in patients with movement disorders with regard to patient-relevant outcomes,
- determine the costs (intervention costs) and assess the cost effectiveness of treatment with the Feldenkrais method in comparison with treatment without the Feldenkrais method in patients with movement disorders as well as
- review ethical, social, legal, and organizational aspects associated with the use of the Feldenkrais method.

### 3 Methods

#### 3.1 Methods – benefit assessment

The benefit assessment's target population is patients with movement disorders. Studies whose participants had minor mobility impairments which were not further specified (e.g. due to age) were disregarded from the assessment. Study participants' movement disorders had to be explicitly measured by a mobility parameter.

The experimental intervention was treatment with the Feldenkrais method. The comparator intervention was treatment without the use of the Feldenkrais method (placebo or sham intervention, treatment with different methods, no therapy). At least 80% of included patients had to meet the inclusion criteria.

The following patient-relevant outcomes were taken into account for the assessment:

- Morbidity, such as
  - pain
  - dysfunction (e.g. of muscles, joints)
  - neurological symptoms (e.g. paraesthesia)
- Health-related quality of life
- Adverse events
- Mortality

Only randomized controlled trials (RCTs) were included in the benefit assessment. There were no restrictions regarding the study duration. The publication had to be in German or English.

A systematic literature search for studies was conducted in the following databases: MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials. In parallel, a search for relevant systematic reviews was conducted in the databases MEDLINE, Embase, Allied and Complementary Medicine Database, Cochrane Database of Systematic Reviews, and HTA Database.

The following sources of information and search techniques were additionally used: study registries as well as viewing of reference lists of identified systematic reviews.

Relevant studies were selected by 2 persons independently from one another. Any discrepancies were resolved by discussion between them. Data were extracted into standardized tables. To assess the qualitative certainty of results, outcome-specific and study-level criteria for the risk of bias were assessed, and the risk of bias was rated as high or low in

each case. Results are typically disregarded in the benefit assessment if they are based on fewer than 70% of the patients to be included in the analysis. The results of the individual studies were described, organized by outcomes.

The report provides a comparative description of the results regarding the patient-relevant outcomes reported in the studies. No metaanalysis was conducted because the studies were not comparable in terms of the investigated experimental interventions or they supplied insufficient data. As proposed in the protocol for data scenarios such as this, a qualitative summary was implemented instead.

For each outcome, a conclusion was drawn regarding the evidence for (greater) benefit and (greater) harm, with 4 levels of certainty of conclusions: there was either proof (highest certainty of conclusions), indication (moderate certainty of conclusions), hint (lowest certainty of conclusions), or neither of the above 3. The latter was the case if no data were available or the available data did not allow any of the other 3 conclusions to be drawn. In this case, the conclusion “There is no hint of (greater) benefit or (greater) harm” was drawn. Subsequently, an assessment of benefit was carried out across outcomes.

### **3.2 Methods – health economic assessment**

The economic assessment investigates, on the one hand, the costs associated with the experimental intervention and the comparator intervention (intervention cost). On the other, it analyses health economic evaluations which draw conclusions on cost effectiveness or on the comparative costs of the experimental intervention versus the comparator intervention.

First, it determined the intervention costs for the Feldenkrais method. The respective information (e.g. Hufeland Service Directory) was searched in online sources.

Then, comparative health economic studies or models were searched. Other than that, the criteria regarding the population and comparator intervention used in the benefit assessment were likewise applied for the inclusion of publications. The search was not restricted to studies from a specific healthcare system or country.

A search in the form of a focused information retrieval was conducted in the following information sources: bibliographic databases, MEDLINE, Embase, HTA database, reference lists of identified systematic reviews. The identified references were selected by 1 person, with a 2<sup>nd</sup> person doing quality assurance.

The information necessary for the assessment was extracted into tables from the publications. The results of the evaluations and the conclusions were described. Additionally, quality aspects of the presented studies and their transferability to the German healthcare system were assessed.

### 3.3 Methods – ethical aspects

Ethical aspects can be derived from ethical principles [7]. Ethical aspects arise when (a) 1 or more principles of medical ethics are disregarded (“ethical risk”) or (b) 2 or more principles are in conflict (“ethical challenge”) [8]. An ethics framework for public health was used as a basis [9] and was expanded to 7 ethical principles following a comparison with the questionnaire by Hofman [10]: potential benefits, potential harm, autonomy, justice, human dignity, efficiency, and legitimacy.

A scoping literature search (PubMed/MEDLINE, PhilPapers, and PEDro) was conducted to identify ethical aspects which apply to the Feldenkrais method and the treatment of movement disorders. The included professional literature was analysed together with the results of the Internet search at the German Feldenkrais Association [5] and the transcripts of patient interviews. The results of the other domains were also analysed for further ethical aspects. In addition, theory-based reflection by the report’s authors (based on the above-mentioned principles approach) served to identify further aspects.

The identified ethical aspects formed the basis for phrasing the specific assessment criteria for the Feldenkrais method. For this purpose, ethically relevant aspects from the social domain were taken into account as well. For assessing the Feldenkrais method, the criteria were worded as check questions. The check questions’ comprehensibility was validated by persons with documented experience practising the Feldenkrais method, rehabilitation medicine, and health technology assessments (HTAs) in the context of a workshop.

All developed check questions were formally reviewed against the background of the prefinal results of the respective domains by all persons involved in the report and persons with documented experience in practising the Feldenkrais method. In the process, the importance for the context of care relevant in this report was estimated, and an assessment conducted. Both formats of the Feldenkrais method were evaluated: Functional Integration (FI, in one-on-one therapy) and Awareness Through Movement (ATM, group therapy).

### 3.4 Methods – social aspects

Social aspects describe empirical facts regarding societal or sociocultural conditions; they may also cover the (potential) consequences of a disorder and/or health technology. They can be classified as social determinants, social implications, or social consequences. Social determinants include, e.g. patients’ sociodemographic characteristics or their living situations. Social implications may include contexts of action (e.g. social or professional interaction with patients), preferences and opinions, or established social norms and values. Finally, social consequences comprise (potential) effects of social determinants and implications for (future) health services, therapeutic relationships, or funding of the technology. For the determination of content (which determinants, implications, or consequences can/should be taken into

account?), existing methods literature was used (Mozygemba et al. [11], Gerhardus and Stich 2014 [12], HTA-Core-Model EUnetHTA [13]).

A scoping literature search (PubMed, Wiso Sozialwissenschaften, IBZ Online, JSTOR, PEDro) was carried out to identify social aspects related to the Feldenkrais method. The included literature was analysed for (1) sociodemographic characteristics and living situation (social determinants) as well as the following main implications: (2) preferences/attitudes and opinions/beliefs of persons (potentially) treated with the Feldenkrais method, (3) social norms/values as well as social and professional attitudes (e.g. physiotherapy) toward the Feldenkrais method or persons treated with it, (4) access to the Feldenkrais method, (5) consequences for healthcare and the social life of users of the Feldenkrais method, and (6) consequences for the funding of the Feldenkrais method.

Alongside the professional journal articles found in this search, the literature included in the HTA report's other domains, other publications, particularly by the German Feldenkrais Association [5], and the 3 patient interviews were analysed for social aspects. Against this background, the authors eventually looked for further social aspects by means of a reflective thoughts process.

### **3.5 Methods – legal aspects**

The analysis of legal aspects involved a scoping search, and the existing legal provisions were reviewed and applied to individual cases. This applied to (a) regulations regarding the Feldenkrais method as a brand, (b) provisions regarding the contract between involved parties, and (c) reimbursement provisions for the treatment method in SHI members (from German Civil Code, German Penal Code, German Social Code Book V, German Trademark Act). Aspects of the guideline developed by Brönneke 2016 [14] were taken into account in this process.

General standards were applied to the specific life circumstances of treatment with the Feldenkrais method by using the common legal interpretation methods (historic, systematic, grammatical, and teleological). Furthermore, relevant comments were used in the presentation and assessment of the legal situation in order to explain the respective relevant standards and, on this basis, incorporate key rulings as well further literature.

### **3.6 Methods – organizational aspects**

A scoping search was conducted for the analysis of social aspects. In this search, the sources identified in the benefit assessment, health economic assessment, legal assessment, and ethical/social assessment as well as patient interviews were screened for organizational aspects of the Feldenkrais method, and this screening was supplemented by an Internet

search as well as discussion among the experts. The identified organizational aspects were summarized in accordance with the framework developed by Perleth 2014 [15].



## 4 Results: Benefit assessment

### 4.1 Results of the comprehensive information retrieval

The information retrieval found 6 randomized controlled studies (7 publications) to be relevant for the research question of this benefit assessment. No planned studies but 2 ongoing potentially relevant studies were found. Furthermore, there were no studies of unclear status, no prematurely terminated studies, and no completed studies without reported results.

The search strategies for bibliographic databases and trial registries are found in the appendix. The last search in literature databases was conducted on 15 January 2021, while the search in the study registries took place on 18 January 2021.

Table 1: Study pool of the benefit assessment

Study	Available documents		
	Full publication	Registry entry (registry name) / information on results	Additional information
Teixeira-Machado 2015, 2017	Yes [16] [17]	No/no	
Ahmadi 2020	Yes [18]	Yes [19] (IRCT) / no	Registered retroactively
Paolucci 2017	Yes [20]	Yes [21] (ClinicalTrials.gov) / no	
Lundblad 1999	Yes [22]	No/no	
Stephens 2001	Yes [23]	No/no	
Torres-Unda 2017	Yes [24]	Yes [25] (ClinicalTrials.gov) / no	Registered retroactively

Abbreviation: IRCT: Iranian Registry of Clinical Trials

### 4.2 Characteristics of the studies included in the assessment

In each of the following countries, 1 of the included studies was conducted: Sweden (Lundblad 1999 [22]), Italy (Paolucci 2017 [20]), Spain (Torres-Unda 2017 [24]), United States (Stephens 2001 [23]), Brazil (Teixeira-Machado 2015 [16], 2017 [17]), and Iran (Ahmadi 2020 [18]), with 4 out of the 6 RCTs being conducted between 1999 and 2019 (no dates available for 2 studies). The studies randomized between 12 and 97 patients (Table 2).

Table 2: Brief overview of the studies included

Study	Therapeutic indication	N	Intervention	Comparator
Teixeira-Machado 2015, 2017	Parkinson's disease	30	ATM (50 sessions)	Educational programme (50 sessions)
Ahmadi 2020	Chronic low back pain	60	ATM (10 sessions)	Educational programme with exercises

Study	Therapeutic indication	N	Intervention	Comparator
Paolucci 2017	Chronic low back pain	53	ATM (10 sessions)	Back School (10 sessions)
Lundblad 1999	Neck–shoulder pain	97	ATM (12 sessions), FI (4 sessions)	1. Physiotherapy (32 sessions) and home exercises 2. Waiting list for group therapy
Stephens 2001	Multiple sclerosis	12	ATM (8 sessions)	Educational programme (4 sessions)
Torres-Unda 2017	Cognitive impairment	41	ATM (30 sessions)	No intervention
Abbreviations: ATM: Awareness Through Movement; FI: Functional Integration; N: number of study participants				

The studies investigated the application of the Feldenkrais method in 5 indications: Parkinson's disease (2 publications on 1 study: Teixeira-Machado 2015, 2017), chronic low back pain (2 studies: Ahmadi 2020, Paolucci 2017), neck–shoulder pain (Lundblad 1999), multiple sclerosis (Stephens 2001), and cognitive impairment (Torres-Unda 2017).

Study participants' mean age was between 33 and 61 years. Two studies (Lundblad 1999 und Ahmadi 2020) included only women, and 1 study (Teixeira-Machado 2015, 2017) provided no information on the sex distribution of investigated participants. The mobility parameters used in the studies differ widely and were difficult to compare.

Five studies used only the “Awareness Through Movement” intervention of the Feldenkrais method, at 8 to 50 sessions. One study (Lundblad 1999) applied 4 sessions of “Functional Integration” and 12 sessions of “Awareness Through Movement”. The comparator groups involved either treatment with active methods such as physiotherapy with home exercises (Lundblad 1999; 1<sup>st</sup> comparator group), Back School (Paolucci 2017), and educational programme with core stability exercises (Ahmadi 2020) or relatively passive strategies such as educational programme without exercises (Teixeira-Machado 2015, 2017, Stephens 2001), waiting list (Lundblad 1999; 2<sup>nd</sup> comparator group), or no intervention (Torres-Unda 2017).

### 4.3 Overview of patient-relevant outcomes

Data on patient-relevant outcomes were extracted from all 6 studies. Table 3 presents an overview of the data available on patient-relevant outcomes from the included studies.

These studies do not offer a parameter providing an adequately complete picture of mobility-related morbidity (below, the mobility parameter is listed separately from other morbidity parameters). The parameters used in the studies often included balance as well; these parameters vary widely between the studies and were virtually impossible to compare. Five

studies each investigated 1 parameter providing some information about mobility, while 1 study (Teixeira-Machado 2015, 2017) investigated 6 such parameters.

Five studies (all except Torres-Unda 2017) measured morbidity based on different parameters, and 3 RCTs (Ahmadi 2020, Paolucci 2017, Lundblad 1999) measured it primarily for pain. Further morbidity parameters used in the studies were depression (Teixeira-Machado 2015, 2017), falls (Stephens 2001), and inability to work (Lundblad 1999).

Health-related quality of life was investigated in only 3 studies (Teixeira-Machado 2015, 2017, Ahmadi 2020, Paolucci 2017), each of them using different scales.

The studies did not investigate the outcomes of mortality and adverse events, which according to the inclusion criteria were equally patient relevant for the HTA report.

All studies measured the investigated parameters both before treatment start and during follow-up (beginning at treatment start) immediately after treatment end, while 1 study (Paolucci 2017) measured them also after 3 months.

Table 3: Matrix of patient-relevant outcomes and measurement instruments used

Study	Morbidity: mobility	Morbidity: pain, other morbidity	Health-related quality of life
<b>Parkinson's disease</b>			
Teixeira-Machado 2015, 2017	TUG ("Timed-Up-and-Go") "Figure-of-eight walk test" "360-degree turn-in-place" "Sitting-and-standing test" "Rollover task" BBS ("Berg Balance Scale")	Depression (Beck Depression Inventory)	PDQL (Parkinson's Disease Quality of Life questionnaire)
<b>Chronic low back pain</b>			
Ahmadi 2020	Oswestry Disability Index	Pain (McGill)	WHOQOL-BREF (World Health Organization's Quality of Life short form)
Paolucci 2017	Waddell Disability Index	Pain (McGill) pain (VAS)	SF-36 (Short Form-36 Health Survey)
<b>Neck-shoulder pain</b>			
Lundblad 1999	Disability <sup>a</sup>	Pain (VAS) <sup>b</sup> Inability to work <sup>c</sup>	Not measured
<b>Multiple sclerosis</b>			
Stephens 2001	EQUISCALE (8 items from Berg and Tinetti tests)	Falls (number)	Not measured
<b>Cognitive impairment</b>			
Torres-Unda 2017	Total SPPB (Short Physical Performance Battery) score	Not measured	Not measured
a. 2 parameters (at work or during leisure time).			

Study	Morbidity: mobility	Morbidity: pain, other morbidity	Health-related quality of life
b. 2 parameters (typical or maximum). c. 2 parameters (days or %; took into account only days). Abbreviations: BBS: Berg Balance Scale; PDQL: Parkinson's Disease Quality of Life questionnaire; SF-36: Short Form-36 Health Survey; SPPB: Short Physical Performance Battery; TUG: Timed-Up-and Go; VAS: visual analogue scale; WHOQO-BREFL: World Health Organization's Quality of Life short form			

#### 4.4 Assessment of the risk of bias of the results

The risk of bias across outcomes was rated as high for all studies.

In all studies, this was primarily due to lack of blinding of participants and treatment providers (although appropriate blinding is admittedly impossible for this form of treatment). Additionally, the study protocol was either missing or registered retroactively for 5 studies (which precludes evaluations of any deviations from plan). Basic characteristics differed significantly 1 study (Lundblad 1999), and such differences were impossible to assess in 2 studies (Teixeira-Machado 2015, 2017 and Ahmadi 2020). The randomization process was unclear for 2 RCTs (Lundblad 1999 and Stephens 2001), while group allocation concealment was unclear for 3 studies (Teixeira-Machado 2015, 2017, Lundblad 1999, and Stephens 2001).

The outcome-specific risk of bias was likewise rated as high for all results.

In addition to the factors applying across outcomes, lack of blinding of outcome recorders was a problem concerning 4 studies (Teixeira-Machado 2015, 2017, Lundblad 1999, Stephens 2001, Torres-Unda 2017) and lack of reported data for all or some outcomes for 3 studies (Teixeira-Machado 2015, 2017; Paolucci 2017 and Stephens 2001; results presented only in figures or not at all).

Two studies (Torres-Unda 2017 und Lundblad 1999) inadequately implemented the intention to treat (ITT) principle. Furthermore, the Lundblad 1999 study results were rated as unsuitable for deriving any benefit because the analyses took into account fewer than 70% of all randomized patients.

#### 4.5 Results on patient-relevant outcomes

Table 4 presents results on patient-relevant outcomes. All studies lack references to deaths and adverse events.

##### Parkinson's disease

In the only study on Parkinson's disease (Teixeira-Machado 2015, 2017), 5 of 6 investigated mobility parameters as well as health-related quality of life differed in a statistically significant way in favour of the Feldenkrais Method (50 "Awareness Through Movement" sessions)

versus an educational programme (50 sessions) after treatment end. However, the results for 1 mobility parameter and health-related quality of life were presented only in a figure (i.e. without reported numbers), with p-values being provided in the publication's body; hence, the results for these 2 parameters are nontransparent or of limited informative value. The results for 1 investigated mobility parameter ("360-degree turn-in-place") as well as morbidity (depression, presented only in a figure) narrowly missed statistical significance ( $p = 0.05$ ).

### **Chronic low back pain**

The 2 studies on chronic low back pain (Ahmadi 2020, Paolucci 2017) investigated patient-relevant outcomes on mobility, morbidity (pain), and health-related quality of life.

In Ahmadi 2020, the patient-relevant outcomes on change in mobility (surveyed using the Oswestry Disability Index) and change in health-related quality of life by treatment end show a statistically significant difference in favour of the Feldenkrais method (10 sessions of "Awareness Through Movement") versus educational programme with core stability exercises (with weekly instruction by a physician). Changes in morbidity (pain) by treatment end did not differ in a statistically significant way between groups.

Paolucci 2017 reports no data on follow-up after treatment end, merely noting that there were no significant differences in morbidity (pain reduction) between the Feldenkrais "Awareness Through Movement" method and Back School (10 sessions each). For 3-month follow-up, Paolucci 2017 shows only figures (i.e. no reported numbers) and p-values; hence, these results are nontransparent and not of particular informative value. Pain-related morbidity, measured using 2 parameters in this follow-up, showed results statistically significantly in favour of the Feldenkrais method, while health-related quality of life results (in the 2 components of SF-36) favoured Back School. The study did not provide any numerical data or figures on mobility (according to Waddell Disability Index) despite the study protocol specifying that they were to be collected, and the corresponding statistical comparison of between-group differences was likewise missing (it was merely noted that treatment in each group resulted in statistically significant improvement, at  $p < 0.001$  each).

### **Neck–shoulder pain**

In the only study on neck–shoulder pain (Lundblad 1999), 1 mobility parameter – disability during leisure time – differed in a statistically significant way ( $p \leq 0.05$ ) between the 3 study groups (12 sessions of Feldenkrais "Awareness Through Movement" and 4 sessions of Feldenkrais "Functional Integration", 32 sessions of group-based physiotherapy, or waiting list) after treatment end. However, due to a major violation of the ITT principle (data available for less than 70% of participants), the results of this study are unusable for deriving benefit.

## Multiple sclerosis

In the only study involving patients with multiple sclerosis (Stephens 2001), the results on patient-relevant mobility outcomes (EQUISCALE) and morbidity (number of falls) did not differ in a statistically significant way between the Feldenkrais group (8 “Awareness Through Movement” sessions) versus the educational programme group (4 sessions) after treatment end. The study did not investigate health-related quality of life.

## Cognitive impairment

The only study on cognitive impairment (Torres-Unda 2017) investigated only 1 patient-relevant parameter, mobility (Short Physical Performance Battery, SPPB score). While the score change by treatment end differed in a statistically significant manner in favour of the Feldenkrais method (30 “Awareness Through Movement” sessions) versus no intervention, this was due to markedly different baseline scores; the 2 groups’ scores were nearly equal at treatment end.

Table 4: Overview of effects of individual studies on patient-relevant outcomes

Therapeutic indication, study (FU)	Mortality	Morbidity: mobility	Morbidity: pain, other morbidity	Health-related quality of life	Adverse events
<b>Parkinson's Disease</b>					
Teixeira-Machado 2015, 2017 (at TE after 25 weeks)	-	↑	↔ Depression	↑	-
<b>Chronic low back pain</b>					
Ahmadi 2020 (at TE after 5 weeks)	-	↑	↔ Pain	↑	-
Paolucci 2017 (at TE after 5 weeks)	-	-	↔ Pain	-	-
Paolucci 2017 (3 months with TE after 5 weeks)	-	-	↑ Pain	↓	-
<b>Neck-shoulder pain</b>					
Paolucci 1999 (at TE after 16 weeks)	-		Pain, inability to work	-	-
<b>Multiple sclerosis</b>					
Stephens 2001 (at TE after 10 weeks)	-	↔	↔ Falls	-	-
<b>Cognitive impairment</b>					
Torres-Unda 2017 (at TE after 30 weeks)	-	↑	-	-	-
↑: Statistically significant effect in favour of the experimental intervention ↓: Statistically significant effect in favour of the control intervention ↔: No statistically significant difference -: The outcome was not surveyed or no data were reported.					

Therapeutic indication, study (FU)	Mortality	Morbidity: mobility	Morbidity: pain, other morbidity	Health-related quality of life	Adverse events
Marked grey: Results reported but unusable for deriving benefit. Abbreviations: FU: follow-up; TE: treatment end					

## 4.6 Evidence map

Table 5 below shows the evidence map regarding patient-relevant outcomes.

Table 5: Evidence map regarding patient-relevant outcomes

Therapeutic indication, comparisons (FU)	Mortality	Morbidity mobility	Morbidity: pain, other morbidity	Health-related quality of life	Adverse events
<b>Parkinson's disease</b>					
50 ATM sessions versus 50 sessions of educational programme, duration 25 weeks (TE)	-	↗	↔ Depression	↗	-
<b>Chronic low back pain</b>					
10 ATM sessions versus educational programme with core stability exercises; duration 5 weeks (TE)	-	↗	↔ Pain	↗	-
10 ATM sessions versus 10 Back School sessions; duration 5 weeks (TE)	-	-	↔ Pain	-	-
10 ATM sessions versus 10 Back School sessions; duration 5 weeks (3 months)	-	-	↗ Pain	↘	-
<b>Neck-shoulder pain</b>					
4 FI and 12 ATM sessions versus 32 physiotherapy sessions or vs. waiting list; duration 16 weeks (TE)	-			-	-
<b>Multiple sclerosis</b>					
8 ATM sessions versus educational programme, duration 10 weeks (TE)	-	↔	↔ Falls	-	-
<b>Cognitive impairment</b>					
30 ATM sessions versus no intervention, duration 30 weeks (TE)	-	↔ <sup>a</sup>	-	-	-
<p>a. Significant results reported in the study are largely due to markedly different scores at baseline; the scores at treatment end were nearly equal in both groups.</p> <p>↗: hint of (greater) benefit</p> <p>↘: hint of lesser benefit</p> <p>↔: no hint, indication, or proof</p> <p>-: The outcome was not surveyed or no data were reported.</p> <p>Marked grey: Results reported but unusable for deriving benefit.</p> <p>Abbreviations: ATM: Awareness Through Movement; FI: Functional Integration; FU: follow-up; TE: treatment end</p>					



**Parkinson's disease**

The only RCT (Teixeira-Machado 2015, 2017) conducted in the therapeutic indication of Parkinson's disease had a high risk of bias of significant results and found a hint of greater benefit of the Feldenkrais method (50 "Awareness Through Movement" sessions) versus educational programme (50 sessions) in terms of improving mobility and health-related quality of life by treatment end. The comparator intervention is deemed to be a passive strategy.

**Chronic low back pain**

For the therapeutic indication of chronic low back pain, results were available on the comparison of the Feldenkrais method versus 2 slightly different interventions. The 2 interventions were deemed to be active strategies.

One RCT (Ahmadi 2020) with a high risk of bias of significant results shows a hint of greater benefit of the Feldenkrais method (10 "Awareness Through Movement" sessions) versus an educational programme with core stability exercises with regard to improving mobility and health-related quality of life by treatment end.

From the other RCT (Paolucci 2017), no hint of greater or lesser benefit of the Feldenkrais method (10 "Awareness Through Movement" sessions) versus Back School (10 sessions) at treatment end can be derived. The significant results with a high risk of bias at the 3-month follow-up after treatment start show a hint of greater benefit of the Feldenkrais method versus Back School with regard to morbidity (pain), but there is also a hint of lesser benefit of Feldenkrais versus Back School with regard to health-related quality of life.

**Neck–shoulder pain**

The results of the study investigating the therapeutic indication of back-shoulder pain (Lundblad 1999) is unsuitable for deriving any benefit. Hence, no hint of benefit or harm can be derived for the Feldenkrais method versus group-based physiotherapy or waiting list in this therapeutic indication.

**Multiple sclerosis**

From the results of the study on the therapeutic indication of multiple sclerosis (Stephens 2001), no hint of benefit or harm of the Feldenkrais method compared to an educational programme can be derived.

**Cognitive impairment**

For the outcome of change in mobility by treatment end, the Torres-Unda 2017 study reports a statistically significant result in favour of the Feldenkrais method (30 sessions of "Awareness

Through Movement”) versus no intervention. This result is primarily due to markedly different scores at baseline; the scores at treatment end were nearly equal in both groups. The 1 RCT (Torres-Unda 2017) on the therapeutic indication of cognitive impairment, which had a high risk of bias of significant results, therefore offers no hint of benefit of the Feldenkrais method (30 “Awareness Through Movement” sessions) versus no intervention at treatment end.

## **5 Results: Health economic assessment**

### **5.1 Intervention costs**

The estimated per-person cost of the Feldenkrais “Awareness Through Movement” intervention equals about €10 to €20 per session, while the per-person cost of the Functional Integration intervention equals about €60 to €90 per session. No further reimbursable or nonreimbursable services or copayments are associated with implementing the interventions.

For the therapeutic indications with a hint of benefit, the estimated per-person costs of overall therapy with the “Awareness Through Movement” intervention equal €500 to €1000 in Parkinson's disease (therapy consisting of 50 sessions in 25 weeks) and €100 to €200 in chronic low back pain (therapy consisting of 10 sessions in 5 weeks). The SHI covers treatment costs only in exceptional cases [5]. For “Functional Integration”, the estimated per-person costs of the overall therapy are €3000 to €4500 in Parkinson's disease and €600 to €900 in chronic low back pain.

The estimated per-person cost for therapeutic Back School (in groups) as the comparator intervention in low back pain equals €19 to €24 per session of approximately equal length. The estimated cost for the overall therapy (consisting of 10 sessions in 5 weeks) equals €193 to €239. About 90% of costs (the “price”) are covered by the health insurance funds. Nonreimbursable copayments for therapeutic Back School equal between €29 and €34 (10% of the price plus €10 one-time prescription charge).

### **5.2 Systematic review of health economic evaluations**

The literature search was conducted on 15 January 2021. The various search steps did not identify any relevant health economic evaluation. The search strategies for bibliographic databases are found in the appendix.

## 6 Results: Ethical, social, legal, and organizational aspects

### 6.1 Results on ethical aspects

The scoping search found 5 relevant publications. Their results were supplemented by information from 3 patient interviews and by theoretical reflection to identify a total of 16 ethical aspects. These aspects largely concern questions of potential benefit and harm (n = 7), autonomy (n = 3), justice (n = 5), and legitimacy (n = 1).

Based on the ethical and social aspects, 7 assessment criteria for the Feldenkrais method were developed in question form. They were organized according to the 3 phases of *availability, execution, and evaluation*. The wording of the criteria was commented and reviewed in 2 rounds over the course of the project. In an expert workshop, all assessment criteria were rated as being “highly relevant” (n = 6) or “potentially highly relevant” (n = 1). Six criteria were deemed at least sometimes problematic, and 1 other criterion as not problematic (the latter is not presented here).

From an ethical perspective, 1 criterion of the Feldenkrais method is “***rather problematic***”:

#### **Potentially erroneous assumptions about benefit due to trademark protection (execution):**

The Feldenkrais method is marketed as a registered trademark for goods or services (®). However, it is important to note that “safety” and “effectiveness” do not represent relevant categories in trademark law and are not being verified in its context. In the absence of empirical data, it is difficult to estimate how commonly trademark protection is misinterpreted. In view of the limited evidence of benefit of the Feldenkrais method (few studies which result in only hints for 2 therapeutic indications), patients are presumably provided with insufficient information about the Feldenkrais method if they interpret trademark protection as representing more than a restriction of the use of the term “Feldenkrais method®”.

Five criteria were viewed as being not always, but ***sometimes problematic***:

**Restricted access due to limited availability:** Overall, the Feldenkrais method is not widely available. Where local availability is met by only local awareness and demand, there is no problem. Discussing this outside a given territory can be problematic if subjective needs created thereby (regardless of potential benefit) cannot be met. No empirical insights were found on this topic, but the scenario seems conceivable, and in isolated cases, this may potentially result in moderate psychological strains on patients.

**Restricted access due to the service being paid out of pocket:** In a system where costs are generally shared in a spirit of solidarity, problems may arise when services are not covered by this system. This would be the case if this intervention, which is not financed through a

solidarity approach, demonstrated proven benefit, and incomes and wealth were distributed in such a way that part of the population was unable to afford the intervention. Given the limited proof of benefit, this issue does not fully apply to the Feldenkrais method. However, this may leave patients feeling excluded and discriminated against, which, in turn, is rated as a moderately severe burden.

**Restricted selection due to limited availability:** Since the availability of the Feldenkrais method is limited, patients have little choice or alternatives with regard to Feldenkrais teachers. The fact that Feldenkrais services are paid out of pocket poses a high initial hurdle. However, when this hurdle has been taken, treatment is open-ended, in contrast to prescribed treatments such as physiotherapy which are typically limited to 6 or 12 sessions. No empirical data were found on this topic, but in the absence of an “externally” specified treatment end date, a sense of dependency or habituation might conceivably develop in patients treated with the Feldenkrais method. If so, this might be associated with some risk of patients continuing the intervention for a long time without achieving added value for their health, despite incurring continued financial burdens. This phenomenon is deemed rather common, and in individual cases, it can have moderately severe effects which tend to be of a financial rather than biological or psychological nature. In this context, it is also worth noting that physicians’ and therapists’ codes of professional ethics do not necessarily apply to Feldenkrais teachers (particularly if they are not healthcare professionals and therefore have not been state examined as a prerequisite for performing therapeutic interventions). “Ethical guidelines of the FVD German Feldenkrais Association” dated 12 June 2021 [26] at least exist and specify that an end of the professional relationship is to be suggested (no further Feldenkrais sessions) if the method offers no added value.

**Unbalanced provision of information:** To enable them to make an informed decision, patients should receive balanced information. Essentially, this means that the decision should be taken based on all relevant aspects for all relevant options for action (“treatment options”). For the Feldenkrais method, the risk of patients not being neutrally informed is high. Since physicians and therapists do not systematically learn about the Feldenkrais method during their studies or apprenticeships, it is safe to assume that information about the Feldenkrais method is most commonly provided by healthcare providers who perform it themselves or are familiar with it. “Supply-induced demand” describes the phenomenon encountered in the healthcare system of the people recommending (prescribing) a service often being the same ones performing it. This potentially results in conflicts of interest which may inappropriately affect professional judgement, with other treatment alternatives being discussed in less detail or not at all. This, in turn, disrupts the process of informed decision making. In the decision, patient expectations and hopes play a role as well. Rather than being excessive, they should be as realistic as possible in order to reduce the risk of patients being disappointed by the service and/or its results. While the risk of not receiving fair and balanced information is seen as

rather high, “only” financial damage is to be expected, which in isolated cases can be moderately severe, however.

**Interpretation and handling of the available evidence:** The available studies provide hints of benefit of the Feldenkrais method for 2 groups (Parkinson's disease and low back pain). Due to a lack of studies, no further conclusions can be drawn. However, this should not be interpreted as proven ineffectiveness. It must further be noted that important parameters (e.g. potential harm) and information (e.g. study protocols) were often not recorded or not reported, which is problematic from an ethical perspective. Making an informed decision requires all relevant information to be reported. While the lack of certain information does not always equate to a deficiency in implementation, it does lead to a justifiably presumed higher risk of bias. However, it is also safe to assume that the noninvasive nature of the Feldenkrais method is associated with less potential harm than pharmacological or surgical interventions. In interventions like the Feldenkrais method or physiotherapy interventions, determining benefit can additionally be complicated by a lack of research tradition in health occupations (little expertise and funding) as well as the outpatient setting and the interaction between teachers and patients. All of these aspects should be taken into account when interpreting the available evidence.

## 6.2 Results on social aspects

On the basis of the scoping search, 3 relevant publications were analysed. The information collection was supplemented by the information from the 3 patient interviews as well as 1 theoretical reflection. As a result, a total of 6 aspects were identified. Among the social determinants, particularly a correlation between age and chronic pain was found. In addition, 3 social implications were identified. Specifically, they concern patient preferences (nondrug/nonsurgical character of the intervention), access (few existing teachers), and sustainability of results (active participation required). Finally, 2 social consequences were described: The Feldenkrais method can influence health services because patients or users report making fewer physician visits. However, it can also affect private life because some patients or users report higher physical functioning and mobility.

The 6 social aspects were taken into account when developing the ethical assessment criteria.

## 6.3 Results on legal aspects

For treatment with the Feldenkrais method, it must first be determined whether the parties will enter into a simple service agreement or treatment contract according to BGB Sections 630a et seq. Two scenarios must be distinguished: “Functional Integration” meets the treatment characteristics required for a treatment contract. The treatment must fulfil professional standards. The patient must be comprehensively informed, particularly about risks, but also about the effectiveness of the method and its limitations. This does not apply

to the “Awareness Through Movement” intervention, which is typically offered in group courses. At least in the currently predominant application in preventive care, this intervention typically lacks a sufficiently concrete anamnestic, diagnostic, or individual therapeutic approach to classify it as treatment; therefore, rules of service agreements apply, as per BGB Sections 611 et seq.

For both alternatives, reimbursement is defined in the contract. In both categories, any violations of contractual duties resulting in harm expose the provider to liability risks and in some cases even to risks under criminal law. The same applies to inadequate patient information – problems therefore arise from the issue identified in the ethics part, namely that the same person recommends/informs about and performs the therapy. Providing realistic information seems necessary, in part to manage expectations and hopes. However, the requirements not being fully met exposes providers to legal claims only if physical harm has been incurred (e.g. because the patient did not utilize other, indicated interventions for this reason).

“Feldenkrais” is a word mark which has been protected under trademark law since 1987. Unauthorized use of the term may lead to claims for injunctive relief or claims for damages under trademark law.

With regard to reimbursement by health insurers, private health insurers must follow the German Medical Fee Schedule (GOÄ). Section 11 SGB V applies to the SHI; if the remedy was prescribed by an SHI physician, it is generally reimbursable. However, the Feldenkrais method has not yet been listed as a remedy.

#### **6.4 Results on organizational aspects**

As per the Perleth 2014 framework [34], information on the potential organizational implications in the “influence on the prerequisites of service provision” and “influence on processes” categories was obtained on the potential application of the Feldenkrais method through the scoping search or the literature from the comprehensive search of the benefit assessment domain and the information provided by the surveyed patients and experts. In Germany, this technology is particularly widespread in its ATM format (group sessions) for preventive purposes [5]. Treatment availability presumably varies greatly, with fewer services being available in rural areas. If health insurers were to cover the Feldenkrais method in therapeutic indications where the method offers proven benefit [16-18,20,24], expansion of service provision would be expected. This would require more providers with (additional) qualification as Feldenkrais teachers. Informing patients in detail about clinical pictures with and without proven benefit of the Feldenkrais method requires the referring providers to spend more staff resources.

## 7 Synthesis of results

The benefit assessment of the Feldenkrais method is based on 6 RCTs investigating 5 therapeutic indications. Studies are still lacking on these interventions' health economic aspects. Ethical, social, and organizational aspects were established based on publications, information from patient interviews, expert knowledge, and theoretical reflection. For analysing legal aspects, the existing legal regulations were additionally used.

Socioethical aspects and topics related to the existing demand for the Feldenkrais method were identified. Presumably, the Feldenkrais method tends to be preferred by social groups who generally strive to use non-drug and non-surgical interventions for preventing and treating diseases. Since chronic pain is more common in advanced age, "age" is a possible determinant of demand for the Feldenkrais method. Additionally, it was found that erroneous assumptions may be made regarding the (added) benefit of the Feldenkrais method particularly because the trademark-protected name of the method is viewed very favourably. From an ethical perspective, this effect is assessed as "rather problematic": In case of absence of benefit, this can lead to out-of-pocket costs (which differ in relevance for different social groups) and foregoing of effective therapy.

This HTA report investigated the use of the Feldenkrais method exclusively as a therapeutic intervention in persons with movement disorders rather than for prevention or in persons with movement impairments described in more detail (e.g. in advanced age). From a social perspective, it was found that these groups of persons also expect the Feldenkrais method to favourably influence their private and social lives through perceived greater mobility, which can further promote demand for the Feldenkrais method.

RCTs were identified for 5 therapeutic indications, and hints were found for (greater) benefit in 2 therapeutic indications (Parkinson's disease and chronic low back pain).

Hints for greater benefit were found for the therapeutic indication of Parkinson's disease versus the passive strategy of educational programme in the form of lectures. They concerned improved mobility and health-related quality of life in the follow-up at treatment end (after 25 weeks).

Inconsistent results were found for the comparison of Feldenkrais method versus active strategies in the therapeutic indication "chronic low back pain". Compared with an educational programme involving trunk stabilization exercises, there is a hint of greater benefit of the Feldenkrais method with regard to improved mobility and health-related quality of life at treatment end (after 5 weeks). Compared to Back School, there is a hint of greater benefit of the Feldenkrais method in terms of pain reduction, but also a hint of lesser benefit of this method regarding health-related quality of life in the follow-up after 3 months.



However, directly at treatment end (follow-up after 5 weeks), no significant differences in patient-relevant outcomes were found.

Lack of evidence for other therapeutic indications might be explained by a lack of RCTs, reflecting a need for research. From an ethical perspective, lack of evidence from such studies was viewed as problematic for informed decision-making, as was the potential misinterpretation of lack of evidence as proving lack of benefit.

The evidence found for the benefit assessment concerns only group interventions in the ATM (“Awareness Through Movement”) format, rather than one-on-one interventions in the FI format, with 1 study investigating only 4 FI sessions in combination with 12 ATM sessions. The studies lacked any references to deaths and adverse events, resulting in no hint of harm. The studies did not investigate long-term benefit. The RCTs likewise did not investigate any benefit of the Feldenkrais method in comparison with active strategies typically applied in many therapeutic indications, such as extensive physiotherapy.

The per-person costs of the individual interventions equal €10 to €20 per ATM group session or €60 to €90 per FI one-on-one session and are typically paid out of pocket by patients. This factor can be of differing relevance for different social groups, and for certain groups, it was identified as an important socioethical aspect. The estimated out-of-pocket cost of the investigated overall therapies were €100 to €200 per person for ATM and €600 to €900 per person for FI one-on-one sessions in chronic low back pain (10 sessions) and €500 to €1000 per person or €3000 to €4500 per person for one-on-one FI sessions for people with Parkinson's disease (50 sessions).

Concerning the use of the Feldenkrais method for therapeutic indications with a determined hint of benefit, potential topics which are in part problematic from an ethical and organizational perspective were found, particularly regarding limited access to the method. They comprise insufficient patient information about the determined benefit, very limited availability of the Feldenkrais method in Germany, limited selection of Feldenkrais teachers, basic medical qualification of Feldenkrais teachers, and costs to be paid by patients out of pocket. These ethical problems must be seen in relative terms, however, since only hints, but no proof or at least indications of (greater) benefit of the Feldenkrais method were found, and alternatives are available, e.g. physiotherapy.

The social, legal, and organizational assessment identified other relevant aspects as well. Use of the Feldenkrais method requires some patient collaboration (to ensure continuity of the intervention) and might lead to lower utilization of medically trained care providers. From a legal perspective, providers are exposed to a liability risk in case of proven physical harm. If the costs of the Feldenkrais method were to be covered by health insurance for therapeutic

indications with a demonstrated benefit, the service would need to be available nationwide with appropriately trained personnel.

## **8 Discussion**

### **8.1 HTA report compared with other publications**

The literature search found 2 systematic reviews explicitly on the Feldenkrais method: Ernst and Canter 2005 [27] (search in August 2003) with 6 included RCTs and Hillier and Worley 2015 [28] (search in July 2014) with 20 included RCTs. The large number of studies is owed to the fact that these reviews did not limit their focus on the use of the Feldenkrais method in movement disorders, but also included studies with healthy volunteers or elderly people without specific therapeutic indication. Further, these analyses included outcomes which are not patient relevant. The 2 systematic reviews describe the data from low-quality RCTs with heterogeneous results as being promising for the Feldenkrais method and emphasize a need for further research.

In contrast to the mentioned systematic reviews, other reviews exist whose analyses are often based on lower-level evidence (e.g. case series). For a benefit assessment such as the one carried out in this HTA report, this evidence is disallowed due to its low informative value if RCTs are feasible and available. The present HTA report was therefore carried out in accordance with IQWiG methods.

### **8.2 HTA report compared with guidelines**

No explicit guidelines for the application of the Feldenkrais method were identified.

### **8.3 Critical reflection on the approach used**

In the systematic assessment of the Feldenkrais method for movement disorders, some methodological aspects should be addressed.

The assessment was based on a strict approach, and studies not explicitly listing patients' movement disorders were excluded. However, it is conceivable for patients with movement disorders to have participated in several other studies.

Additionally, no specific patient-relevant parameter exists which would reflect only mobility and would do so with sufficient comprehensiveness. The parameters used in the studies often took into account balance as well; these parameters vary widely between the studies and are virtually impossible to compare. The studies looked for parameters which provide at least some information about mobility or some aspects of mobility.

So far, only individual studies are available on different indications; studies on health economic aspects are missing as well. Furthermore, only 2 small ongoing studies of questionable relevance were identified; therefore, the availability of evidence is not expected to meaningfully change in the short term.

In general, it should be noted that the present HTA report is based on RCTs. However, because studies for a benefit assessment require substantial funding and methodological expertise, for complex interventions such as the Feldenkrais method, they are typically available only in small numbers or only on certain therapeutic indications. Therefore, lack of evidence and RCTs should be interpreted in a neutral manner to indicate “unclear benefit” rather than being erroneously viewed as proof of lack of benefit.

## 9 Conclusion

The Feldenkrais method is presumably preferred by social groups who generally strive to use non-drug and non-surgical interventions for preventing and treating diseases. Since chronic pain is more common in advanced age, older people are likely to be more interested in this method. This HTA report investigates the use of the Feldenkrais method as a therapeutic intervention, i.e. only in people with movement disorders, rather than for preventive purposes or in persons with mobility impairments which are not defined in more detail. Demand is nurtured, in part, by the Feldenkrais method being expected to favourably affect private and social life due to greater self-perceived physical mobility. Since the Feldenkrais method's trademark protection is viewed positively, these groups may harbour erroneous assumptions with regard to the benefits to be expected. From an ethical perspective, this tends to be viewed critically because users who do not reap any benefit may have incurred costs to be paid out of pocket (the relevance of this aspect differs between social groups) and not utilized effective therapies.

A total of 6 RCTs, all with a high risk of bias, were identified for 5 therapeutic indications, and hints of (greater) benefit were determined for 2 therapeutic indications.

For patients with Parkinson's disease, there is a hint of greater benefit of the Feldenkrais method in comparison with the passive strategy of an educational programme in the form of lectures. This benefit consists of improved mobility and health-related quality of life at the end of treatment.

In the comparison with active strategies, the available evidence for patients with chronic low back pain is inconsistent. Compared with an educational programme involving trunk stabilization exercises, there is a hint of greater benefit of the Feldenkrais method with regard to improved mobility and health-related quality of life at the end of the 5-week treatment period. In comparison with back school, there is a hint of greater benefit of the Feldenkrais method with regard to pain reduction, but also a hint of lesser benefit of this method with regard to health-related quality of life after 3 months. However, no differences in effects were found directly at the end of therapy.

There is no hint of either long-term benefit of the Feldenkrais method or for its benefit in other therapeutic indications. It was also impossible to derive any hint of harm from the Feldenkrais method, with the studies failing to provide data on deaths and adverse events. The question about the benefit of the Feldenkrais method in comparison with active strategies such as extensive physiotherapy generally remains open.

The determined evidence is based on group interventions in the "Awareness Through Movement" (ATM) format rather than one-on-one interventions in the "Functional

Integration” format (only 4 sessions investigated in 1 study). The intervention costs equal €10 to €20 per person and group session or €60 to €90 per one-on-one session. These costs are typically to be paid out of pocket by patients, a fact which is of differing relevance for different social groups. No studies on health economic aspects are available.

If greater benefit were to be confirmed for certain therapeutic indications, some problematic issues might arise from an ethical or organizational perspective, particularly in view of limited access to the method. Since liability issues are conceivable in case of demonstrable physical injuries, the use of the Feldenkrais method as a therapeutic intervention would require corresponding basic medical qualifications of Feldenkrais teachers, possibly with state accreditation.

From a social and organizational perspective, use of the Feldenkrais method requires some patient collaboration (to ensure continuity of the intervention) and potentially leads to lower utilization of medically trained healthcare providers. If the costs of the Feldenkrais method were to be covered by the SHI for therapeutic indications with established benefit, the service would need to be offered nationwide by appropriately trained personnel. Additional resources would likely be needed.

Overall, little evidence is available. From an ethical perspective, the absence of evidence from RCTs is problematic for informed decision making but does not constitute evidence of an absent benefit. Only 2 small, ongoing RCTs of questionable relevance were identified, and therefore, the availability of evidence is not expected to change in the short term. Due to the limited availability of data, further research is needed, particularly regarding long-term effects of the Feldenkrais method, its application in various therapeutic indications, and in comparison with further active comparator therapies typically used in practice, e.g. physiotherapy.

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Please see full HTA report for the full reference list.

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*The full HTA report (German version) is published under*

<https://www.iqwig.de/sich-einbringen/themencheck-medizin/berichte/ht20-05.html>

## Appendix A – Topics of the EUnetHTA Core Model

The European Network for Health Technology Assessment (EUnetHTA) is a network of European HTA agencies. EUnetHTA promotes the exchange of HTA information between its members and developed the core model [13] for this purpose. IQWiG is also a member of the network.

In order to make it easier for readers of this HTA report to find information on the superordinate domains of the EUnetHTA Core Model, Table 6 indicates where the relevant information can be found. The original names of the domains of the core model are used to describe the topics.

Table 6: Domains of the EUnetHTA Core Model

<b>EUnetHTA domain</b>	<b>Information in chapters and sections of the HTA report</b>
Health problem and current use of the technology (CUR)	<b>Background</b> Chapter 1
Description and technical characteristics of technology (TEC)	
Safety (SAF)	<b>Benefit assessment</b> Section 3.1 Chapter 4
Clinical effectiveness (EFF)	
Costs and economic evaluation (ECO)	<b>Health economic evaluation</b> Section 3.2; Chapter 5
Ethical analysis (ETH)	<b>Ethical aspects</b> Section 3.3; Section 6.1
Patients and social aspects (SOC)	<b>Social aspects</b> Section 3.4; Section 6.2
Legal aspects (LEG)	<b>Legal aspects</b> Section 3.5; Section 6.3
Organizational aspects (ORG)	<b>Organizational aspects</b> Section 3.6; Section 6.4

## Appendix B – Search strategies

### B.1 – Search strategies for the benefit assessment

#### B.1.1– Searches in bibliographic databases

##### 1. MEDLINE

*Search interface: Ovid*

- Ovid MEDLINE(R) 1946 to January Week 2 2021
- Ovid MEDLINE(R) Daily Update January 14, 2021
- Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations 1946 to January 14, 2021
- Ovid MEDLINE(R) Epub Ahead of Print January 14, 2021

#	Searches
1	(feldenkrais* or (awareness adj1 through adj1 movement) or (sensory adj1 awareness adj3 training*)).mp.
2	1 not (comment or editorial).pt.
3	2 and (english or german).lg.

##### 2. Embase

*Search interface: Ovid*

- Embase 1974 to 2021 January 14

#	Searches
1	feldenkrais*.sh.
2	(feldenkrais* or (awareness adj1 through adj1 movement) or (sensory adj1 awareness adj3 training*)).mp.
3	or/1-2
4	3 not medline.cr.
5	4 not (Conference Abstract or Conference Review or Editorial).pt.
6	5 and (english or german).lg.

##### 3. The Cochrane Library

*Search interface: Wiley*

- Cochrane Central Register of Controlled Trials: Issue 1 of 12, January 2021
- Cochrane Database of Systematic Reviews: Issue 1 of 12, January 2021

#	Searches
#1	(feldenkrais* or (awareness near/1 through near/1 movement) or (sensory near/1 awareness near/3 training*)):ti,ab in Trials
#2	(feldenkrais* or (awareness near/1 through near/1 movement) or (sensory near/1 awareness near/3 training*)):ti,ab in Cochrane Reviews, Cochrane Protocols

#### 4. AMED - The Allied and Complementary Medicine Database

Search interface: EBSCOhost

#	Searches
1	(feldenkrais* OR (awareness AND through AND movement) OR (sensory AND awareness AND training*))

#### 5. Health Technology Assessment Database

Search interface: INAHTA

#	Searches
1	(feldenkrais* OR (awareness AND through AND movement) OR (sensory AND awareness AND training*))

### B.1.2 – Searches in study registries

#### 1. ClinicalTrials.gov

**Provider: U.S. National Institutes of Health**

- URL: <http://www.clinicaltrials.gov>
- Type of search: Expert Search

Search strategy
feldenkrais OR ("awareness through" AND movement) OR ("sensory awareness" AND training)

#### 2. International Clinical Trials Registry Platform Search Portal

**Provider: World Health Organization**

- URL: <http://apps.who.int/trialsearch>
- Type of search: Standard Search

Search strategy
feldenkrais OR awareness through movement OR sensory awareness training

## B.2 – Search strategies for the health economic evaluation

### 1. MEDLINE

Search interface: Ovid

- Ovid MEDLINE(R) 1946 to January Week 2 2021
- Ovid MEDLINE(R) Daily Update January 14, 2021
- Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations 1946 to January 14, 2021
- Ovid MEDLINE(R) Epub Ahead of Print January 14, 2021

#	Searches
1	(feldenkrais* or (awareness adj1 through adj1 movement) or (sensory adj1 awareness adj3 training*)).mp.
2	1 not (comment or editorial).pt.
3	2 and (english or german).lg.

### 2. Embase

Search interface: Ovid

- Embase 1974 to 2021 January 14

#	Searches
1	feldenkrais*.sh.
2	(feldenkrais* or (awareness adj1 through adj1 movement) or (sensory adj1 awareness adj3 training*)).mp.
3	or/1-2
4	3 not medline.cr.
5	4 not (Conference Abstract or Conference Review or Editorial).pt.
6	5 and (english or german).lg.

### 3. Health Technology Assessment Database

Search interface: INAHTA

#	Searches
1	(feldenkrais* OR (awareness AND through AND movement) OR (sensory AND awareness AND training*))