

## 임상연구에서 사용되고 있는 NRS에 대한 분석 : 무작위대조군연구를 중심으로

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### Analysis of the Numeric Rating Scale (NRS) Used in Clinical Studies Based on Randomized Controlled Studies

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#### ABSTRACT

**Objectives:** The purpose of this study was to review the status of numeric rating scale (NRS) usage and suggest the potential for use in multicenter retrospective studies of various diseases.

**Methods:** Articles published from 2011 to 2021 that used the keywords "NRS", "Multi-center", and "RCT" were identified in foreign databases, including EMBASE, PubMed, CENTRAL. The articles were analyzed according to their use of "NRS" by symptoms and by disease group using the major classifications of the Korean Standard Classification of Diseases (KCD-7).

**Results:** Classification by symptom in a total of 288 articles illustrates that the NRS was not only commonly used in pain evaluation but also for non-pain symptoms. In usage with non-pain symptoms, chief complaint of patients was the most common at 79%, and other factors included treatment satisfaction, evaluation of daily life, and sleep quality. In disease classification according to the KCD-7, the NRS was commonly used in connection with musculoskeletal and connective tissue diseases but was also utilized in various other disease groups.

**Conclusions:** This study confirms usage of the NRS in multi-center RCTs, as the NRS was widely used in all types of diseases and symptoms. Considering the result and the advantages of the NRS, it is recommended for use as a daily evaluation tool for the collection of common data in multicenter retrospective studies.

**Key words:** numeric rating scale (NRS), multicenter, retrospective study, PROM

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## 1. 서 론

최근 한의계에서는 국가 주도의 대규모 R&D

· 투고일: 2021.07.21, 심사일: 2021.10.08, 게재확정일: 2021.10.08  
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연구에서 증례연구까지 다양한 임상연구가 수행되고 있다. 그 중 다기관 연구는 단일 기관 연구에 비해 더 짧은 기간에 대규모 연구를 시행할 수 있어 환자의 등록률을 높이고 일반화 가능성을 높일 수 있지만 기관 간 공동 연구를 위해 막대한 노력, 시간, 자금 등의 현실적 문제 등이 발생한다<sup>1,2</sup>. 이에 비해, 다기관 후향적 연구는 전향적 연구에 비

해 상대적으로 저렴하고 다양한 임상 데이터에 접근이 가능하다는 장점이 있으나 의료 데이터는 구조와 형식의 이질성, 데이터의 질과 양 등의 문제로 인해 연구자 간의 공유 및 통합이 쉽지 않다<sup>1,3</sup>.

한방 의료계에서도 전향적 연구의 여러 현실적 문제들로 인해 후향적 연구를 시행하는 경우가 많으나 한방병원급 의료기관을 제외한 한의원 등에서는 EMR 구축이 미비한 상황이며 특정 질환을 제외하고 질환별 사용 평가지표가 체계화 되어있지 않아 공용 데이터의 수집 및 관리를 더욱 어렵게 한다<sup>4</sup>. 하지만, 일차의료기관 대상의 공익적 임상연구를 위한 의료데이터 수집 등에서 다기관 후향적 연구의 필요성은 증대되고 있다.

통증 척도로 다용되고 있는 NRS는 일반적으로 증상을 0에서 10 사이의 숫자로 표현하는 척도로 10에 가까울수록 심한 증상을 나타낸다. 간편성으로 임상에서 적용하기 매우 쉬운 척도이기에 기존의 임상 연구들에서 다양한 질환이나 증상에 적용되고 있음이 확인된다면 NRS가 통증 질환이 아닌 경우에도 임상에서 다양하게 사용되고 있음을 판단할 수 있을 것이다. 그렇다면 기존의 데이터에 더해 향후 NRS의 적극적인 사용으로 축적된 데이터를 통하여 일차의료기관 기반의 다기관 후향적 연구의 의료데이터로서 NRS의 활용도는 증가될 수 있겠다. 그러나, 아직 이에 대한 NRS의 사용 현황과 그 활용 가능성에 대한 국내 논문은 전무한 상황이다.

이에 본 저자는 해외에서 출판된 다기관 무작위 배정 연구를 대상으로 한정하여 NRS 평가지표의 사용 현황을 확인하고 그 활용 가능성에 대하여 고찰해보고자 한다.

## II. 대상 및 방법

### 1. 정보원 및 검색전략

NRS 사용 경향을 파악하기 위하여 영문 데이터베이스 검색 사이트인 Pubmed(www.pubmed.com),

Embase(www.embase.com), Cochrane Library(www.cochranelibrary.com)의 검색원에서 2011년 1월부터 2021년 6월까지 발간된 논문 전체를 대상으로 선별하였다.

본래 다기관 후향적 연구에서의 활용을 위해 기존 다기관 후향적 연구들에서의 NRS 평가지표 사용 현황 및 활용성을 확인하고자 하였으나 다기관 후향적 연구에서 NRS의 사용 현황을 검색한 결과 단일 질환들과 특정 평가지표를 사용한 연구만이 확인되고 다양한 질환을 대상으로 하는 다기관 후향적 연구에서의 데이터를 수집하기에 어려움이 있었다. NRS의 활용도에 대한 충분한 현황을 파악하기에 한계가 있기에 해외에서 출판된 다기관 무작위 배정 연구를 대상으로 한정하여 그 현황을 파악해보고자 하였다.

검색 엔진 키워드는 'multicenter', 'multicentre', 'multi center', 'multi centre', 'Numeric rating scale', 'Numerical rating scale'를 제목과 초록에서 검색하여 'Randomized controlled trial[MeSH]'와 각 검색 엔진의 특성에 따라 조합하여 검색을 진행하였다.

### 2. 선별 방법

두 명의 연구자는 제목 및 초록을 바탕으로 우선 관련성을 판단하였으며 추가적인 확인이 필요한 경우 해당 논문의 전문을 검토해 본 주제에 해당하는 논문인지 최종 결정하도록 하였다. 논문 선별은 무작위 대조 임상시험에 한정하였으며 NRS를 선정기준 등에만 사용하고 결과 평가지표로 사용하지 않은 논문들은 배제하였고 연구 목적에 따라 일차 결과 또는 이차적 결과의 여부에 상관없이 NRS가 결과지표로 사용된 논문을 검색하였다.

3개의 해외 데이터베이스에서 검색된 논문 중 중복을 제외하고 총 321편의 논문이 검색되었으며 무작위 임상연구가 아닌 논문과 결과 평가지표로 NRS가 사용되지 않은 논문 26편을 배제하여 295편의 논문을 선별하였다. 이후 초록에 주제와의 관련성 여부가 분명히 명시되어 있지 않은 논문들의

경우, 전문을 읽고 2차 screening을 시행하였으며 결과 평가지표로 NRS를 사용하지 않은 7편을 추가 배제하여 최종 288편을 연구 대상으로 선정하였다(Fig. 1).

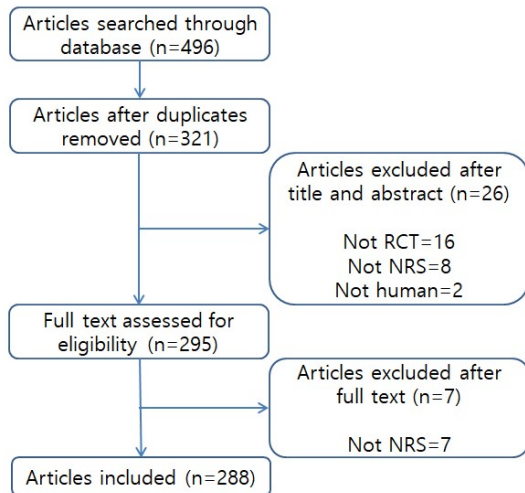


Fig. 1. Flow chart of publication selection process.

### 3. 연구 자료분석

본 연구를 위하여 독립된 두 명의 연구자는 실험군과 대조군에서 NRS를 사용하여 평가한 증상에 따라 분류하였으며 알려진 바와 같이 통증에 사용하는 빈도가 우세성을 보이는지 확인하고 통증 평가에 사용하지 않은 논문에서는 구체적으로 어떠한 증상의 평가에 사용되고 있는지 분석하였다. 또한 NRS가 KCD-7 분류 하에 어떤 질환군에서 사용되고 있는지 분석하였으며 논문에 연구 질환이 구체적으로 언급되어 있지 않은 경우에는 전문에서의 질환에 대한 설명을 읽고 두 연구자가 상의하여 최종 결정하였다. 이 중 NRS가 특정 질환의 평가지표로 사용되지 않고 복수의 질환에 사용되거나, 수술 또는 시술 등에 대한 평가에 사용된 경우는 기타 질환으로 분류하였다.

## III. 결 과

### 1. NRS usage in pain and non-pain symptoms

총 288편의 논문 중 통증 평가를 위해 NRS가 사용된 경우는 총 225편(78%), 통증 이외의 증상 평가에 사용된 논문은 54편(19%)에 해당 되었고 NRS를 통증과 통증 이외의 증상 평가지표로 모두 사용한 논문은 9편(3%)이었다(Fig. 2).

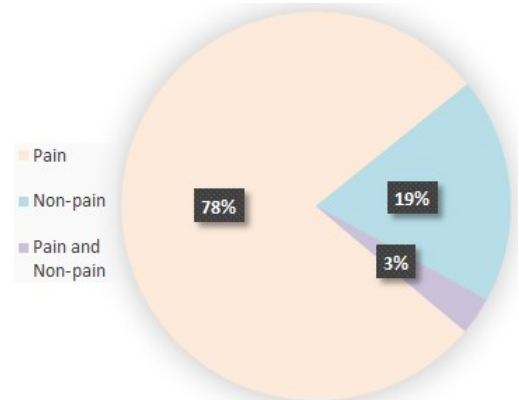


Fig. 2. NRS usage in pain and non-pain symptoms.

### 2. NRS usage in non-pain symptoms

통증이 이외의 증상 평가에 NRS를 사용한 63편 논문의 사용 분포를 보면 환자의 주소증 평가에 사용한 경우는 50편(79%)이었으며 그 외 치료에 대한 환자의 만족도와 삶의 질 등에 사용한 경우가 13편(21%)이었다.

주소증을 평가하기 위하여 NRS가 사용된 총 50편의 논문 중 소양감 등의 피부 관련 증상에 사용한 경우가 32편(64%)으로 가장 많았으며 그 다음으로 호흡기 관련 증상이 4편(8%)이었다. 그 외 피로감이 3편(6%), 오심과 강직이 각 2편(4%) 사용되었으며 기타 증상(일경불순, 출산 불편감, 변비, 딸국질 등)에 각 1편 사용되었다(Table 1).

주소증 외의 증상 평가에 NRS가 사용된 총 13편의 논문 중 치료에 대한 환자의 만족도를 평가

하는 데 사용한 경우가 6편이었고, 일상생활 능력 평가, 삶의 질과 수면의 질을 평가하는 데 사용한 경우가 각 2편이었으며 1편에서는 치료에 대한 환자의 불안감을 평가하는 데 사용되었다(Table 2).

3) NRS usage in disease groups classified by KCD-7

어떤 질환군에서 환자 평가에 있어 NRS를 많이 사용하는지 확인하기 위해 KCD-7의 분류에 따라 NRS가 사용된 질환을 분석하였다. 통증에서 NRS가 가장 많이 사용된 바와 같이 총 288편의 논문 중 근골격 계통 및 결합조직의 질환군에서 사용된 경우가 116편(40.3%)으로 가장 많았으며 그 다음으로 는 피부 및 피하조직의 질환이 33편(11.5%), 신생물 질환이 29편(10.0%)으로 많았다. 그 외에도 신경계통의 질환과 소화계통의 질환에서 각각 22편(7.6%)과 19편(6.6%) NRS가 사용되었다. Unclassified로 특정 코드를 부여하지 못한 경우는 질환이 전문에도 구체적으로 언급되지 않아 단정 지을 수 없거나 복수의 질환군에 동시에 사용된 경우, 원인질환이 복합적일 수 있는 시술 또는 수술 평가에 사용된 경우에 해당되었다(Table 3).

Table. 1. NRS Usage in Non-pain Chief Complaints

Chief complaint	Number	Percentage
1 Pruritus	31	62%
2 Dyspnea	3	6%
3 Fatigue	3	6%
4 Nausea	2	4%
5 Spasticity	2	4%
6 General psoriasis symptoms	1	2%
7 General pulmonary symptoms	1	2%
8 Dysmenorrhea	1	2%
9 Discomfort during delivery	1	2%
10 Constipation	1	2%
11 Hiccup	1	2%
12 Lactose intolerance	1	2%
13 Eye discomfort	1	2%
14 Neck and arm bothersomeness	1	2%

Table. 2. NRS Usage in Other Non-pain Symptoms

Other symptoms	Number	Percentage
1 Patient satisfaction in treatment	6	46.1%
2 Performance of daily activities	2	15.3%
3 Quality of sleep	2	15.3%
4 Quality of life	2	15.3%
5 Anxiety	1	7.6%

Table. 3. NRS Usage in Disease Groups Classified by KCD-7

Disease code	Disease name	Number	Percentage
M00-M99	Diseases of the musculoskeletal system and connective tissue	116	40.3%
L00-L99	Diseases of the skin and subcutaneous tissue	33	11.5%
C00-D48	Neoplasms	29	10.0%
G00-G99	Diseases of the nervous system	22	7.6%
K00-K93	Diseases of the digestive system	19	6.6%
S00-T98	Injury, poisoning and certain other consequences of external causes	14	4.9%
N00-N99	Diseases of the genitourinary system	11	3.8%
I00-I99	Diseases of the circulatory system	7	2.4%
A00-B99	Certain infectious and parasitic diseases	4	1.4%
R00-R99	Symptoms, signs and abnormal clinical and laboratory findings, NEC	4	1.4%
O00-O99	Pregnancy, childbirth and the puerperium	3	1.0%
E00-E90	Endocrine, nutritional and metabolic diseases	2	0.7%
Unclassified	Unspecified other diseases	24	8.3%

#### 4) NRS point distribution

총 288편의 논문 중 0-10 NRS 평가지표가 사용된 경우는 총 260편으로 대다수를 차지하였으며 0-100 NRS가 5편, 0-20 NRS와 0-5 NRS가 각각 1편에 해당 되었으며 논문에 정확히 명시되지 않은 경우가 21편에 해당되었다. 0-10 NRS가 아닌 다른 점수의 NRS를 사용한 이유는 언급되지 않았으며 검색된 논문에서도 경향성이 나타나진 않았다(Fig. 3).

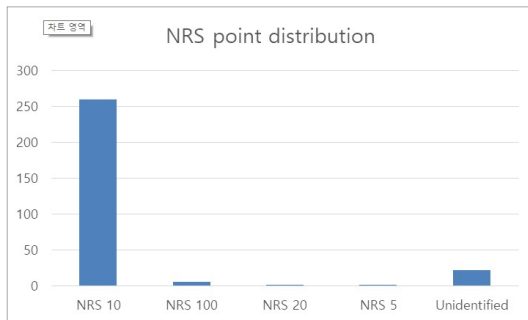


Fig. 3. NRS point distribution.

#### 5) Outcome measurement type

총 288편의 논문 중 NRS가 primary outcome으로 사용된 경우는 총 205편(71%)에 해당되었고 secondary outcome으로 사용된 경우는 83편(29%)이었다. 알려진 바와 같이 통증에 주로 활용하고 있지만 피부 및 신경계 질환과 삶의 질, 환자 만족도 등의 평가에 있어서도 일차 평가지표로 활용되고 있음을 확인하였다(Fig. 4).

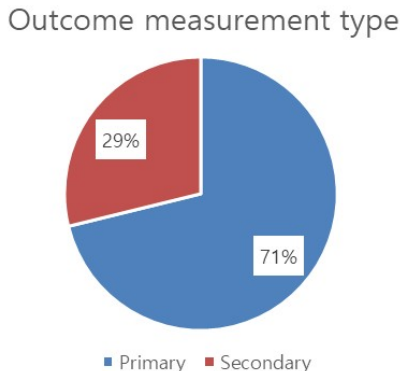


Fig. 4. Outcome measurement type.

## IV. 고 찰

근거 중심 의학과 임상 연구가 의학적 지식의 향상과 활용에 있어 필수적이라는 것은 너무 당연한 사실이다. 그러나 의학연구의 필요성과 의료인과 연구진이 이를 시행할 수 있는 능력의 한계 차이는 의학 연구자들이 당면하는 어려움들에 대한 더 깊은 이해의 필요성을 제시한다<sup>5</sup>.

외국의 설문조사에 따르면 연구진들이 겪는 어려움에 있어 환자 등록이 44%로 가장 큰 빈도를 차지하였고 데이터의 수집이 22%로 그 다음을 차지하였으며 이에 따라 단일기관 연구는 다기관 연구에 비해 더 큰 어려움을 겪고 있다고 제시하였다. 상대적으로 적은 환자의 연구는 임상적으로 중요한 결과의 도출을 어렵게 할 수 있는 반면 다기관 연구는 짧은 기간 동안 많은 대상자를 모집할 수 있다는 장점이 크고 다양한 환자군의 모집으로 연구 결과의 일반화에 유리할 수 있다<sup>2,5</sup>.

그 중 전향적 다기관 연구의 현실적 문제들을 일부 해소시켜 줄 수 있는 후향적 다기관 연구는 다양한 의료 분야에서 연구자들이 과거의 의학 차트를 통해 환자를 평가하고 이해하게 해주며 차후의 전향적 연구에 방향성을 제시할 수 있다는 장점이 있다. 이는 80% 이상을 차지하면서도 제대로 수집, 관리되지 않아 버려지는 각종 진료 기록 등의 비정형 데이터를 활용할 수 있는 좋은 수단이다. 그러나 다른 기관 간 연구에서의 이질성은 이러한 결과를 종합하고 해석하는 데 많은 시간을 소모하게 하는 등의 기술적 어려움을 야기하고 있다<sup>1-3,6</sup>. 이에 연구자들이 다양한 질환에서 공통적으로 사용할 수 있는 공통 평가지표를 확인한다면 정형화가 부족한 한방 임상에서 이를 더욱 사용하고 연구에 활용하는 데 도움이 될 수 있다.

특히 다양한 평가지표 중 객관적 결과에 대한 명확한 기준이 없는 임상과 짧은 시간 내에 환자가 주장하는 주요 증상을 빠르게 확인할 필요성이 있는 외래 같은 임상 환경에서 PROM은 환자 또

는 보호자의 증상 경험이나 건강 상태 인식에 대한 통찰력을 빠르게 제시해 준다. 증상을 해석하는데 있어 환자, 보호자와 의사가 무엇을 중점적으로 보는지는 다를 수 있다. 예를 들어 Tsai, S의 연구에 따르면 경직 증상에 대하여 환자는 가동범위를, 간병인은 전반적 고긴장 상태를, 의사는 속도 의존적 요소를 가장 연관시켜 생각하였다. 이는 증상을 이해하는 데 있어 현재 각 질환의 주된 평가지표가 환자의 경험에 대한 관점과 치료에 대한 만족도를 충분히 반영하지 못할 수 있다는 뜻이며 환자 중심 평가지표의 필요성을 의미한다고 볼 수 있다. 환자들은 스스로 관여되는 것을 원하며 그들이 평가할 수 있는 측면이 있을 수 있다. 많은 사람을 평가해야 하는 의사와 달리 환자 중심의 평가는 한 명의 평가만 이루어지기 때문에 응답률을 높이면서 관찰자 편향을 배제할 수 있다<sup>7-9</sup>. 또한 원격 환자 모니터링에 있어서도 치료 방향에 영향을 미치는 환자의 중간 질병 활동에 대해 보고 받을 수 있기 때문에 종합적으로 환자의 치료 경험과 반응에 대한 이해를 향상 시킴으로써 의사-환자간 의사소통 결정 과정을 개선시키고 환자 만족도를 증진시키게 되며 장기적으로 더 좋은 치료 결과를 도출해 낼 수 있다. 이러한 결과로 실제 영국, 미국 등 나라에서는 암 아동의 삶의 질, 염증성장 질환 등에 웹 기반의 PROM 평가를 사용하고 있으며 이후 치료 관해율이 증가 되었다는 보고도 이루어지고 있다. 이것이 최근 의료에서 환자 중심의 평가를 점점 중요시하며 많이 사용하는 이유이며 질병에 대한 병리학적 요소 외에도 사회환경적 부분을 포함하는 행동과학적 분석을 가능케 하기에 질적, 양적인 연구를 수행하는 데 큰 역할을 할 수 있다<sup>10-14</sup>.

다양한 질환과 증상에 포괄적으로 활용하여 사용하고 있는 PROM으로는 NRS, Visual analog scale(VAS), Global assessment(GA) 등이 있다. 이중 GA는 주로 이전 시점과 대비하여 현재 건강 상태의 변화를 확인하는 데 가장 많이 사용하는 평

가지표 중 하나이다. 그러나 현재 중증도에 대한 수치가 반영되어 있지 않기 때문에 일반적으로 NRS 또는 VAS와 함께 사용하는 편이며 환자가 이전 건강 상태에 대해 정확히 기억하지 못할 수 있다는 한계와 재현성에 대한 비관적인 견해가 있다<sup>9,15-17</sup>. VAS는 NRS와 함께 통증에서 가장 흔하게 사용되는 PROM으로 서로 혼동하여 사용하는 경우가 많다. 가장 큰 차이로 알려진 것은 NRS와는 달리 VAS는 실제적인 비례척도이며 특정 숫자 외의 영역도 포함하기 때문에 더 많은 범위를 포함한다는 것이다. 그러나 환자들은 증상을 VAS에 표시할 때 정확하지 않은 짐작으로 표시하는 경향이 있어 재현성이 떨어질 수 있고 환자의 감정이나 인지 상태에 의해 영향을 받을 수 있다. 또한 특정 숫자를 먼저 생각하고 표시한다는 보고가 있으며 Rasch 분석에 따르면 다른 숫자 척도와 마찬가지로 비례 척도로서의 의미가 떨어진다고 판단되기도 한다<sup>10,17-19</sup>.

숫자 평가 척도(NRS)는 세계적으로 임상에서 가장 빈번하게 사용되는 PROM이며 질병 또는 변화의 중증도를 측정하는데 있어 편리하고 빠르다는 장점 때문에 널리 사용되고 있다<sup>9,17</sup>. 또한 NRS는 PROM 중 개념이 매우 간단하여 교육수준이 낮거나 일부 능력이 상실된 환자도 쉽게 이해할 수 있고 언어와 문화에 상관없이 동등하게 사용이 가능하며 기록하기도 쉬워 모든 환자들이 1분안에 손쉽게 평가할 수 있다. 이러한 결과로 환자 선호도를 확인한 Lisanne Renskers의 연구에서도 사용된 간편한 PROM인 VAS, Verbal rating scale(VRS), Likert scale 중 모든 결과에서 NRS가 우세한 결과를 나타냈다. 또한 NRS는 구두와 기록에 있어 모두 사용이 가능하므로 우선상으로도 사용할 수 있고 통증 평가에 많이 사용하는 평가지표 중 심리적인 측면에 대한 반영이 더 잘 이루어진다고 하였다<sup>9,10,17</sup>.

일차적 진료에 사용할 포괄적인 PROM에 대한 연구에서는 갖추어야 할 항목으로 연령과 성별 등

에 제한 없이 환자 참여가 이루어지면서 만성질환과 가벼운 증세를 포함한 다양한 증상과 부작용, 환자 삶에 대한 영향 등을 반영할 수 있어야 하며 환자의 건강에 대한 걱정과 만족도 등을 포함하면서 10분 이내에 스스로 관리하고 보고될 수 있어야 한다고 제시하고 있다<sup>14</sup>. 본 연구에서 해외 연구에서 사용되고 있는 NRS의 사용 현황과 장점을 살펴본 바로는 NRS는 이러한 요건들을 대부분 만족하는 평가지표라는 것을 확인할 수 있다.

이미 해외, 그리고 국내에서 다양하게 사용되고 있는 NRS이지만 이를 포괄적으로 사용하는 데 있어 NRS가 가지고 있는 여러 한계에 대해 고려해 봐야 한다. 첫째로, 기준점이 애매하여 해석하는데 편향이 발생할 수 있다. 대부분의 NRS 사용에 있어 양쪽 끝과 중간 지점에 대해서만 기준을 제시하고 있는데 가장 흔하게 쓰는 10점 만점의 NRS를 예로 들면 0점의 경우 증상이 없다는 간단한 인식이 가능하나 5점은 중간 정도의 증상, 10점은 경험해 보았던 가장 심한 증상, 상상할 수 있는 가장 큰 증상 등으로 환자마다의 경험과 상상력에 따라 좌우되는 차이가 발생한다. 이는 결과의 해석에 있어 차이를 발생시킬 수 있으므로 국제적으로 쉽게 인식 가능한 동일한 기준의 제시가 필요하다<sup>9,19</sup>. 두 번째로는 변화의 해석에 대한 문제이다. 이는 NRS의 가장 큰 문제로 여겨지는 점인 비례척도가 아니라는 것에서 비롯된다. 일반적으로 10점 만점의 NRS 점수상으로 2점 또는 기준점으로부터 30%의 차이가 발생할 때 의미가 있는 변화라고 보는 경향이 있다. 그러나 중간 지점에서의 점수 차이와 양 끝에서의 점수 차이의 의미는 상대적으로 다르게 해석될 수 있고 Rasch 분석에 따르면 각 숫자에서 가지는 의미의 차이는 S곡선의 형태로 나타난다고 보고 있다<sup>9,17</sup>. 그러므로 NRS를 결과로서 해석하는 데 있어 연구자들은 점수 변화를 실제 의미를 가지는 수치로 변환시켜 평가할 필요성이 있다. 세 번째로, NRS는 통증에 관련된 평가에 있어서는 많은 연구가 이루어지는 상황이나 그 외 질

환과 증상 평가에 대해서는 민감도, 신뢰도, 타당도 등에 대한 근거가 아직 부족하다. 그러므로 기존에 여러 질환과 증상에서 대표적으로 사용되던 평가지표들과 비교한 추가적인 연구를 통해 이에 대한 근거가 더 마련되어야 한다.

실제로 NRS의 임상 적용을 위해 다양한 질환과 증상에서의 호환성을 확인하는 연구들이 이루어지고 있다. Lisanne Renskers<sup>10</sup>, Dafna Gladman<sup>20</sup> 등의 연구에서는 환자의 통증 외에도 피로도, 질병 활동, 그리고 삶의 질 평가에 NRS를 평가지표로 사용하였으며 구성 타당도, 민감도, 그리고 환자 선호도 등에서 우세한 결과를 보여 NRS를 임상과 연구에서 사용할 것을 권장하고 있다. S TSAI 등<sup>7</sup>의 연구에서 NRS는 경직 평가에 있어 Modified Ashworth Scale, Tardieu R2와 유의한 상관관계를 나타냈으며 Ngoc Quan Phan 등<sup>21</sup>의 연구에서 NRS는 소양감 평가에 있어 높은 타당도를 보였다.

이러한 NRS를 적용한 데이터를 바탕으로 통증<sup>22</sup>, 소양감 및 수면불량<sup>23</sup> 등에 대한 다기관 후향적 연구가 해외에서 이루어지는 바 있으나 아직까지 다양한 질환과 증상에 대한 연구는 이루어지지 않고 있으며 국내에서는 현재까지 다기관 후향적 연구를 위해 NRS를 사용한 경우가 거의 없다. 통증 질환에 관련해서는 로컬 한의원 및 한방병원 다빈도 질환이며 NRS의 가능성이 확인된 만큼 다기관 후향적 연구의 공통지표로 사용하는 데 무리가 없다고 판단된다. 통증 질환이 아닌 질환에서는 다기관 후향적 연구에서의 사용 현황은 데이터의 부족으로 확인하지 못하였지만 기존에 이루어지고 있는 무작위 배정 연구를 통해 다양한 질환과 증상에서 NRS가 사용되고 있음을 확인하였기에 실제 임상 환경에서 NRS가 통증이 아닌 다른 질환과 증상에서도 다용되고 있음을 판단할 수 있다.

이에 우선 호환성 연구가 이루어지고 해외에서 RCT 연구가 시행되고 있는 피부 질환군과 피로도, 삶의 질 증상 평가 등에 NRS 평가지표의 사용이 가능해 보이며, RCT는 시행되고 있으나 기존의

평가지표와의 호환성이 확인되지 않은 중앙, 신경계 질환 등에 대한 평가지표로서는 추가적인 연구를 통한 검증이 요구된다고 할 수 있다.

## V. 결 론

PROM은 일차의료에서 환자의 주요 증상을 확인하는 데 있어 필수적이다. 그러나 아직까지 모든 일차의료 환경에서 다양한 환자의 질환과 증상에 공통적으로 사용 가능한 것으로 입증된 PROM은 없다<sup>14</sup>. 본 연구에서 해외 RCT 논문을 통해 NRS의 사용 현황을 확인해 본 결과 근골격계 질환과 통증 평가 외에도 대부분의 다양한 질환군과 증상에 있어서 두루 사용되고 있는 평가지표이며 NRS가 가지고 있는 다양한 장점들을 고려했을 때 정형화가 부족한 한방의 진료 환경에서 일상적인 평가지표로 사용을 권장하며 다기관 후향적 연구에서 공용 데이터를 수집하는데 이용할 공용 평가지표로서의 가치가 있다고 판단된다.

## 감사의 글

This work was supported by clinical research grant from Pusan National University Hospital in 2021.

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**【Supplementary file for paper】 Analysis of NRS Used in Clinical Studies:  
Based on Randomized Controlled Studies**

List of 288 papers included for analysis

1. Clinical trial of the p38 MAP kinase inhibitor diltapimod in neuropathic pain following nerve injury
2. Corticosteroid injections for greater trochanteric pain syndrome: a randomized controlled trial in primary care
3. A phase 3, randomized, placebo-controlled trial of depofoam® bupivacaine (extended-release bupivacaine local analgesic) in bunionectomy
4. Capsaicin Instillation for Postoperative Pain following Total Knee Arthroplasty: A Preliminary Report of a Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Multicentre Trial
5. Night-time splinting after fasciectomy or dermo-fasciectomy for Dupuytren's contracture: A pragmatic, multi-centre, randomised controlled trial
6. A randomized, double-blind, placebo-controlled, parallel-group, enriched-design study of nabiximols\* (Sativex®), as add-on therapy, in subjects with refractory spasticity caused by multiple sclerosis
7. Motion style acupuncture treatment (MSAT) for acute low back pain with severe disability: A multicenter, randomized, controlled trial protocol
8. Effectiveness of physical therapy as an adjunct to epidural steroid injections in the treatment of lumbar spinal stenosis: A pilot randomized controlled trial
9. A multicenter randomized controlled trial to compare subacute 'treatment as usual' with and without mental practice among persons with stroke in dutch nursing homes
10. A randomized, multicenter, pilot study comparing the efficacy and safety of a bupivacaine-collagen implant (XaraColl®) with the ON-Q PainBuster® Post-op Pain Relief System following open gynecological surgery
11. Pilates based core stability training in ambulant individuals with multiple sclerosis: Protocol for a multi-centre randomised controlled trial
12. Study Protocol- Lumbar Epidural Steroid Injections for Spinal Stenosis (LESS): A double-blind randomized controlled trial of epidural steroid injections for lumbar spinal stenosis among older adults
13. Immediate effects of motion style acupuncture treatment (MSAT) in acute low back pain with severe disability: A multicenter, randomized, controlled trial
14. The efficacy and safety of DepoFoam bupivacaine in patients undergoing bilateral, cosmetic, submuscular augmentation mammoplasty: A randomized, double-blind, active-control study
15. A spicamycin derivative (KRN5500) provides neuropathic pain relief in patients with advanced cancer: A placebo-controlled, proof-of-concept trial
16. Treatment outcomes of pulpotomy in permanent molars with irreversible pulpitis using biomaterials: a multi-center randomized controlled trial
17. A multi-centre randomised double-blind placebo-controlled trial to evaluate the value of a single bolus intravenous alfentanil in CT colonography
18. A multicenter, randomized, controlled study evaluating preventive etanercept on postoperative pain after inguinal hernia repair
19. Nitrous oxide for early analgesia in the emergency setting: A randomized, double-blind multicenter prehospital trial
20. A randomized, double-blind, placebo-controlled trial of a chemokine receptor 2 (CCR2) antagonist in posttraumatic neuralgia

21. Evaluation of a novel chemokine receptor 2 (CCR2)-antagonist in painful diabetic polyneuropathy
22. Electroacupuncture for chemotherapy-induced peripheral neuropathy: Study protocol for a pilot multicentre randomized, patient-assessor-blinded, controlled trial
23. Hydroxychloroquine effectiveness in reducing symptoms of hand osteoarthritis (HERO): Study protocol for a randomized controlled trial
24. Moxibustion for treating knee osteoarthritis: study protocol of a multicentre randomised controlled trial
25. Limaprost alfadex and nonsteroidal anti-inflammatory drugs for sciatica due to lumbar spinal stenosis
26. A Randomized, Controlled Trial of Gabapentin Enacarbil in Subjects with Neuropathic Pain Associated with Diabetic Peripheral Neuropathy
27. Effects of motion style acupuncture treatment in acute low back pain patients with severe disability: A multicenter, randomized, controlled, comparative effectiveness trial
28. Finnish Degenerative Meniscal Lesion Study (FIDELITY): A protocol for a randomised, placebo surgery controlled trial on the efficacy of arthroscopic partial meniscectomy for patients with degenerative meniscus injury with a novel 'RCT within-a-cohort' study design
29. Randomized Study of Pregabalin in Patients with Cancer-Induced Bone Pain
30. The effect of pelvic physiotherapy on reduction of functional constipation in children: Design of a multicentre randomised controlled trial
31. A prospective, randomized multicenter study comparing conventional laparoscopic cholecystectomy versus minilaparotomy cholecystectomy with ultrasonic dissection as day surgery procedure--1-year outcome
32. A randomized controlled trial of nonoperative treatment versus open reduction and internal fixation for stable, displaced, partial articular fractures of the radial head: The RAMBO trial
33. Standardized treatment of chinese medicine decoction for cancer pain patients with opioid-induced constipation: A multi-center prospective randomized controlled study
34. Prevention of low back pain: effect, cost-effectiveness, and cost-utility of maintenance care - study protocol for a randomized clinical trial
35. Water exchange vs. carbon dioxide insufflation in unsedated colonoscopy - A multicenter, single-blinded, randomized controlled trial
36. A phase III randomized, placebo-controlled study of topical amitriptyline and ketamine for chemotherapy-induced peripheral neuropathy (CIPN): A University of Rochester CCOP study of 462 cancer survivors
37. Are orange lollies effective in preventing nausea and vomiting related to dimethyl sulfoxide? A multicenter randomized trial
38. Magnetic resonance-guided focused ultrasound for patients with painful bone metastases: Phase III trial results
39. Moxibustion treatment for knee osteoarthritis: A multi-Centre, non-blinded, randomised controlled trial on the effectiveness and safety of the moxibustion treatment versus usual care in knee osteoarthritis patients
40. Preoperative pain neuroscience education for lumbar radiculopathy: A multicenter randomized controlled trial with 1-year follow-up
41. Hydromorphone extended release for neuropathic and non-neuropathic/nociceptive chronic low back pain: a post hoc analysis of data from a randomized, multicenter, double-blind, placebo-controlled clinical trial
42. Rationale and design of a multicenter randomized clinical trial with memantine and dextromethorphan in ketamine-responder patients
43. EMA401, an orally administered highly selective angiotensin II type 2 receptor antagonist, as a novel treatment for postherpetic neuralgia: A randomised, double-blind, placebo-controlled phase 2 clinical trial
44. Cost-utility of exercise therapy added to general practitioners' care versus general practitioners' care alone in patients with hip osteoarthritis
45. An intra-articular, extended-release formulation of triamcinolone acetonide prolongs and amplifies analgesic

- effect in patients with osteoarthritis of the knee: a randomized clinical trial
46. Epidural steroid injections compared with gabapentin for lumbosacral radicular pain: Multicenter randomized double blind comparative efficacy study
  47. A multicentre, open-label, follow-on study to assess the long-term maintenance of effect, tolerance and safety of THC/CBD oromucosal spray in the management of neuropathic pain
  48. Imipramine and pregabalin combination for painful polyneuropathy: A randomized controlled trial
  49. Efficacy and safety of pregabalin in the treatment of patients with painful diabetic peripheral neuropathy and pain on walking
  50. Emergency department femoral nerve blocks for acute hip fracture pain: A randomized controlled trial
  51. A randomised controlled trial of three or one breathing technique training sessions for breathlessness in people with malignant lung disease
  52. Acupuncture for chronic fatigue syndrome and idiopathic chronic fatigue: a multicenter, nonblinded, randomized controlled trial
  53. Moxibustion treatment for knee osteoarthritis: A multi-centre, non-blinded, randomised controlled trial
  54. Pain reduction with oral methotrexate in knee osteoarthritis, a pragmatic phase iii trial of treatment effectiveness (PROMOTE): Study protocol for a randomized controlled trial
  55. Comparison of vestipitant with ondansetron for the treatment of breakthrough postoperative nausea and vomiting after failed prophylaxis with ondansetron
  56. Daylight photodynamic therapy with methyl aminolevulinate cream is effective and nearly painless in treating actinic keratoses: A randomised, investigator-blinded, controlled, phase III study throughout Europe
  57. Effects of Shinbaro pharmacopuncture in sciatic pain patients with lumbar disc herniation: Study protocol for a randomized controlled trial
  58. Pregabalin in the treatment of herpetic neuralgia: Results of a multicenter Chinese study
  59. Minimally invasive decompression versus x-stop in lumbar spinal stenosis: A randomized controlled multicenter study
  60. Preoperative neuroscience education for lumbar radiculopathy patients—a randomised control trial
  61. Phase 2a, randomized, double-blind, placebo-controlled, multicenter, parallel-group study of a H4R-antagonist (JNJ-39758979) in Japanese adults with moderate atopic dermatitis
  62. A comparison of differences between the systemic pharmacokinetics of levobupivacaine and ropivacaine during continuous epidural infusion: A prospective, randomized, multicenter, double-blind controlled trial
  63. A randomized double-blind, placebo-controlled efficacy and safety study of ALO-02 (extended-release oxycodone surrounding sequestered naltrexone) for moderate-to-severe chronic low back pain treatment
  64. Ultramicrosized palmitoylethanolamide in spinal cord injury neuropathic pain: A randomized, double-blind, placebo-controlled trial
  65. A randomized multicenter study of minilaparotomy cholecystectomy versus laparoscopic cholecystectomy with ultrasonic dissection in both groups
  66. Randomized trial of low-dose morphine versus weak opioids in moderate cancer pain
  67. Nicoboxil/nonivamide cream effectively and safely reduces acute nonspecific low back pain - a randomized, placebo-controlled trial
  68. Topical nonivamide/nicoboxil effectively and safely reduces acute unspecific low back pain: A randomised, controlled trial
  69. Cebranopadol, a novel first-in-class analgesic: Results from a study in patients with moderate to severe pain following bunionectomy
  70. Cebranopadol, a novel first-in-class analgesic: Efficacy, safety, tolerability in patients with mixed chronic low back pain

71. Are strong opioids equally effective and safe in the treatment of chronic cancer pain? A multicenter randomized phase IV 'real life' trial on the variability of response to opioids
72. Analgesic, the extracts of Vaccinia-inoculated rabbit skin, effectively alleviates the chronic low back pain with little side effect - A randomized multi-center double-blind placebo-controlled phase 3 clinical trial
73. Cebranopadol, a novel first-in-class analgesic: Efficacy, safety, tolerability in patients with pain due to diabetic peripheral neuropathy
74. Randomized double-blind trial of pregabalin versus placebo in conjunction with palliative radiotherapy for cancer-induced bone pain
75. Efficacy and safety of nicoboxil/nonivamide ointment for the treatment of acute pain in the low back - A randomized, controlled trial
76. Knowledge of pain management in patients with painful bone metastases: A multicentre randomized trial on pain education
77. Access to an active, interactive self-assessment e-health platform improves patient-physician communication in rheumatoid arthritis: Results of a randomized controlled trial including 320 patients over 1 year
78. BAT117213: Ileal bile acid transporter (IBAT) inhibition as a treatment for pruritus in primary biliary cirrhosis: Study protocol for a randomised controlled trial
79. Assessment of the effectiveness and safety of Ethosuximide in the Treatment of non-Diabetic Peripheral Neuropathic Pain: EDONOT - Protocol of a randomised, parallel, controlled, double-blinded and multicentre clinical trial
80. Electroacupuncture for chemotherapy-induced peripheral neuropathy: A pilot multicenter randomized, patient-assessor blinded, controlled trial
81. The efficacy of continuous-flow cryo and cyclic compression therapy after hip fracture surgery on postoperative pain: Design of a prospective, open-label, parallel, multicenter, randomized controlled, clinical trial
82. Hiloterapy verses ice packs in reducing post-operative pain
83. The STAP-study: The (cost) effectiveness of custom made orthotic insoles in the treatment for plantar fasciopathy in general practice and sports medicine: Design of a randomized controlled trial
84. Efficacy and tolerability of buccal buprenorphine in opioid-naïve patients with moderate to severe chronic low back pain
85. Continued treatment with ixekizumab over 60 weeks provides sustained improvements in itch and other patient reported outcomes: Results from UNCOVER-2, a Phase 3 trial
86. Use of elagolix for the management of endometriosis-associated pain: Secondary efficacy results from two randomized, placebo-controlled Studies
87. Safety and efficacy of Tongkuaixiao ointment in reliving cancer-induced pain: a multicenter double-blind placebo-controlled randomized trial
88. Secukinumab delivers greater improvement in health-related quality of life compared to ustekinumab in subjects with moderate-to-severe plaque psoriasis: 16-week data from the CLEAR study
89. Randomized Sham-controlled Double-Blind Multicenter Clinical Trial to Ascertain the Effect of Percutaneous Radiofrequency Treatment for Sacroiliac Joint Pain: Three-month Results
90. Randomised sham-controlled double-blind multicentre clinical trial to ascertain the effect of percutaneous radiofrequency treatment for lumbar facet joint pain
91. Local administration of HTX-011, a long-acting biochronomer-based bupivacaine/meloxicam combination, in hernia repair: Initial results
92. OnabotulinumtoxinA Improves Pain in Patients With Post-Stroke Spasticity: Findings From a Randomized, Double-Blind, Placebo-Controlled Trial

93. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of Shuangbai San for Treating Primary Liver Cancer Patients with Cancer Pain
94. Comparison of the Tolerability Profile of Controlled-Release Oral Morphine and Oxycodone for Cancer Pain Treatment. An Open-Label Randomized Controlled Trial
95. Double cupping versus single cupping in chronic low back pain (CLBP): Randomized controlled trial
96. Clinical Experience With Desvenlafaxine in Treatment of Patients With Fibromyalgia Syndrome
97. Systems-2: Randomized phase II trial of standard versus dose escalated radiotherapy for pain in malignant pleural mesothelioma
98. A randomized controlled trial of gabapentin in provoked vulvodynia: Racial differences
99. Efficacy and safety of ixekizumab (IXE) compared to ustekinumab (UST) in patients with moderate-to-severe plaque psoriasis: A randomised head-to-head trial
100. 12-month follow-up of a prospective, multi-center, randomized, trial comparing safety and effectiveness of cooled radiofrequency ablation to corticosteroid injection for management of osteoarthritic knee pain
101. Acupuncture for analgesia in the emergency department: A multicentre, randomised, equivalence and non-inferiority trial
102. Efficacy and safety of guaifenesin for upper back, neck, and shoulder pain: A Phase II proof-of-concept, multicenter, placebo-controlled, repeat-dose, parallel-group study
103. Secukinumab improves scalp pain, itching, scaling and quality of life in patients with moderate-to-severe scalp psoriasis
104. The effect of nurse-led pain education of patients with painful bone metastases on pain and quality of life: A multicenter randomized trial
105. Impact of delafloxacin (DLX) and vancomycin/aztreonam (VAN/AZ) on resolution of signs and symptoms of acute bacterial skin and skin structure infections (ABSSSI)
106. Antiemetic Corticosteroid Rotation from Dexamethasone to Methylprednisolone to Prevent Dexamethasone-Induced Hiccup in Cancer Patients Treated with Chemotherapy: A Randomized, Single-Blind, Crossover Phase III Trial
107. Cervical disc arthroplasty with the Prestige LP disc versus anterior cervical discectomy and fusion, at 2 levels: results of a prospective, multicenter randomized controlled clinical trial at 24 months
108. Study-protocol for a randomized controlled trial comparing clinical and radiological results after three different posterior decompression techniques for lumbar spinal stenosis: the Spinal Stenosis Trial (SST) (part of the NORDSTEN Study)
109. Effect of radiofrequency denervation on pain intensity among patients with chronic lowback pain the mint randomized clinical trials
110. Assessment of the effectiveness and safety of ethosuximide in the treatment of abdominal pain related to irritable bowel syndrome - IBSET: Protocol of a randomised, parallel, controlled, double-blind and multicentre trial
111. Effects of herbal medicine for dysmenorrhea treatment on accompanied acne vulgaris: A study protocol for a randomized controlled trial
112. Tolerability, Safety, and Effectiveness of Oxycodone DETERx in Elderly Patients  $\geq 65$  Years of Age with Chronic Low Back Pain: A Randomized Controlled Trial
113. Guselkumab therapy improves patient-reported signs, symptoms and health-related quality of life of patients with moderate-severe psoriasis with inadequate response to ustekinumab: Results from phase III NAVIGATE study
114. Efficacy and Safety of Transdermal Buprenorphine versus Oral Tramadol/Acetaminophen in Patients with Persistent Postoperative Pain after Spinal Surgery
115. Postoperative continuous-flow cryocompression therapy in the acute recovery phase of hip fracture

- surgery-A randomized controlled clinical trial
116. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of Nalbuphine ER Tablets for Uremic Pruritus
  117. Efficacy and safety of 0.625% and 1.25% capsaicin patch in peripheral neuropathic pain: Multi-center, randomized, and semi-double blind controlled study
  118. Evolution of pain at 3 months by oral resveratrol in knee osteoarthritis (ARTHROL): Protocol for a multicentre randomised double-blind placebo-controlled trial
  119. Efficacy and safety of oxynorm® compared to morphine sulfate administering through iv continuous infusion in moderate-severe cancer-related pain
  120. Early rehabilitation after lumbar disc surgery is not effective or cost-effective compared to no referral: a randomised trial and economic evaluation
  121. The effect of a perioperative ketamine infusion on the incidence of chronic postsurgical pain-a pilot study
  122. Efficacy of paracetamol, diclofenac and advice for acute low back pain in general practice: design of a randomized controlled trial (PACE Plus)
  123. Comparative effectiveness and cost-effectiveness of Chuna manual therapy versus conventional usual care for nonacute low back pain: Study protocol for a pilot multicenter, pragmatic randomized controlled trial (pCRN study)
  124. The Norwegian Cervical Arthroplasty Trial (NORCAT): 2-year clinical outcome after single-level cervical arthroplasty versus fusion-a prospective, single-blinded, randomized, controlled multicenter study
  125. Flex-201: A multicenter, randomized, blinded study to evaluate the efficacy and tolerability of FLX-787 in MS
  126. Protocol for the upcoming study: Patient input monitoring of pain in the emergency room: Novel electronic log (pimpernel): A randomised controlled trial of an electronic pain score display in adults in the emergency department
  127. Safety, efficacy and tolerability of oro-mucosal tetrahydrocannabinol/cannabidiol therapy to reduce spasticity in children and adolescents. results of a multicentre, double blind placebo controlled trial
  128. Treatment of thoracolumbar burst fractures: Extended follow-up of a randomized clinical trial comparing orthosis versus no orthosis
  129. Randomized sham-controlled, double-blind, multicenter clinical trial on the effect of percutaneous radiofrequency at the ramus communicans for lumbar disc pain
  130. Serlopitant for treatment of chronic pruritus: Results of a randomized, multicenter, double-blind, placebocontrolled phase 2 clinical trial
  131. A Randomized, Double-blind, Placebo-controlled Trial of Certolizumab Pegol in Women with Refractory Interstitial Cystitis/Bladder Pain Syndrome
  132. Is pharmacologic treatment better than neural mobilization for cervicobrachial pain? A randomized clinical trial
  133. Effects of a single intra-articular injection of a microsphere formulation of triamcinolone acetonide on knee osteoarthritis pain: A double-blinded, randomized, placebo-controlled, multinational study
  134. Prospective, Multicenter, Randomized, Crossover Clinical Trial Comparing the Safety and Effectiveness of Cooled Radiofrequency Ablation With Corticosteroid Injection in the Management of Knee Pain From Osteoarthritis
  135. 6-and 12-month results of a prospective, multi-center, randomized, trial comparing safety and effectiveness of cooled radiofrequency ablation to corticosteroid injection for management of osteoarthritic knee pain
  136. Comparative effectiveness and economic evaluation of Chuna manual therapy for chronic neck pain: protocol for a multicenter randomized controlled trial
  137. Pain education of patients with painful bone metastases reduces pain: a multicentre randomised trial

138. The Janus kinase 1 (JAK1) inhibitor PF-04965842 reduces signs and symptoms of moderate to severe atopic dermatitis (AD)
139. An e-health interactive self-assessment website (Sanoia®) in rheumatoid arthritis. A 12-month randomized controlled trial in 320 patients
140. Results from a randomized, double-blind, placebo-controlled, exploratory, multicenter study of GBR 830 in adult patients with moderate-to-severe atopic dermatitis
141. Topical DSI07 for the treatment of mild-to-moderate Atopic Dermatitis: Results from ADVANTAGE, an 8 week phase 2b randomized, double-blind, vehicle-controlled study
142. Analgesic Efficacy and Safety of Prolonged-Release Oxycodone/Naloxone in Korean Patients with Chronic Pain from Spinal Disorders
143. Zopiclone versus placebo for short-term treatment of insomnia in patients with advanced cancer: Study protocol for a double-blind, randomized, placebo-controlled, clinical multicenter trial
144. Efficacy and safety of electrical moxibustion for knee osteoarthritis: Study protocol for a randomized controlled trial
145. Perioperative pregabalin and intraoperative lidocaine infusion to reduce persistent neuropathic pain after breast cancer surgery: A multicenter, factorial, randomized controlled pilot trial
146. Pregabalin and lidocaine to alter neuropathic pain after breast cancer surgery: Results of a pilot factorial-design randomized controlled trial
147. Randomized clinical trial of preoperative high-dose methylprednisolone on postoperative pain at rest after laparoscopic appendectomy
148. Protocol of the randomised placebo controlled pilot trial of the management of acute sciatica (SCIATICA): A feasibility study
149. Is intravenously administered, subdissociative-dose KETamine non-inferior to MORPHine for prehospital analgesia (the KETAMORPH study): Study protocol for a randomized controlled trial
150. A randomized, double blind, multicenter trial to evaluate clinical effectiveness of 4.4 mhz-radio frequency compared with ultrasound for patients with subacute low back pain
151. Effect of pain neuroscience education combined with cognition-targeted motor control training on chronic spinal pain a randomized clinical trial
152. A multicenter, randomized, double-blind, placebo-controlled trial of nalbuphine ER tablets for uremic pruritus
153. Efficacy and safety of single-dose onabotulinumtoxinA in the treatment of symptoms of osteoarthritis of the knee: results of a placebo-controlled, double-blind study
154. Sufentanil sublingual tablet 30mcg for moderate-to-severe acute pain in the ED
155. Efficacy and safety of topical JTE-052, a Janus kinase inhibitor, in Japanese adult patients with moderate-to-severe atopic dermatitis: a phase II, multicentre, randomized, vehicle-controlled clinical study
156. Resolution of signs and symptoms (S&S) of acute bacterial skin and skin structure infections (ABSSSI) with delafloxacin (DLX) IV/oral therapy
157. A randomized, multicenter, double-blind, parallel pilot study assessing the effect of mechanical adhesiolysis vs adhesiolysis with corticosteroid and hyaluronidase administration into the epidural space during epiduroscopy
158. Acetaminophen or Nonsteroidal Anti-Inflammatory Drugs in Acute Musculoskeletal Trauma: A Multicenter, Double-Blind, Randomized, Clinical Trial
159. IMPROVEMENT OF CLINICAL SYMPTOMS OF LACTOSE INTOLERANCE WITH A NOVEL PREBIOTIC GALACTO-OLIGOSACCHARIDE, RP-G28
160. Effectiveness of endoscopic totally extraperitoneal (TEP) hernia correction for clinically occult inguinal hernia (EFFECT): Study protocol for a randomized controlled trial



161. Traditional and augmented reality mirror therapy for patients with chronic phantom limb pain (PACT study): results of a three-group, multicentre single-blind randomized controlled trial
162. Personality Modulates the Efficacy of Art Intervention on Chronic Pain in a Population of Patients with Alzheimer's Disease
163. Flex-201: A multicenter, randomized, blinded study to evaluate the utility of flx-787 in treating MS spasticity
164. Is postoperative bracing after pedicle screw fixation of spine fractures necessary? Study protocol of the ORNOT study: A randomised controlled multicentre trial
165. A randomized, multicenter, double-blind, placebo-controlled Phase II clinical trial of serlopitant for the treatment of chronic pruritus
166. Effects of Rate on Analgesia in Kilohertz Frequency Spinal Cord Stimulation: Results of the PROCO Randomized Controlled Trial
167. Efficacy of immediate-release oxycodone for dyspnoea in cancer patient: Cancer dyspnoea relief (CDR) trial
168. Non-invasive high-frequency impulse neuromodulation for treatment of chronic back pain: A multicenter, randomized, sham-controlled trial
169. Decompression alone versus decompression with instrumental fusion the NORDSTEN degenerative spondylolisthesis trial (NORDSTEN-DS): Study protocol for a randomized controlled trial
170. Women's experience of childbirth according to the type of pushing at delivery - Eole Study
171. Analgesia with nitrous oxide/oxygen and acetaminophen compared to morphine analgesia in patients with acute myocardial infarction: Results from the SCADOL II clinical trial
172. A prospective, multi-center, randomized, clinical trial comparing the effectiveness and safety of cooled radiofrequency ablation versus a single injection of hyaluronic acid in the management of oa knee pain
173. Effect of filgotinib on patient-reported outcomes in active psoriatic arthritis: Results from equator, a randomized, phase 2 study
174. Twelve-month analgesia and rescue, by cooled radiofrequency ablation treatment of osteoarthritic knee pain: Results from a prospective, multicenter, randomized, cross-over trial
175. Gabapentin as add-on to morphine for severe neuropathic or mixed pain in children from age 3 months to 18 years - Evaluation of the safety, pharmacokinetics, and efficacy of a new gabapentin liquid formulation: Study protocol for a randomized controlled trial
176. The effectiveness of progressive muscle relaxation and interactive guided imagery as a pain-reducing intervention in advanced cancer patients: A multicentre randomised controlled non-pharmacological trial
177. Screw fixation versus hemiarthroplasty for nondisplaced femoral neck fractures in elderly patients: A multicenter randomized controlled trial
178. Methoxyflurane Versus Standard of Care for Acute Trauma-Related Pain in the Emergency Setting: Protocol for a Randomised, Controlled Study in Italy (MEDITA)
179. Tramadol/dexketoprofen (TRAM/DKP) compared with tramadol/paracetamol in moderate to severe acute pain: Results of a randomised, double-blind, placebo and active-controlled, parallel group trial in the impacted third molar extraction pain model (DAVID study)
180. Certolizumab pegol-treated patients with non-radiographic axial spondyloarthritis demonstrate improvements in sleep quality and Other Patient Reported Outcomes
181. A preventive program for work-related musculoskeletal disorders among surgeons: Outcomes of a randomized controlled clinical trial
182. Reducing arthritis fatigue impact: Two-year randomised controlled trial of cognitive behavioural approaches by rheumatology teams (RAFT)
183. The effects of music on anxiety and pain in patients during carotid endarterectomy under regional

- anesthesia: A randomized controlled trial
184. Clinical research on the clinical effectiveness and cost-effectiveness of Chuna manual therapy for temporomandibular disorder: A study protocol for a multicenter randomized controlled trial
  185. Significant pain reduction with oral methotrexate in knee osteoarthritis: results from the promote randomised controlled phase iii trial of treatment effectiveness
  186. Effectiveness and cost-effectiveness of acupuncture with Doin therapy for chronic neck pain: A study protocol for a multicentre, randomised controlled clinical trial
  187. Evaluating the analgesic effect and advantage of transcutaneous electrical acupoint stimulation combined with opioid drugs for moderate to severe cancer-related pain: A study protocol for a randomized controlled trial
  188. Comparative effectiveness of Chuna manual therapy versus conventional usual care for non-acute low back pain: A pilot randomized controlled trial
  189. Patient controlled analgesia (PCA) versus non-PCA intravenous hydromorphone titration for severe cancer pain: A randomized, controlled, multicenter, phase III trial, HMORCT09-1
  190. Nebulized versus intravenous morphine titration for the initial treatment of severe acute pain in the emergency department: Study protocol for a multicenter, prospective randomized and controlled trial, CLIN-AEROMORPH
  191. A Randomized Controlled Trial to Evaluate the Effect of Pulsed Radiofrequency as a Treatment for Anterior Cutaneous Nerve Entrapment Syndrome in Comparison to Anterior Neurectomy
  192. Effect of NGM282, an FGF19 Analogue, on Pruritus in Patients with Primary Sclerosing Cholangitis: Analysis of a Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial
  193. Improvement in ocular symptoms and signs in patients with Demodex anterior blepharitis using a novel terpinen-4-OL (2.5%) and hyaluronic acid (0.2%) cleansing wipe
  194. The effect of contact needle therapy on fatigue in patients with cancer in palliative care: A study protocol for a randomized controlled trial
  195. Relugolix, a novel oral gonadotropin-releasing hormone antagonist, in the treatment of pain symptoms associated with uterine fibroids: a randomized, placebo-controlled, phase 3 study in Japanese women
  196. Efficacy and safety of sustained-release oxycodone compared with immediate-release morphine for pain titration in cancer patients: A multicenter, open-label, randomized controlled trial (SOCIAL)
  197. Analgesic efficacy of preemptive local wound infiltration plus laparoscopic-assisted transversus abdominis plane block versus wound infiltration in patients undergoing laparoscopic colorectal resection: study protocol for a randomized, multicenter, single-blind, noninferiority trial
  198. Consistent Efficacy of Buprenorphine Buccal Film in Opioid-Naive and Opioid-Experienced Patients with Moderate to Severe Chronic Low Back Pain
  199. A randomized, placebo- and active-controlled, multicountry, multi-center parallel group trial to evaluate the efficacy and safety of a fixed-dose combination of 400 mg ibuprofen and 100 mg caffeine compared with ibuprofen 400 mg and placebo in patients with acute lower back or neck pain
  200. Acute Cuff Tear Repair Trial (ACCURATE): Protocol for a multicentre, randomised, placebo-controlled trial on the efficacy of arthroscopic rotator cuff repair
  201. MC2-01 cream has improved overall psoriasis treatment efficacy compared to calcipotriene plus betamethasone dipropionate topical suspension
  202. CONVEY, A Phase 2 placebo-controlled, double-blind, enriched enrollment randomized withdrawal study design of vixotrigine for the treatment of pain in participants with confirmed small fiber neuropathy
  203. Dupilumab efficacy and safety in adolescents with moderate-to-severe atopic dermatitis: Results from a multicenter, randomized, placebo-controlled, double-blind, parallel-group, Phase III study
  204. 61. Multi-modal analgesia protocol significantly decreased opioid requirements following lumbar spine

- surgery: results from a feasibility trial
205. Efficacy of electro-acupuncture and manual acupuncture versus sham acupuncture for knee osteoarthritis: Study protocol for a randomised controlled trial
  206. Short-term effect of occupational therapy intervention on hand function and pain in patients with thumb base osteoarthritis - Secondary analyses of a randomized controlled trial
  207. Efficacy and safety of upadacitinib in a randomized, double-blind, placebo-controlled, multicenter phase 2/3 clinical study of patients with Active Ankylosing Spondylitis
  208. Efficacy and safety of apremilast in patients with moderate-to-severe plaque psoriasis of the scalp: Results of a Phase III, multicenter, randomized, placebo-controlled, double-blind study
  209. Improving the quality and acceptance of colonoscopy preparation by reinforced patient education with short message service: results from a randomized, multicenter study (PERICLES-II)
  210. Ixekizumab significantly reduced pain, inflammation, and fatigue in patients with radiographic axial spondylarthritis (r-axsps)/ankylosing spondylitis (as)
  211. Early fixation versus conservative therapy of multiple, simple rib fractures (FixCon): protocol for a multicenter randomized controlled trial
  212. Randomized, double-blind, placebo-controlled, multicenter clinical study of the efficacy and safety of intravesical instillation of KRP-116D (50% dimethyl sulfoxide) for interstitial cystitis/bladder pain syndrome in Japanese subjects
  213. Heat-inactivated Bifidobacterium bifidum MIMBb75 (SYN-HI-001) in the treatment of irritable bowel syndrome: a multicentre, randomised, double-blind, placebo-controlled clinical trial
  214. Poststroke shoulder pain in subacute patients and its correlation with upper limb recovery after robotic or conventional treatment: A secondary analysis of a multicenter randomized controlled trial
  215. Inhaled Methoxyflurane Provides Greater Analgesia and Faster Onset of Action Versus Standard Analgesia in Patients With Trauma Pain: InMEDIATE: A Randomized Controlled Trial in Emergency Departments
  216. Cooled Radiofrequency Ablation Compared with a Single Injection of Hyaluronic Acid for Chronic Knee Pain: A Multicenter, Randomized Clinical Trial Demonstrating Greater Efficacy and Equivalent Safety for Cooled Radiofrequency Ablation
  217. Cooled radiofrequency ablation provides extended clinical utility in the management of knee osteoarthritis: 12-month results from a prospective, multi-center, randomized, cross-over trial comparing cooled radiofrequency ablation to a single hyaluronic acid injection
  218. Vr4popka: Virtual reality induced hypnosis for postoperative pain after total knee arthroplasty
  219. Postendodontic Pain after Pulpotomy or Root Canal Treatment in Mature Teeth with Carious Pulp Exposure: A Multicenter Randomized Controlled Trial
  220. Does a screening trial for spinal cord stimulation in patients with chronic pain of neuropathic origin have clinical utility and cost-effectiveness (TRIAL-STIM)? A randomised controlled trial
  221. Clinical efficacy and safety of gyebutang granule combined with acupuncture for knee osteoarthritis: Multicenter, randomized, assessor-blinded, 2-armed parallel, controlled trial
  222. Hypnosis and communication reduce pain and anxiety in peripheral intravenous cannulation: Effect of Language and Confusion on Pain During Peripheral Intravenous Catheterization (KTHYPE), a multicentre randomised trial
  223. Treatment of radicular pain with epidural clonidine micropellets: A phase 3 prospective, randomized, multicenter, double-blind, sham-controlled study
  224. Gabapentin for chronic pelvic pain in women (GaPP2): a multicentre, randomised, double-blind, placebo-controlled trial
  225. Impact of bupivacaine injection to trocar sites on postoperative pain following laparoscopic hysterectomy: Results from a prospective, multicentre, double-blind randomized controlled trial

226. Cooled Radiofrequency Ablation Treatment of the Genicular Nerves in the Treatment of Osteoarthritic Knee Pain: 18- and 24-Month Results
227. Effectiveness and safety of electrical moxibustion for knee osteoarthritis: A multicenter, randomized, assessor-blinded, parallel-group clinical trial
228. Tolperisone 100 and 200 mg three times daily (TID) for acute muscle spasm of the back: A doubleblind, randomized, placebo-controlled, multicenter phase 3 study
229. SAT-250 FAR INFRARED THERAPY: EFFECTS ON VASCULAR ACCESS BLOOD FLOW, KT/V AND NEEDLING PAIN IN HEMODIALYSIS PATIENTS
230. The effectiveness and cost-effectiveness of motion style acupuncture treatment (MSAT) for acute neck pain: A multi-center randomized controlled trial
231. Efficacy, safety, and economic assessment of hominis placental pharmacopuncture for chronic temporomandibular disorder: A protocol for a multicentre randomised controlled trial
232. Lactobacillus acidophilus DDS-1 and bifidobacterium lactis UABla-12 improve abdominal pain severity and symptomology in irritable bowel syndrome: Randomized controlled trial
233. Investigation of topical intranasal cocaine for sinonasal procedures: a randomized, phase III clinical trial
234. Effect of therapeutic suggestions during general anaesthesia on postoperative pain and opioid use: Multicentre randomised controlled trial
235. A Multicenter, Prospective, Randomized, Placebo-Controlled, Double-Blind Study of a Novel Pain Management Device, AT-02, in Patients with Fibromyalgia
236. A study on the effectiveness of pharmacopuncture for chronic neck pain: A protocol for a pragmatic randomized controlled trial
237. Comparative effectiveness of chuna manipulative therapy for non-acute lower back pain: A multi-center, pragmatic, randomized controlled trial
238. Analgesic efficacy of pre-emptive local wound infiltration plus laparoscopic-assisted transversus abdominis plane block versus wound infiltration in patients undergoing laparoscopic colorectal resection: results from a randomized, multicenter, single-blind, non-inferiority trial
239. Secukinumab Provides Significant Improvement of Spinal Pain and Lowers Disease Activity in Patients with Axial Spondyloarthritis: 24-week Results from a Randomized Controlled Phase 3b Trial
240. Secukinumab provides significant improvement of spinal pain in patients with axial spondyloarthritis: Results from the 24-week phase 3 skippain study
241. Real-world use of the sufentanil sublingual tablet system for patient-controlled management of acute postoperative pain: a prospective noninterventional study
242. Anatomic Lead Placement Without Paresthesia Mapping Provides Effective and Predictable Therapy During the Trial Evaluation Period: Results From the Prospective, Multicenter, Randomized, DELIVERY Study
243. Management of postoperative pain after elective craniotomy: A prospective randomized controlled trial of a neurosurgical enhanced recovery after surgery (ERAS) program
244. Non-invasive high-frequency impulse neuromodulation for treatment of chronic back pain: A multicenter, randomized, sham-controlled trial
245. No differences in cost-effectiveness and short-term functional outcomes between cemented and uncemented total knee arthroplasty
246. Ixekizumab treatment results in more rapid and sustained resolution of patients' itch, skin pain and improvement in quality of life in patients with moderate-to-severe psoriasis compared to ustekinumab
247. Open-label randomised pragmatic trial (CONTACT) comparing naproxen and low-dose colchicine for the treatment of gout flares in primary care

248. Certolizumab pegol-treated patients with non-radiographic axspa demonstrate improvements in sleep quality and other patient reported outcomes
249. Arthroscopic partial meniscectomy for a degenerative meniscus tear: a 5 year follow-up of the placebo-surgery controlled FIDELITY (Finnish Degenerative Meniscus Lesion Study) trial
250. Phase 2B randomized study of nemolizumab in adults with moderate-to-severe atopic dermatitis and severe pruritus
251. Effect of Oral Carbohydrate Intake during Labor on the Rate of Instrumental Vaginal Delivery: A Multicenter, Randomized Controlled Trial
252. Efficacy and safety of baricitinib in moderate-to-severe atopic dermatitis: Results from a randomized, double-blinded, placebo-controlled phase 3 clinical trial (BREEZE-AD5)
253. A multi-center, randomized controlled trial by the Integrative Management in Japan for Epidemic Disease (IMJEDI study-RCT) on the use of Kampo medicine, kakkonto with shosaikotokakikyosekko, in mild-to-moderate COVID-19 patients for symptomatic relief and prevention of severe stage: A structured summary of a study protocol for a randomized controlled trial
254. Efficacy of electro-acupuncture and manual acupuncture versus sham acupuncture for knee osteoarthritis
255. SOMA-trial: Surgery or medication for women with an endometrioma? Study protocol for a randomised controlled trial and cohort study
256. Patient-controlled subcutaneous analgesia using sufentanil or morphine in home care treatment in patients with stage III-IV cancer: A multi-center randomized controlled clinical trial
257. Extracorporeal Shockwave Therapy for Chronic Knee Pain: A Multicenter, Randomized Controlled Trial
258. Relapse after conservative surgery combined with triptorelin acetate versus conservative surgery only in women with focal adenomyosis: Study protocol for a multicenter, prospective, randomized controlled trial
259. Rationale and design of the MODIFY study: A phase 3 multicenter, double-blind, randomized, placebo-controlled, parallel-group study to determine the efficacy and safety of lucerastat oral monotherapy in adult subjects with Fabry disease
260. The BUSCOPAN study: a randomized-controlled non-inferiority trial of a continuous butylscopolamine infusion versus placebo in patients with a renal colic not responding to oral non-steroidal anti-inflammatory drugs
261. Efficacious and well-tolerated treatment of chronic hand eczema and related itch with topical delgocitinib
262. Cannabidiol in acute low back pain—a protocol and rationale of a clinical effectiveness trial
263. Cannabinoids and an anti-inflammatory diet for the treatment of neuropathic pain after spinal cord injury (The CATNP Study): study protocol for a randomized controlled trial
264. Secukinumab treatment leads to normalization of quality of life and disease symptoms in psoriasis patients with or without prior systemic psoriasis therapy: the PROSE study results
265. P18.03 Randomized Trial With BIALOE to Prevent Esophagitis in Lung Cancer Patients Treated With Concurrent Radical Chemoradiotherapy
266. Efficacy and safety of <sup>188</sup>Re-HEDP in lung cancer patients with bone metastases: a randomized, multicenter, multiple-dose phase IIa study
267. Dupilumab provides favourable long-term safety and efficacy in children aged  $\geq 6$  to  $< 12$  years with uncontrolled severe atopic dermatitis: results from an open-label phase IIa study and subsequent phase III open-label extension study
268. Two prophylactic pain management regimens for medical abortion  $\leq 63$  days' gestation with mifepristone and misoprostol: A multicenter, randomized, placebo-controlled trial
269. Once-daily upadacitinib versus placebo in adolescents and adults with moderate-to-severe atopic dermatitis (Measure Up 1 and Measure Up 2): results from two replicate double-blind, randomised controlled

- phase 3 trials
270. Safety and efficacy of upadacitinib monotherapy in adolescents and adults with moderate-to-severe atopic dermatitis: Results from two pivotal, phase III, randomized, double-blinded, monotherapy, placebo-controlled studies (Measure Up 1 and Measure Up 2)
  271. Intravenous patient-controlled analgesia hydromorphone combined with pregabalin for the treatment of postherpetic Neuralgia: A multicenter, randomized controlled study
  272. Ambulatory continuous peripheral nerve blocks to treat postamputation phantom limb pain: a multicenter, randomized, quadruple-masked, placebo-controlled clinical trial
  273. Percutaneous Peripheral Nerve Stimulation (Neuromodulation) for Postoperative Pain: A Randomized, Sham-controlled Pilot Study
  274. A multicenter, randomized, double-blind, placebo-controlled trial of nalbuphine ER tablets for uremic pruritus
  275. Study protocol for a randomised, placebo-controlled, single-blind phase II study of the efficacy of morphine for dyspnoea in patients with interstitial lung disease (JORTC-PAL 15)
  276. Multimodal physical therapy versus topical lidocaine for provoked vestibulodynia: a multicenter, randomized trial
  277. Safety and efficacy of prednisone versus placebo in short-term prevention of episodic cluster headache: a multicentre, double-blind, randomised controlled trial
  278. Safety and efficacy of upadacitinib in combination with topical corticosteroids in adolescents and adults with moderate-to-severe atopic dermatitis: Results from the pivotal phase III, randomized, double-blind, placebo-controlled AD Up study
  279. Efficacy and safety of EMA401 in peripheral neuropathic pain: results of two randomised, double-blind, phase 2 studies in patients with postherpetic neuralgia and painful diabetic neuropathy
  280. Long-term Efficacy of Baricitinib in Adults with Moderate to Severe Atopic Dermatitis Who Were Treatment Responders or Partial Responders: An Extension Study of 2 Randomized Clinical Trials
  281. Calcipotriene and betamethasone dipropionate cream combines high efficacy, favorable safety, and treatment preference in a single product for topical treatment of psoriasis
  282. STeroids Against Radiculopathy (STAR) trial: a statistical analysis plan
  283. Long-term effect of multimodal occupational therapy and surgery on pain and hand function in patients with carpometacarpal osteoarthritis
  284. Influence of Baseline Kinesiophobia Levels on Treatment Outcome in People With Chronic Spinal Pain
  285. Efficacy and safety of oral nalbuphine extended release in prurigo nodularis: Results of a Phase II randomized controlled trial with an open-label extension phase
  286. Effectiveness of interactive augmented reality-based telerehabilitation in patients with adhesive capsulitis: protocol for a multi-center randomized controlled trial
  287. Efficacy and safety of intravesical instillation of KRP-116D (50% dimethyl sulfoxide solution) for interstitial cystitis/bladder pain syndrome in Japanese patients: A multicenter, randomized, double-blind, placebo-controlled, clinical study
  288. Efficacy and safety of Shi-style cervical manipulation therapy for treating acute and subacute neck pain: study protocol for a randomized controlled trial