Study Title: Necessity of fusion following decompression surgery in patients with single-level lumbar stenosis

A randomized controlled clinical trial to compare the long-term clinical outcomes of two surgery methods (decompression versus decompression and fusion) in patients with single-level lumbar stenosis.

Trial Number:	1-22/11.01.22
Trial registration number:	NCT05273879
Date and Version No:	Version 2 08.09.22

Chief Investigator: Professor Andrey Grin

Study participants:

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2) Pirogov National Medical and Surgical Center, Moscow, Russia;

3) Federal State Budgetary Institution "Federal Center for Brain and Neurotechnologies" FMBA, Moscow, Russia;

4) Moscow Scientific and Practical Center for Medical Rehabilitation, Restorative and Sports Medicine, Moscow, Russia.

Contents

1 ABBREVIATIONS

ASA - American Society of Anesthesiologists

CONSORT - Consolidated Standards of Reporting Trials

CPGQ - chronic pain grade questionnaire

CPCI - Chronic Pain Coping Inventory

CT - computed tomography

EQ-5D-5L - EuroQol five-dimensional five-level descriptive system questionnaire

Mo - month

MRI - magnetic resonance imaging

ODI – Oswestry Disability Index

PCS - Pain Catastrophizing Scale

p/o – postoperatively

SF-36 - Short Form-36 questionnaire

SPIRIT - Standard Protocol Items: Recommendations for Interventional Trials

VAS – Visual Analogue Scale

2 BACKGROUND AND RATIONALE

2.1 Background

Degenerative lumbar disease is one of the most common chronic diseases worldwide. The general incidence of lumbar stenosis accompanied by a significant deterioration in the quality of life reaches 5% among patients aged < 50 years and approximately 10–15% among elderly patients (50–70 years old). Moreover, lumbar stenosis appears to be one of the most common causes of decompression and fusion interventions in the lumbar spine in 50+ years old patients [1]. Applicable surgery includes the removal of bone and ligamentous structures compressing the cauda equina roots inside the spinal canal. The necessity for significant facet joint resection results in instability of the corresponding spinal segment and/or kyphotic deformation, leading to an obligatory subsequent interbody fusion.

One of the most controversial and unresolved problems of current degenerative spine management is the necessity of spinal segment fusion in patients with grade C and D lumbar stenosis according to the Schizas classification [2] without any radiological signs of instability. A meta-analysis published in 2020 reported a highly controversial comparison between decompression and decompression supplemented by fusion techniques [3]. The authors did not find any clinically significant differences between the two surgical methods. Based on multiple retrospective studies, these conclusions were highly restricted by the significant heterogeneity of the study groups. Severely ill patients, patients with severe comorbidities, and/or patients with risk factors for pseudarthrosis typically undergo less invasive methods of surgery, avoiding fusion techniques.

A network meta-analysis [4] compared the results of 20 prospective randomised trials using various methods of degenerative

spine treatment solutions. Among these, only one [5] fully focused on this problem. This study was initiated 15 years ago and had several limitations, including a high level of group heterogeneity (for example, in lumbar stenosis severity) and a wide range of surgical techniques. Moreover, the authors did not address the impact of postoperative rehabilitation treatment on long-term clinical outcomes. In addition, the authors did not consider sagittal imbalance of the spine, which could have a significant impact on treatment outcomes.

2.2 Rationale

We aim to compare the long-term clinical outcomes of two surgery methods (decompression versus decompression and fusion) in patients with single-level lumbar stenosis.

3 ENDPOINTS

3.1 Primary endpoint

The primary endpoint includes the dynamics of ODI parameters at the end of the 24-month follow-up compared to the baseline level [8]. This patient-reported measurement precisely estimates the impairment of a participant's quality of life resulting from low back pain, and clearly reflects the clinical outcome of the treatment. Parameter assessment is to be considered at all stages of the study beginning from baseline examination, followed by a follow-up examination 2 years postoperatively. The questionnaire consists of 10 sections, comprising six statements per section. Each answer is assessed using six grades (ranging from 0 to 5) with a maximum score of 50 points per participant. Subsequently, the total score is converted into a percentage ratio (from 0 to 100%). If any of the sections are not applicable or have been withdrawn for ethical reasons, the total score is calculated within nine sections and is divided by 45.

3.2 Secondary endpoints

The SF-36 v.1 scale (standard form) provides a comprehensive evaluation of the quality of life both pre- and postoperatively [9]. The SF-36 questionnaire consists of 36 questions grouped into eight sections assessing physical functioning, role functioning, bodily pain, general health condition, vitality, social functioning, emotional state, and mental health. The maximum score of each section is limited to 100 points. These eight scales will be aggregated into two summary measures: physical and mental health summary scores.

Another scale assessing participants' quality of life is the EQ-5D-5L [10]. This questionnaire is widely used in multiple prospective European studies focusing on lumbar stenosis treatment. Currently, we believe this scale is applicable for comparing our results with literature data. The EQ-5D-5L questionnaire consists of five sections

(mobility, self-care, usual activities, pain, and anxiety) comprising five levels per section, supplemented with the EQ-VAS visual analogue scale. The obtained results can be easily converted into a single numerical value (index) adjusted for the patient's region of residence. Currently, there are no approved values for calculating this index in the Russian Federation [11]. Therefore, at baseline, a simple comparison of the specific numerical values for each parameter will be applied. If feasible, we will calculate this index at the end of the study.

The Won-Korff Chronic Pain Syndrome Assessment Scale (chronic pain grade questionnaire, CPGQ) [12] is focused on the assessment of pain severity and its impact on participants' quality of life. Grade 0 corresponds to the absence of pain, while grade IV corresponds to a severe decrease in the quality of life due to severe pain.

The Pain Catastrophizing Scale (PCS) [13] was created to estimate the psychological aspects of pain perception, attenuating the exaggerated negative perception of painful stimuli. The questionnaire contains 13 questions assessed in points (ranging from 0 points (no symptoms) to 4 points (negative perception is experienced constantly).

The Chronic Pain Coping Inventory (CPCI) [14] includes 64 questions, allowing one of eight alternative scales to differentiate between participants' preferred strategies for managing chronic pain.

Preoperatively, the physical status of all included participants will be assessed using the American Society of Anesthesiologists (ASA) scale. This classification identifies five classes of physical status depending on the presence of concomitant diseases (ranging from Class I (healthy patient) to Class V (dying).

In addition, the total cost of surgery and hospital stay will be calculated based on the cost of surgical intervention and inpatient

treatment and the indirect cost of patients' occupational disability. Two years postoperatively, the cost of subsequent treatment in the rehabilitation centre, additional treatment of possible postoperative complications, and/or treatment of other manifestations of degenerative spine disease are to be considered.

All participants who have undergone spine instrumentation will be examined for intervertebral fusion parameters using the criteria of Tan et al. [15]; grade 1 corresponds to complete bone union, whereas grade 4 corresponds to pseudarthrosis. Moreover, the time of fusion development will be estimated.

Finally, sagittal balance parameters will be analysed in all patients, including pelvic tilt, pelvic deviation from the vertical, S1 vertebral tilt, and vertical axis displacement.

4 KEY STUDY GROUP

This study will run using a combination of research staff and clinical staff of both hospitals.

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5 TRIAL DESIGN AND REGISTRATION

This study is an open-label, non-inferior, multicentre, randomised controlled trial. All enrolled subjects will be divided into two concurrent groups based on the surgical technique applied (decompression or decompression with fusion).

The current protocol was developed using the SPIRIT checklist template (Standard Protocol Items: Recommendations for Interventional Trials) [6].

This clinical study was registered in the http://www.clinicaltrials.gov database (Identifier NCT05273879). The results will be published according to CONSORT standards (Consolidated Standards of Reporting Trials) [7].

6 PATIENTS AND PROCEDURES

6.1 Study setting

This study involves five surgeons from three independent centres performing surgery on patients with degenerative spines. These included Sklifosovsky Research Institute for Emergency Medicine and Federal Center for Brain and Neurotechnologies as major centres, and Pirogov's National Medical and Surgical Center as a Level 3 trauma centre. All participating spine surgeons are highly experienced (more than 12 years) in surgery for degenerative spine diseases and perform at least 180 operations annually. Both surgical techniques (decompression and decompression with fusion) have been used in all three clinical centres for more than 10 years. Fusion is routinely used in cases of instability that are confirmed radiologically or intraoperatively. The decompression technique was selected based on the surgeon's personal opinion. However, all surgeons are highly experienced in both types of surgery.

In all cases, rehabilitation treatment is to be carried out by Branch No. 3 of the Moscow Scientific and Practical Center for Medical Rehabilitation, Restorative and Sports Medicine. Three experienced rehabilitation specialists will participate in the study. To avoid postoperative treatment heterogeneity, they will use a unified protocol for the postoperative treatment of all patients in the study.

6.2 Patient Selection

Primary patient selection will be performed before admission. The study will include participants aged 45–75 years with symptomatic single-level stenosis at the levels –L2-L3, L3-L4, L4-L5, or L5-S1 vertebrae. The inclusion and exclusion criteria are presented in Table 1. Patients who meet the inclusion criteria but refuse to participate in the study will be marked with an appropriate explanation.

All patients will be informed about the upcoming study. Written and oral informed consent is required prior to the randomisation procedure. A flow chart of the trial is provided in Fig. 1.

Table 1

Inclusion and exclusion criteria

Inclusion Criteria:
- age ranging from 45 to 75 years
- C or D grade lumbar stenosis at the level of L2-L3, L3-L4, L4-L5, or L5-S1 vertebrae (classification by Shizas et al.) according to MRI evaluation
- a clinical manifestation of lumbar stenosis (neurogenic claudication syndrome and/or radiculopathy)
- insufficient conservative therapy within 3 months prior to surgery
- informed consent was obtained from all included subjects
Exclusion Criteria:
- spondylolisthesis exceeding 3 mm
- spinal instability according to functional radiography
- sagittal imbalance (type 4 according to C. Barrey)
- bone density of the vertebrae at the surgery level below 100 HU
- clinically significant multi-level spinal stenosis (two or more segments)
- previously performed surgeries at the lumbar level
- severe sacroiliac or lumbar facet joint pain
- risk of anaesthesia exceeding four or five grades according to ASA
- inability to participate in control examinations within 2 years, postoperatively
- participation in other clinical trials related to surgical or conservative treatment of spine diseases

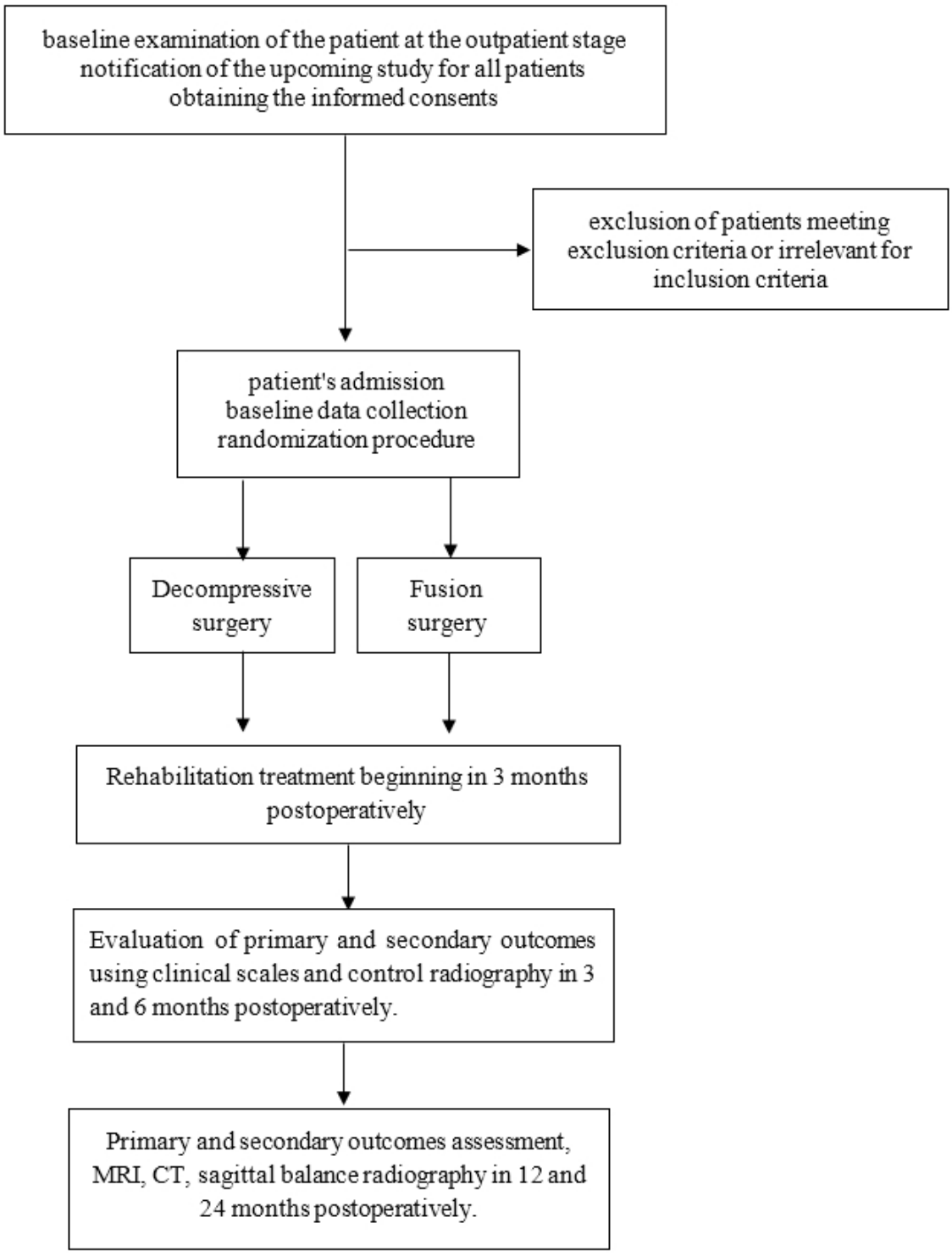

Fig. 1 Patient flow chart

6.3 Interventions

All surgical procedures are to be performed under general endotracheal anaesthesia.

In the decompression group, laminotomy of the corresponding adjacent vertebrae, partial flavectomy and medial facetectomy are planned to be performed unilaterally. Depending on the surgeon's personal preferences, the following two options are available: 1) equivalent decompression procedure contralaterally and 2) crossover contralateral decompression. Irrespective of the selected option, the spinous process, the interspinous and supraspinous ligaments, part of the facet joints, and the corresponding part of the vertebral arch must be preserved intact in all participants.

In the fusion group, the surgical course will consist of two stages: (a) decompression performed using one of the above-mentioned methods followed by (b) transforaminal interbody fusion using cage (TLIF) and fixation using pedicle screws.

6.4 Randomization procedure

All participants who meet the inclusion criteria and provide informed consent will be randomly divided into two equal groups (1: 1) according to the applied surgical technique. For the block randomisation procedure, stratification based on the severity of lumbar stenosis (Schizas C and D) will be performed. Randomisation will be provided one day preoperatively by an independent remote study team member excluded from any other study roles. Randomisation parameters will be documented in the participants' records.

6.5 Blinding

This is planned to be an open-label study. All enrolled participants will be informed of the selected type of surgery. Importantly, in each case, both the patient and the surgeon will have no impact on the selection of the surgical technique. Follow-up outcome evaluations (Table 2) will be performed by clinicians not involved in the patient's treatment.

7 DATA COLLECTION

The study coordinators in all involved clinical centres are responsible for data collection and administration at baseline and during follow-up. All examinations (questionnaires, scales, radiography, and CT) will be performed during personal follow-up visits at the original centre of surgery performance. All the obtained data will be stored in the data centre of the Sklifosovsky Research Institute for Emergency Medicine. These data will be unavailable to all parties until the final analysis. The timetable for data collection is presented in Table 2.

Table 2

Timetable for data collection

	Preoperatively	Inpatient stay	3 mo p/o	6 mo p/o	12 mo p/o	24 mo p/o
Demographics, lifestyle, clinical data	+					
Informed consent	+					
Clinical measures						
ODI	+		+	+	+	+
SF-36	+		+	+	+	+
EQ-5D-5L	+		+	+	+	+
ASA	+					
Psychological measures						
CPGQ	+		+	+	+	+
PCS	+		+	+	+	+
CPCI	+		+	+	+	+
Radiography of the lumbar spine		+	+	+		
Radiograph sagittal balance assessment	+				+	+
CT	+				+	+
MRI	+				+	+
Randomization		+				
Admittance and surgery data		+				
Cost of surgical treatment and hospital stay		+				
Cost of rehabilitation treatment			+			
Cost of treatment in other clinical facilities			+	+	+	+
Complications, repeated surgeries		+	+	+	+	+
Follow-up visits and other healthcare facilities			+	+	+	+

8 STATISTICS

8.1 Sample size calculation

Following a non-inferiority study design, we calculated the sample size based on the primary outcome. According to the most recent randomised trial [5], the standard deviation for the ODI in the fusion group is 20 points. With a non-inferiority margin of $\delta = 12$, two-sided α-level of 0.05, power of 80%, and 1:1 allocation ratio, the required sample size is 70 patients. Considering the potential of 20% of patients missing the obligatory follow-up procedures, we plan to include at least 86 patients (43 patients per group).

8.2 Statistical analysis

The results will be analysed using the intention-to-treat principle. Statistical significance will be defined as $p < 0.05$ based on a two-sided test. No adjustments for multiple tests are planned. The normality of variables will be evaluated using the Shapiro-Wilk statistic. Student's t-test (for normally distributed data) and Pearson's Chi-square test (for categorical data) will be used to reveal differences in symptom rates among the groups. Multiple linear regression will be used to measure point estimates and confidence intervals for group differences in the ODI and clinical scale scores from baseline to the 2-year follow-up.

The non-parametric Mann-Whitney U test will be used to reveal differences in continuous variables between groups both pre- and postoperatively. Continuous data within the groups will be compared using the Wilcoxon test. Categorical parameters among the groups will be compared using Fisher's exact two-tailed test.

Complication incidence during the 2-year follow-up will be compared between groups using Kaplan–Meier survival curves and the log-rank test. The significance of the risk factors (predictors) for all

registered complications will be evaluated using univariate and multivariate logistic regression models.

For missing outcome data, multiple imputations will be used.

9 INTERIM ANALYSIS AND TERMINATION RULES

Interim analysis of the obtained follow-up data will be available by 12 months postoperatively for at least 20 patients in each cohort. The criteria for study termination include the following: 1) the number of repeated surgeries in any group exceeds 50%, 2) any group demonstrates a higher frequency of negative neurological postoperative outcomes and/or significant decline of ODI level compared to baseline by at least 10 points, and 3) the number of postoperative complications exceeding 50% in any group.

An interim analysis will be performed by a side investigator not involved in patient treatment. All investigators involved in the statistical analysis will have no access to any neurological examination protocols, ODI data, and repeated surgery rate statistics in all analysed groups at all stages of the study.

10 ETHICS AND DISSEMINATION

The current study will be conducted in accordance with the Helsinki Declaration of the World Medical Association. The provided protocol was approved by the local ethical committees of the Sklifosovsky Research Institute for Emergency Medicine (№1-22/ 11.01.22), Pirogov's National Medical Surgical Center (№2/16.02.2022,) and Federal Center for Brain and Neurotechnologies (№01 / 04-03-22).

All the study data will be stored in the Sklifosovsky Research Institute for Emergency Medicine database. The preliminary and final results of the study will be provided in peer-reviewed neurosurgical and spinal journals and presented at international conferences.

11 FUNDING

Provided study will be funded from the local budgets of all participating hospitals. Article processing charges are supported by Moscow Center for Innovative Technologies in Healthcare (Moscow, Russia).

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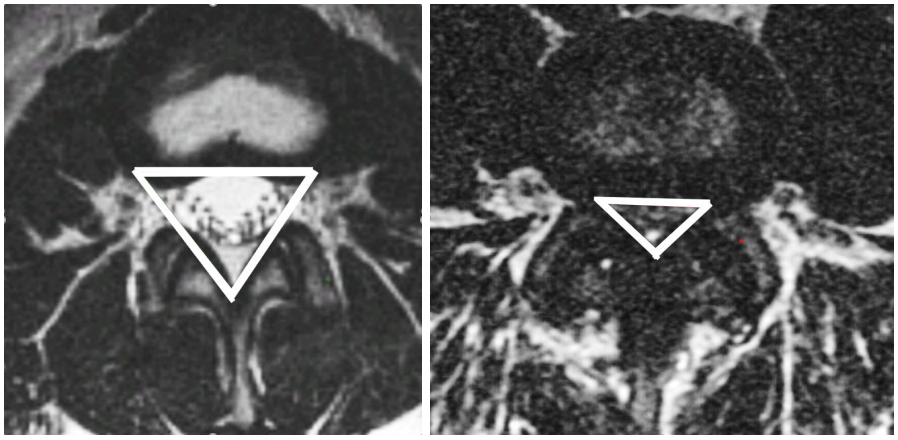
SUPPLEMENT 1. INFORMATION FOR PATIENTS AND CONSENT FORM

PART 1. RELATING INFORMATION

INTRODUCTION

Dear patient! We appreciate your interest in the provided study. Earlier, you were diagnosed with degenerative spine disease and degenerative stenosis of the spinal canal, requiring surgical treatment. In this introduction of the Relating information section, we'd like to inform you about key aspects of this disease and potential treatment alternatives.

Degenerative spine disease is the one of the most widely diagnosed chronic diseases. General occurrence of lumbar stenosis resulting in life quality worsening in the Russian Federation reaches 5% among under 50 years old and exceed 10-15% among patients of 50 to 70 years old. In the most cases, it is acquired and results from the continuous degenerative spine transformation (arthrosis, intervertebral joints enlargement, ligament thickening and formation of bone outgrowths – "osteophytes" – on the vertebral back wall). Besides the key supporting function, spine is the "container" for the spinal cord and spinal roots providing signal transmission between the brain and internal organs. Spine degenerative transformation followed by spine structures enlargement and spinal canal narrowing, resulting in compression of spinal cord and/or spinal roots (Fig. 1).



a b

Fig. 1 A typical example of the spinal canal stenosis on the MRI images. Spinal canal is outlined by triangles: a – normal spinal canal; b – spinal canal is narrowed by the stenosis.

Clinical symptoms of the spinal stenosis result from both direct compression of spinal roots located in the spinal canal and compression of the adjacent blood vessels. Blood flow reduction in the root bundle eventually result in irreversible disorder of motor

function, reaching severe disability of the patient in some cases. Major clinical symptoms include:

1. Low back pain;
2. Intermittent neurogenic lameness (claudication) getting worse after walking and getting better while sitting or bending forward;
3. The leg pain along the compressed nerve root;
4. Weakness and atrophy of the corresponding leg muscles.

Degenerative lumbar stenosis is diagnosed using combination of clinical data and results of the magnetic resonance imaging (MRI). Other examinations (computed tomography, X-ray, electroneuromyography) are auxiliary and are used for the final clarification of spine disorders and preoperative planning.

Currently, lumbar stenosis is classified into 4 grades (A, B, C, and D) based on the MRI data. Grade A is the mildest, while grade D is the most severe and reflects almost complete block of the spinal canal and severe compression of the residing structures.

In all cases of the symptomatic lumbar stenosis, the first line of treatment is conservative and comprises anti-inflammatory, decongestant and vascular therapy, physiotherapy and therapeutic exercise. Treatment course duration should not be less than 3 months. If no improvement if achieved, decompensation might be diagnosed dictating the feasibility of neurosurgical treatment. It should be noted that *ANY* grade of the lumbar stenosis can be completely asymptomatic and not demanding any surgery!

The main surgery goal is the widening of the transformed spinal canal and removal of outgrowing bone and ligamentous structures compressing blood vessels. Some surgical methods involve wide decompression resulting in elimination of important supporting structures. This might cause the vertebral dislocation and exacerbation of clinical symptoms (spine instability). It should be noted that modern decompression techniques performed using microscope and microsurgical instruments significantly decrease the volume of removed spine structures and the risk of instability development.

To prevent instability development, surgeon might use the spinal fixation resulting in intervertebral fusion formation. In such cases, intervertebral disk is removed following by insertion of special implant (cage) between two vertebral bodies. Then adjacent vertebrae are fixed using special screw and rod system.

One of the most important queries of the modern spine surgery is the necessity of vertebral screw fixation after the spinal canal decompression assuming that key supporting structures are preserved. To date, only one clinical study demonstrating high-level reliability and focused on this problem has been performed (Försth P. et al. A Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis. N Engl J Med. 2016 Apr 14;374(15):1413-23). Unfortunately, it faces serious criticism among spine surgeons due to multiple disadvantages of groups recruiting and selection of surgical techniques. For this reason, results of this study may not be considered as golden standard for modern spine surgery.

Other available studies demonstrate low-level reliability and mostly provide the experience of a single clinical center performing various surgeries in patients with lumbar stenosis. Moreover, many of them report inconsistent and contradicting results. Summarizing the reported data, we can identify several conclusions of implant application in spine surgery:

1. Spine fixation allows to perform wider bone resection resulting in clinical improvement;
2. Spine fixation during stenosis grade C and D surgery decreases the rate of reoperations of the exact spine segment within 10 postoperative years;
3. Spine fixation during stenosis grade C and D surgery decreases the risk of postoperative spine deformity.

On the other hand, negative aspects of the spine fixation are also mentioned:

1. Spine fixation during stenosis grade C and D surgery increases intraoperative blood loss, the risk of early postoperative complications, and the duration of in-hospital treatment;
2. Spine fixation significantly increases surgery duration;
3. Implant insertion increases the risk of adjacent level syndrome development resulting in formation of the upper and lower levels stenosis;
4. The fact of constant presence of titanium implants in the spine.

Meanwhile, modern minimally invasive surgical techniques in patients having grade C or D stenosis provide sufficient root decompression without wide removal of bone structures (laminectomy).

STUDY DESCRIPTION

Why should you read this section?

You were invited to participate in the study due to diagnosed degenerative lumbar stenosis graded C or D level. Before you are included, you must read this section including information about purposes, procedures, potential risk and/or adverse factors of the study. If you have any questions reading this section, the inspecting physician, corresponding investigators, or the Head of the Study. Contact details of all participating parties are provided on a separate page. In this way, you can provide the completely informed consent if you decide to be included into the study.

Purpose of the Study

The key purpose of the Study is to compare the efficiency of two surgical techniques in patients having single-level degenerative lumbar stenosis. No novel and/or experimental methods are to be applied in the study. Both surgical techniques are routine and experienced methods approved for the application in the Russian Federation by the corresponding approving legal institutes. In the first group only spinal canal decompression will be performed, while in the second group the same

decompression will be followed by instrumented spinal fusion. Advantages and disadvantages of both techniques are provided in the Introduction section. The main outcome of the Study is the identification of the most effective technique for degenerative lumbar stenosis.

Study duration

Study follow-up is 2 years. The total number of 86 patients will be included, living in the Russian Federation and ready to attend the control visits. All diagnostic and treatment procedures will be paid using CMI (compulsatory medical insurance), HMC (high-tech medical care) or Institution funds.

Responsibilities of the Patient in the Study

There are several important demands for the participants supporting their complete health monitoring, including:

- Providing of complete anamnestic information about the main and concomitant diseases and full history of drug treatment (both past and ongoing);
- Attend all planned control visits;
- Immediately inform investigators about any health changes, new complaints or symptoms, additional visit to any medical centers for medical assistance;
- Decline the study inclusion if control visits can be missed or if you participate in any other clinical studies.

The order of the Study interventions and procedures

Primary examination

During pre-hospital primary examination you will be examined by a competent specialist evaluating the potential possibility of your inclusion in the Study according to the list of inclusion and exclusion criteria. Investigator will clarify all aspects of the Study, request the signed Informed Consent, and collect the required data to arrange the admission.

Admission and treatment method selection

During the Day 1 after admission your physician will collect the required data including demographics, concomitant diseases and the present disease history. You will be asked to complete several questionnaires: Oswestry Disability Index (ODI) scale, Life quality evaluation scale SF-36, EuroQol Five-Dimensional (EQ-5D) questionnaire, Van Korf chronic pain grade questionnaire (CPGQ), The Pain Catastrophizing scale (PCS), and Chronic Pain Coping Inventor scale. Also, you will be examined by the neurologist, clinical psychologist and anesthesiologist. The final selection of surgical technique will be determined one day prior to surgery during council of the operating neurosurgeon and study group. Investigators consider the medical history and clinical data, general health status, and MRI, CT and X-ray data. All patients meeting inclusion

criteria and not having contraindications for surgery will be exposed to block randomization of surgical technique selection. Council results will be indicated in the medical record.

Surgery

All surgical interventions will be performed by the experienced spinal surgeons (at least 10 years of spinal surgery experience and 100 or more spine interventions yearly). Depending on the council opinion and results of randomization, one of two surgical techniques will be applied:

1. Microsurgical decompression of spinal canal, vertebral rare supporting structure preserved;
2. Microsurgical decompression of spinal canal followed by combined interbody fusion using interbody cage and transpedicular screws (TLIF, transforaminal lumbar interbody fusion).

Complication risks

During in-hospital treatment, a standard informed consent for the surgical intervention is required to be signed. Both surgical and conservative treatment can have potential risk of complications. Prior to any procedures, you will be informed about all potential complications. Present study does not apply any novel, experimental or poorly studied technologies. All applied surgical techniques are well practiced and highly developed, and are being applied in the Russian Federation for more than 15 years.

Hospital check-out

Prior to check-out, a control lumbar CT imaging will be performed assessing the position of inserted implants and structure of decompression. Also, neurologist will evaluate the dynamics of radicular syndrome. A timetable for control visits in 3, 6, 12 and 24 months post-surgery will be configured.

Subsequent rehabilitation

All included patients obey to participate in rehabilitation course in Moscow Research and Practical Center for Medical Rehabilitation, restorative, and sports medicine of the Moscow Healthcare Department. After the check-out from the rehabilitation center, you will be provided with key recommendations for the subsequent lifestyle. All participants obey to follow these recommendations to prevent progression of degenerative spine disease.

Control visits in 3 and 6 months

During these visits you will be examined by the neurosurgeon collecting following data: complaints, general health status, medication specter, admission to other clinical centers or any other medical assistance. You will be asked to fill several questionnaires evaluating current quality of life and its dynamics comparing to the last control visit. Also, implant position and potential lspine deformity angles will be assessed using X-ray.

Control visits in 12 and 24 months

Besides the above-mentioned data (examination and questionnaires) you will be exposed to an extensive examination including:

- Control lumbar CT assessing bone fusion and/or implant-associated complications (for the fusion group) or intervertebral disk and facet joints structure on the operated level (for the decompression group);
- Lumbar MRI assessing spine structure at the operated level and adjacent segments;
- Full-spine X-ray assessing global sagittal balance.

Final study completion

During the last control visit in 24 months you will receive the final recommendations for the subsequent life style and restorative treatment. If any complications or persistent pain syndrome are observed, you will be provided with palliative treatment alternatives in the corresponding clinical center or other specialized clinics.

Participation in the Study is voluntary. You may cease participating in the Study at any time and without any explanations. If you decide to exit the Study, we ask you to notify your physician, corresponding investigator or operated neurosurgeon. Please, pay attention that you are not allowed to participate in any other alternative clinical studies of degenerative spine disease until your participation termination is confirmed.

Financial compensation for participation

No financial and/or monetary compensation for participation in the Study is assumed. No sponsorship or special funding is applied. All costs including examinations and treatment are paid using CMI (compulsatory medical insurance), HMC (high-tech medical care) or Institution funds. If any surgery complications are observed, additional treatment will be performed with no costs.

Exclusion from the Study

Your participation in the Study can be terminated at any time for the following reasons:

1. Additional treatment is needed inconsistent with the study protocol.
2. You do not follow instructions of your physician.
3. Suring the study, a condition was registered meeting exclusion criteria.
4. An expected number of patients are already recruited.
5. The Study was terminated by one of the participating Clinical Centers or authorized governmental institutions.

Use of personal data

During the Study, collection of personal data is performed. Participant's privacy and personal data safety is the priority objective of the Study. Identifying personal information is available only to the principal investigator and corresponding performers. In all other databases, a unique number will be assigned to your file. In all medical reports and publications your personality will not be identified.

If you sign the Informed Consent, you accept the conditions of personal data collection and use, including name, surname and father's name, sex, age, phone number, lifestyle aspects, medical history, weight, and height. We are not allowed to use your personal data without your signed Informed Consent' in this case your participating is impossible.

At any time of the Study, you are allowed to correct or delete your personal data. Also, you may exit the Study at any time, including the stage of personal data collection.

Study results

Study results will be provided on the portal of ClinicalTrials.gov (http://www.clinicaltrials.gov). No personal information is published on this source.

Contact information

If you have any questions about the Study. You can contact the principal investigator or corresponding performers, or the Ethical Committee of any participating Clinical Center.

Principal investigator: Andrew A. Grin', M.D., Ph.D., Prof., Head of the Department of Neurosurgery of N.V. Sklifosovsky Research Institute of Emergency Medicine, Professor of the Faculty of Neurosurgery and Neurological Intensive Care of A.I. Evdokimov Moscow State Medical and Stomatological University, Head Neurosurgeon of the Moscow Healthcare Department; E-mail: GrinAA@sklif.mos.ru.

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This consent was reviewed and approved by Ethical Committees of all participating Clinical Centers. If you have any questions concerning ethical aspects of the Study, you can contact the corresponding committee.

Clinical Center:	Ethical Committee contacts:	Approval number:
Sklifosovsky Institute for Emergency Medicine	B. Suharevskaya Pl., 3, b.5, Moscow, Russian Federation +7 (495) 628-35-02	1-22/11.01.22
N.I. Pirogov National Medical and Surgical Center	Nijnyaya Pervomayskaya str., 65, room 634 +7 (499) 464-03-03, ext. 1232	2/16.02.2022
Federal Center of Brain and Neurotechnologies	Ostrovityanova str., 1, b.10 +7 (495) 280-35-50	01/04-03-22

PART 2. INFORMED CONSENT

I, (Name and Surname)_____

provide my voluntary consent to participate in the Study "Open multicenter randomized clinical trial evaluating the need for spinal stabilizing following decompression in patients having single-level degenerative lumbar stenosis".

I received the comprehensive and detailed explanation from my physician concerning my participation in the Study, its structure, purpose and duration.

I confirm that I read carefully the provided information and understood it. I was provided with clear and detailed information. I was able to ask any emerging questions.

I understand that participation in the Study is voluntary. I am allowed to cancel my consent at any time and without explanation, and it will have no impact on my subsequent treatment.

I realize that authorized staff of the controlling institutes and Ethical Committees can use my personal information and medical documentation. Signing this consent, I provide the access rights to them.

I realize that the Study implies the collection of confidential data. My name will never be provided to any third party.

I guarantee that I will never try to limit the distribution of the Study results.

I agree to participate in the Study and cooperate with the principal investigator and corresponding performers. I obey to inform them in any case of abnormal conditions.

I agree to inform my physician or other doctors about my participation in the Study.

I confirm that investigators are allowed to contact my relatives or friends, attending physician or other doctors participating in my treatment to obtain any information about my health status, if it is required for the Study.

I received copies of the signed Informed Consent and Information for the Patient.

Patient:

_____

Name, Surname, Father's Name Sign Date

Physician:

_____

Name, Surname, Father's Name Sign Date

SUPPLEMENT 2. SCALES DESCRIPTION

SF-36 scale

INSTRUCTIONS: This questionnaire contains questions about your views on your health. The information provided will help you keep track of how you feel and how well you are coping with your normal activities. Answer each question by marking your answer as indicated. If you are not sure how to answer a question, please choose the answer that best reflects your opinion.

1. In general, would you say your health is (circle one number):

Excellent 1
Very Good 2
Good 3
Fair 4
Poor 5

2. Compared to one year ago, how would you rate your health in general now? (circle one number)

Much better now than one year ago.....1
Somewhat better now than one year ago 2
About the same 3
Somewhat worse now than one year ago 4
Much worse than one year ago 5

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	LIMITATIONS OF ACTIVITIES:	**Yes, Limited a Lot**	**Yes, Limited a Little**	**No, Not Limited at all**
a	Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
b	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c	Lifting or carrying groceries	1	2	3
d	Climbing several flights of stairs	1	2	3
e	Climbing one flight of stairs	1	2	3
f	Bending, kneeling, or stooping	1	2	3
g	Walking more than a mile	1	2	3
h	Walking several blocks	1	2	3
i	one block	1	2	3
j	Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (circle one number on each line):

		Yes	No
a	Cut down the amount of time you spent on work or other activities	1	2
b	Accomplished less than you would like	1	2
c	Didn't do work or other activities as carefully as usual	1	2
d	Didn't do work or other activities as carefully as usual	1	2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (circle one number on each line):

		Yes	No
a	Cut down the amount of time you spent on work or other activities	1	2
b	Accomplished less than you would like	1	2
c	Didn't do work or other activities as carefully as usual	1	2

6. Emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (circle one number)

Not at all 1
Slightly 2
Moderately 3
Severe 4
Very Severe 5

7. How much bodily pain have you had during the past 4 weeks? (circle one number)

None 1
Very Mild 2
Mild 3
Moderate 4
Severe 5
Very Severe 6

8. B During the past 4 weeks, how much did pain interfere with your normal work including both work outside the home and housework? (circle one number)

Not at all 1
A little bit 2
Moderately 3
Quite a bit 4
Extremely 5

9. These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling (circle one number on each line):

		All of the time	Most of the time	A good Bit of the Time	Some of the time	A little bit of the time	None of the Time
a	Did you feel full of pep?	1	2	3	4	5	6
b	Have you been a very nervous person?	1	2	3	4	5	6
c	Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d	Have you felt calm and peaceful?	1	2	3	4	5	6
e	Did you have a lot of energy?	1	2	3	4	5	6
f	Have you felt downhearted and blue?	1	2	3	4	5	6
g	Did you feel worn out?	1	2	3	4	5	6
h	Have you been a happy person?	1	2	3	4	5	6
i	Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities like visiting with friends, relatives, etc. (circle one number)

All of the time 1
Most of the time.....2
Some of the time 3
A little bit of the time 4
None of the Time.....5

11. How true or false is each of the following statements for you? (обведите одну цифру в каждой строке)

		Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a	I seem to get sick a little easier than other people	1	2	3	4	5
b	I am as healthy as anybody I know	1	2	3	4	5
c	I expect my health to get worse	1	2	3	4	5
d	My health is excellent	1	2	3	4	5

Oswestry Disability Index

INSTRUCTIONS
Please answer every section and circle in each section only the ONE number that applies to you.

Section 1: Pain Intensity

A. I have no pain at the moment
B. The pain is very mild at the moment
C. The pain is moderate at the moment
D. The pain is fairly severe at the moment
E. The pain is very severe at the moment
F. The pain is the worst imaginable at the moment

Section 2 – Personal care (washing, dressing etc)

A. I can look after myself normally without causing extra pain
B. I can look after myself normally but it causes extra pain
C. It is painful to look after myself and I am slow and careful
D. I need some help but manage most of my personal care
E. I need help every day in most aspects of self-care
F. I do not get dressed, I wash with difficulty and stay in bed

Section 3 – Lifting

A. I can lift heavy weights without extra pain
B. I can lift heavy weights but it gives extra pain
C. Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed eg. on a table
D. Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
E. I can lift very light weights
F. I cannot lift or carry anything at all
G.

Section 4 – Walking

A. Pain does not prevent me walking any distance
B. Pain prevents me from walking more than 2 kilometers
C. Pain prevents me from walking more than 1 kilometer
D. Pain prevents me from walking more than 500 meters
E. I can only walk using a stick or crutches I am in bed most of the time

Section 5 – Sitting

A. I can sit in any chair as long as I like
B. I can only sit in my favorite chair as long as I like
C. Pain prevents me sitting more than one hour
D. Pain prevents me from sitting more than 30 minutes
E. Pain prevents me from sitting more than 10 minutes
F. Pain prevents me from sitting at all

Section 6 – Standing

A. I can stand as long as I want without extra pain
B. I can stand as long as I want but it gives me extra pain
C. Pain prevents me from standing for more than 1 hour
D. Pain prevents me from standing for more than 3 minutes
E. Pain prevents me from standing for more than 10 minutes
F. Pain prevents me from standing at all

Section 7 – Sleeping

A. My sleep is never disturbed by pain
B. My sleep is occasionally disturbed by pain
C. Because of pain I have less than 6 hours sleep
D. Because of pain I have less than 4 hours sleep
E. Because of pain I have less than 2 hours sleep
F. Pain prevents me from sleeping at all

Section 8 – Sex life

A. My sex life is normal and causes no extra pain
B. My sex life is normal but causes some extra pain
C. My sex life is nearly normal but is very painful
D. My sex life is severely restricted by pain
E. My sex life is nearly absent because of pain
F. Pain prevents any sex life at all

Section 9 – Social life

A. My social life is normal and gives me no extra pain
B. My social life is normal but increases the degree of pain
C. Pain has no significant effect on my social life apart from limiting my more energetic interests e.g., sport
D. Pain has restricted my social life and I do not go out as often
E. Pain has restricted my social life to my home
F. I have no social life because of pain

Section 10 – Travelling

A. I can travel anywhere without pain
B. I can travel anywhere but it gives me extra pain
C. Pain is bad but I manage journeys over two hours
D. Pain restricts me to journeys of less than one hour
E. Pain restricts me to short necessary journeys under 30 minutes
F. Pain prevents me from travelling except to receive treatment

Health Questionnaire (EQ-5D-5L)

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- ☐ I have no problems in walking about
- ☐ I have slight problems in walking about
- ☐ I have moderate problems in walking about
- ☐ I have severe problems in walking about
- ☐ I am unable to walk about

SELF-CARE

- ☐ I have no problems washing or dressing myself
- ☐ I have slight problems washing or dressing myself
- ☐ I have moderate problems washing or dressing myself
- ☐ I have severe problems washing or dressing myself
- ☐ I am unable to wash or dress myself

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

- ☐ I have no problems doing my usual activities
- ☐ I have slight problems doing my usual activities
- ☐ I have moderate problems doing my usual activities
- ☐ I have severe problems doing my usual activities
- ☐ I am unable to do my usual activities

PAIN / DISCOMFORT

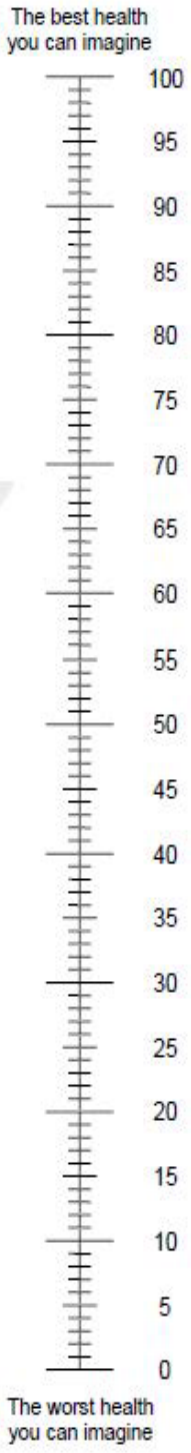
- ☐ I have no pain or discomfort
- ☐ I have slight pain or discomfort
- ☐ I have moderate pain or discomfort
- ☐ I have severe pain or discomfort
- ☐ I have extreme pain or discomfort

ANXIETY / DEPRESSION

- ☐ I am not anxious or depressed
- ☐ I am slightly anxious or depressed
- ☐ I am moderately anxious or depressed
- ☐ I am severely anxious or depressed
- ☐ I am extremely anxious or depressed

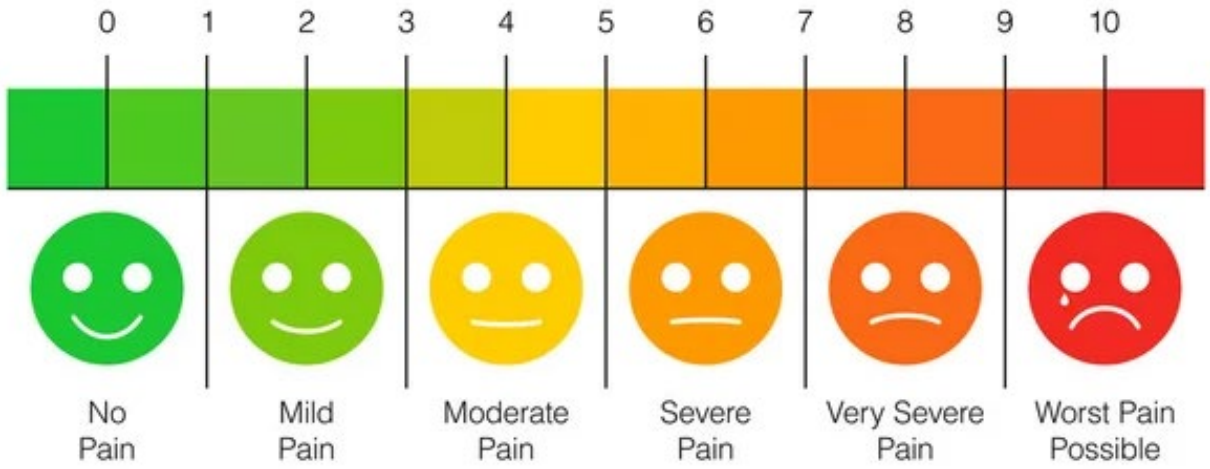
- We would like to know how good or bad your health is **TODAY**.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is **TODAY**
- Now, please write the number you marked on the scale in the below.

YOUR HEALTH TODAY = ☐



VAS pain scale

Indicate the number that corresponds, in your opinion, to the severity of pain in the neck.



Pain coping inventory (PCI F.W. Kraaimaat and A.W.M. Evers)

People who suffer from pain develop various ways to manage this pain. On the next pages are a number of statements about what you do or think when you are in pain. We ask you to indicate how often you act or think as described. You do this by choosing one of the possible answers behind the statement. Take your time when you work from one statement to the next. There are no right or wrong answers: it is rather your opinion that matters. It goes without saying that not all statements will apply to you.

1. I quit my activities.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

2. I continue my activities, but with less effort.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

3. I continue my activities, but in a slower pace.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

4. I continue my activities, but less precise.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

5. I confine myself to simple activities.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

6. I take care that I don't have to exert myself physically.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

7. I take rest by sitting or lying down.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

8. I take on a comfortable bodily posture.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

9. I take a bath or shower.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

10. I take care that I don't get upset.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

11. I retreat in a restful environment.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

12. I take care that I am not bothered by annoying sounds.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

13. I take care that I am not bothered by the light (e.g., by putting on sunglasses, closing the curtains).
1 – hardly ever 3 – often
2 - sometimes 4 – very often

14. I take care of what I eat or drink.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

15. I pretend the pain is not present.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

16. I pretend the pain does not concern my body.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

17. I focus on the pain all the time.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

18. I imagine the pain less violent than it really is.
1 – hardly ever 3 – often
2 - sometimes 4 – very often

19. I think of pleasant things or events.

1 – hardly ever 3 – often

2 - sometimes 4 – very often

20. I distract myself by undertaking a physical activity (e.g., walking, cycling or swimming).

1 – hardly ever 3 – often

2 - sometimes 4 – very often

21. I distract myself by reading, listening to music, watching a tv-programme or something like it.

1 – hardly ever 3 – often

2 - sometimes 4 – very often

22. I do something I find pleasant.

1 – hardly ever 3 – often

2 - sometimes 4 – very often

23. I self-administer other physical stimuli (e.g., by clenching my fists, by pinching myself, by pressing or rubbing on the site of the pain).

1 – hardly ever 3 – often

2 - sometimes 4 – very often

24. I think of all things that remain undone because I am in pain.

1 – hardly ever 3 – often

2 - sometimes 4 – very often

25. I start worrying.

1 – hardly ever 3 – often

2 - sometimes 4 – very often

26. I wonder about the cause of the pain.

1 – hardly ever 3 – often

2 - sometimes 4 – very often

27. I think that the pain will worsen.

1 – hardly ever 3 – often

2 - sometimes 4 – very often

28. I think of moments when I was not in pain.

1 – hardly ever 3 – often

2 - sometimes 4 – very often

29. I think I go mad with pain.

1 – hardly ever 3 – often

2 - sometimes 4 – very often

30. I remember other people's difficulties.

1 – hardly ever 3 – often

2 - sometimes 4 – very often

31. I think that others do not understand what it is to be in such pain.

1 – hardly ever 3 – often

2 - sometimes 4 – very often

32. I separate myself.

1 – hardly ever 3 – often

2 - sometimes 4 – very often

33. When I am outdoors, I try to return home as soon as possible.

1 – hardly ever 3 – often

2 - sometimes 4 – very often

34. I have a way of my own to lessen the pain or make it more bearable

1 – hardly ever 3 – often

2 - sometimes 4 – very often

Von Korff questionnaire

Instructions: You are asked several questions about the pain you are experiencing. Use the intermediate values of the scale from 0 to 10 points to answer, where **0 points = no pain**, and **10 points = the most severe pain** that could be. In question 4, indicate the number of days.

№	Question	Points
1.	How would you rate your pain on a 0-10 scale at the present time right now?	
2.	During the past **6 months** how intense was your **worst** pain?	
3.	During the past **6 months** on the **average** how intense was your pain? (That is your usual pain at times you were experiencing pain.)	
4.	About how many days in the past 6 months have you been kept from your usual activities (work school or housework) because of your pain?	Days:
5.	In the past 6 months how much has the pain interfered with your daily activities?	
6.	In the past 6 months how much has the pain changed your ability to take part in recreational social and family activities?	
7.	In the past 6 months how much has the pain changed your ability to work (including housework)?	

Pain Catastrophizing Scale

Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery.

We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

1. I worry all the time about whether the pain will end.

0 – not at all
1 - to a slight degree
2 - to a moderate degree
3 - to a great degree
4 – all the time

2. I feel I can't go on.

0 – not at all
1 - to a slight degree
2 - to a moderate degree
3 - to a great degree
4 – all the time

3. It's terrible and I think it's never going to get any better.

0 – not at all
1 - to a slight degree
2 - to a moderate degree
3 - to a great degree
4 – all the time

4. It's awful and I feel that it overwhelms me.

0 – not at all
1 - to a slight degree
2 - to a moderate degree
3 - to a great degree
4 – all the time

5. I feel I can't stand it anymore.

0 – not at all
1 - to a slight degree
2 - to a moderate degree
3 - to a great degree
4 – all the time

6. I become afraid that the pain will get worse.

0 – not at all
1 - to a slight degree
2 - to a moderate degree
3 - to a great degree
4 – all the time

7. I keep thinking of other painful events.

0 – not at all
1 - to a slight degree
2 - to a moderate degree
3 - to a great degree
4 – all the time

8. I anxiously want the pain to go away.

0 – not at all
1 - to a slight degree
2 - to a moderate degree
3 - to a great degree
4 – all the time

9. I can't seem to keep it out of my mind.

0 – not at all
1 - to a slight degree
2 - to a moderate degree
3 - to a great degree
4 – all the time

10. I keep thinking about how much it hurts.

0 – not at all
1 - to a slight degree
2 - to a moderate degree
3 - to a great degree
4 – all the time

11. I keep thinking about how badly I want the pain to stop.

0 – not at all
1 - to a slight degree
2 - to a moderate degree
3 - to a great degree
4 – all the time

12. There's nothing I can do to reduce the intensity of the pain.

0 – not at all
1 - to a slight degree
2 - to a moderate degree
3 - to a great degree
4 – all the time

13. I wonder whether something serious may happen.

0 – not at all
1 - to a slight degree
2 - to a moderate degree
3 - to a great degree
4 – all the time