SCENAR Therapy: A Therapeutic Alternative for the Treatment of Chronic Low Back Pain With or Without Radicular Symptoms?

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Examination Committee

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Contents

Glossary

- **TENS:** Transcutaneous Electrical Nerve Stimulation
- **SCENAR:** Self-Controlled Energo-Neuro Adaptive Regulation
- **CE:** *Conformité Européenne* (European Conformity) marking
- **ANSM:** French National Agency for Medicines and Health Products Safety
- **AFSSAPS:** former French Agency for the Safety of Health Products
- **CHU:** University Hospital Centre (*Centre Hospitalier Universitaire*)
- **VAS (French: EVA):** Visual Analogue Scale
- **Hz:** Hertz
- **FM:** Frequency Modulation
- **SDM (French: MSD):** Subjective Dose Mode
- **IDM (French: MID):** Individual Dose Mode
- **PAG (French: SGPA):** Periaqueductal Grey Matter
- **MRN (French: NRM):** Median Raphe Nucleus
- **CR (French: RC):** Consultation Result
- **OA (French: AT):** Occupational Accident
- **OD (French: MP):** Occupational Disease
- **HAS:** French National Authority for Health
- **DN4:** *Douleur Neuropathique en 4 Questions* questionnaire
- **NHP:** Nottingham Health Profile
- **QoL:** Quality of Life
- **NSAID:** Non-steroidal Anti-inflammatory Drug
- **WHO:** World Health Organization
- **95% CI:** 95% confidence interval around an estimate
- **p:** p value used to assess statistical significance
- **M0 / D0:** Baseline; start of the protocol
- **D28 / M1:** Day 28; end of the first month
- **M2:** End of the second month
- **M3:** End of the third month
- **M4:** End of the fourth month

I. Introduction

Low back pain is a major public health issue, as discussed in the dedicated chapter (see V.1, *A Public Health Issue*). The principal problem is progression to chronic pain and the lack of satisfactory therapeutic options for some patients. Numerous treatments are recommended (see V.3, *Management of Low Back Pain*), but the persistence of symptoms suggests that few are effective, while surgery is far from being a universal solution.

Like TENS (Transcutaneous Electrical Nerve Stimulation), SCENAR (Self-Controlled Energo-Neuro Adaptive Regulation) could have a place as an adjunctive treatment for chronic low back pain. Given its CE marking (Appendix 1), the device could already be used on a large scale in France; the ANSM, formerly AFSSAPS, authorised the device to be placed on the French market in 2012 (see II.1, *History of SCENAR*).

SCENAR was introduced at Poitiers University Hospital in 2013 by Professor Rigoard. It is used in the neurosurgery department to treat spinal pain and trigeminal neuralgia, and in the pain centre for various types of pain. A total of 185 patients with low back pain were treated with SCENAR therapy between 2013 and 2018 (see VI.1, *Retrospective Study*). The retrospectively analysed Visual Analogue Scale (VAS) results encouraged us to conduct a prospective study in twenty patients, in order to analyse additional parameters such as quality of life and use of analgesic medication. The purpose of this project is to analyse use of the SCENAR device in chronic low back pain and, if the effects are substantial, to promote its use in general practice.

According to information provided by Mr Grinberg, who served as Chairman and Chief Executive Officer of OKB RITM for 35 years before being succeeded by Mr Starovoitov in 2012, 500 devices were sold in Europe before CE marking was obtained. After this marking was obtained in 2001, approximately 500 professional devices and 2,000 home-use devices were sold each year in Europe. Since approximately 2001, around 12,000 professional devices and 60,000 home devices have been sold in Europe. Seventy per cent of users are located in German-speaking countries, 20% in England and the remaining 10% in the rest of the world. We do not know how many physicians use this device in routine practice.

II. SCENAR

1. History of SCENAR

The creation of a feedback-controlled stimulation device was the outcome of lengthy work by a team of scientists at the OKB RITM design bureau, based at the Taganrog Radio Engineering Institute (TRTI) in Russia. The first device prototypes (ENS 2 and ENS 3) were designed in 1983. (1)

After several years of research and improvement, the scientists at OKB RITM developed a more advanced device, which was named SCENAR (Self-Controlled Energo-Neuro Adaptive Regulation). (2)

In 1986, the first Soviet-level studies were organised at the N. N. Priorov Central Institute of Traumatology and Orthopaedics in Moscow and the P. K. Anokhin Research Institute of Physiology in Moscow.

On 12 December 1986, an order was received from the USSR Ministry of Defence to launch the first series of devices. Funding for the SCENAR concept was included in the Soviet *Buran* space programme. SCENAR was regarded as a universal portable medical assistant for cosmonauts, capable, according to its designers, of correcting and regulating health problems arising under space-flight conditions.

The device was patented for the first time on 4 January 1987 (authors: Zakharevich V. G., Nechushkin A. I., Karasev A. A., Revenko A. N. and Kibirev A. A.). (1) An improved model was then patented on 6 March 1989 (authors: Revenko A. N., Karasev A. A., Kibirev A. A. and Dygai A. I.).

The first invention patent belonged to the Taganrog Radio Engineering Institute, while the second invention and the international patent belonged to OKB RITM at TRTI. In 1989, the RITM design bureau registered the trademarks “SKENAR” © (Cyrillic-form trademark) and “SCENAR” ©.

From 1990 onwards, SCENAR devices that had undergone sufficient clinical and technical testing were accredited by the USSR Ministry of Health for use both at home and in healthcare facilities.

Since then, these mechanisms have been refined and approved. For more than ten years, the Soviet government required numerous tests to demonstrate the device’s reliability. These tests enabled the scientists to acquire extensive experience in this field.

Using the expertise gained through these studies, methods were developed for treating a variety of health problems.

Since 2001, SCENAR devices have been manufactured for the European market in accordance with CE requirements (Appendix 1).

In 2012, the ANSM authorised marketing in France and use by the general public. (2) In France, a home version of the SCENAR device is marketed from approximately EUR 600.

In France, SCENAR is used extensively in Dr Monique Latare’s department at Dax Hospital Centre. The physician uses it daily during consultations, and a nurse trained in SCENAR performs approximately twenty sessions per day for spinal pain or neuralgia.

2. The SCENAR Device (Appendix 2)

a) Operating Principle

Electro-impulse therapy with feedback control is a non-invasive method intended to stimulate the body's self-regulation. The therapy is based on the principle that every living organism requires energy exchange with its environment in order to live. Disease is considered a consequence of disruption of these exchanges. Homeostasis - the physiological equilibrium of living organisms - is lost, and the body's energy becomes insufficient to maintain good health.

The characteristics of the electrical waveform delivered by the device are proposed to help the body restore the homeostasis it has lost.

The transmitted waveform has the following particular features:

- A biphasic impulse resembling a nerve impulse, making the signal familiar to the human body.
- An impulse of variable amplitude that is not harmful because it is brief. (6) This is said to: (4)(5)
    - Excite C fibres, nociceptive fibres with a high excitation threshold (according to the Erlanger-Gasser classification; Appendix 3). These fibres enable the release of neuromediators such as endorphins (analgesic substances), substance P (which increases stimulation of nociceptive fibres) and neuropeptides (which may improve symptoms). By stimulating the painful area, the brain receives a message and responds in order to correct the situation; this is described as a reflex feedback-control mechanism.
    - Increase the permeability of the membranes of stimulated cells. This promotes the entry of bioactive substances into the cell and modifies the potential of the intercellular fluid, thereby stimulating exchange between the intercellular and interstitial fluids. The result is more rapid activation of the body's self-regulatory process.

According to article (5), the device may also:

- Accelerate the movement of macrophages formed in the intercellular space, producing a rapid, localised immune response.
- Increase antioxidant enzymes and thereby inhibit oxidative stress. Cells would then recover the energy level required for their activity.
- Improve circulation in the treated area. Haemodynamic (blood-flow) and anti-oedema (lymphatic) effects are described, with a resulting reduction in inflammatory processes.

The associated feedback control is described as reinforcing the effects of the device. (3) By measuring skin impedance, the device continuously adapts the characteristics of the current and thus avoids habituation, which would reduce the effects. The feedback-control system is also described as delivering the dose required for the cell to recover sufficient energy for its activity.

In summary, SCENAR is said to stimulate the body's own resources so that the body itself corrects the pathological process and progressively restores homeostasis over the course of treatment. The stated aim is to help the individual activate self-regulatory processes.

After treatment, pain and medication use are said to decrease and the course of illness to be shortened. Restoration of physical function is described as almost immediate. Quality of life would therefore be favourably affected.

The device consists of a handheld unit with a built-in electrode. A screen enables the therapist to monitor treatment. Depending on the treatment, additional external electrodes may also be used (Appendix 2).

b) Treatment Procedure

Before treatment, the following parameters can be adjusted:

- **Power**, also known as action energy. Action energy corresponds to the amplitude of the electrical discharge. It is adjusted according to the patient's sensation, which differs between individuals and anatomical locations. Logically, the "+" button increases power and the "-" button decreases it. Adjustment should be performed on a non-painful area symmetrical to the painful region, because the skin parameters are similar. Before each treatment, the aim is to identify the highest tolerated energy level, which must remain below the patient's pain threshold so that treatment can be accepted.
- **Frequency**, meaning the number of impulses per second. The standard frequency lies between 60 and 90 hertz (Hz). Depending on the device, frequency ranges from 15 to 340 Hz. Frequency determines the depth of stimulation: the higher the frequency, the more superficial the action. The highest frequencies are used for acute pain.
- **Frequency modulation**, which may be activated in FM mode. Frequency then varies from 30 to 120 Hz over time and is said to improve the effects of the device when symptoms persist. It is most often used at the end of treatment after the most active area has been identified. The principle is that at least one frequency within the proposed range will correspond to the selected area. This mode is used with the electrode held stationary.
- **Amplitude modulation**, which produces rhythmic stimulation and may be preferred to improve contraction of smooth muscle and blood vessels.

Treatment may be performed in two ways:

- **Subjective Dose Mode (SDM), or constant mode.** This is used for active complaints. The device is moved over the skin in every direction while maintaining the same power and speed. The electrode must remain fully in contact with the skin, without pressure. When these conditions are respected, treatment is uniform and enables identification of "active areas" (see below).
- **Individual Dose Mode (IDM), or objective mode.** This is applied area by area until the dose has been delivered, signalled by a sound and a zero on the display. The sooner the device sounds, the more active the area. This mode therefore helps identify the areas most sensitive to the SCENAR effect. It is used for chronic problems and on active areas. "Active areas", also known as asymmetries, are skin areas that react differently to movement of the electrode compared with the rest of the body.

In SDM, active areas may be identified by the appearance or disappearance of sound, a change in skin colour (redness or pallor), "sticking" (a form of adhesion that slows movement of the electrode over the affected area), or pain.

In IDM, the initial reaction time determines asymmetry: the higher the figure displayed on the device, the more active the area.

Treatment is carried out in two stages: (6)

- **The standard or initial component.** Treatment is applied to general areas intended to help self-regulatory centres overcome disease more effectively. The principal method described is the "three pathways, six points" technique, used for the whole body; every SCENAR session begins with this method.

- **The complementary component.** Treatment is then applied to different points:
    - **Local treatment:** over the complaint (primary sign: pain, itching, swelling, discomfort, etc.). To avoid increasing pain, treatment should begin on the side symmetrical to the painful area and then progress to the painful side. SDM is applied first, based on the sensations of the patient and therapist, followed by IDM, which visualises the body's adaptation on the device.
    - **Treatment of active areas:** skin regions that react to the device, where secondary signs or asymmetries appear.
    - **Treatment of reflexogenic regions:** skin areas corresponding to projections of organs, as described in SCENAR manuals.
    - **Treatment of acupuncture points:** according to Nakatani, cited in article (3), stimulation of meridians and biologically active points may increase the functional reserves of health.

Treatment can be applied in emergencies as well as for chronic pain. A course normally consists of 6 to 10 sessions, but may extend to 15 or 20 sessions if symptoms, particularly pain, persist. Each session lasts approximately thirty minutes.

c) Contraindications

When used in accordance with its instructions, SCENAR therapy is described as safe and as having no contraindications apart from the following exceptions: (3)

- The SCENAR device must not be used to treat patients with a cardiac pacemaker or other electronic devices, including insulin pumps, hearing implants or implanted neurostimulation electrodes, because interference may cause malfunction.
- SCENAR therapy must not be used for self-treatment by intoxicated individuals, because perception of power and duration of action may be distorted by an increased nociceptive threshold.
- SCENAR must not be used in the periorbital region in people with glaucoma.
- SCENAR therapy must not be used in people with severe intolerance to electrical stimulation.
- SCENAR treatment must not be applied in cases of acute infectious disease without an established diagnosis.
- Allergy to any of the components (nickel).

III. General Considerations on Pain

1. Pathophysiology of Pain

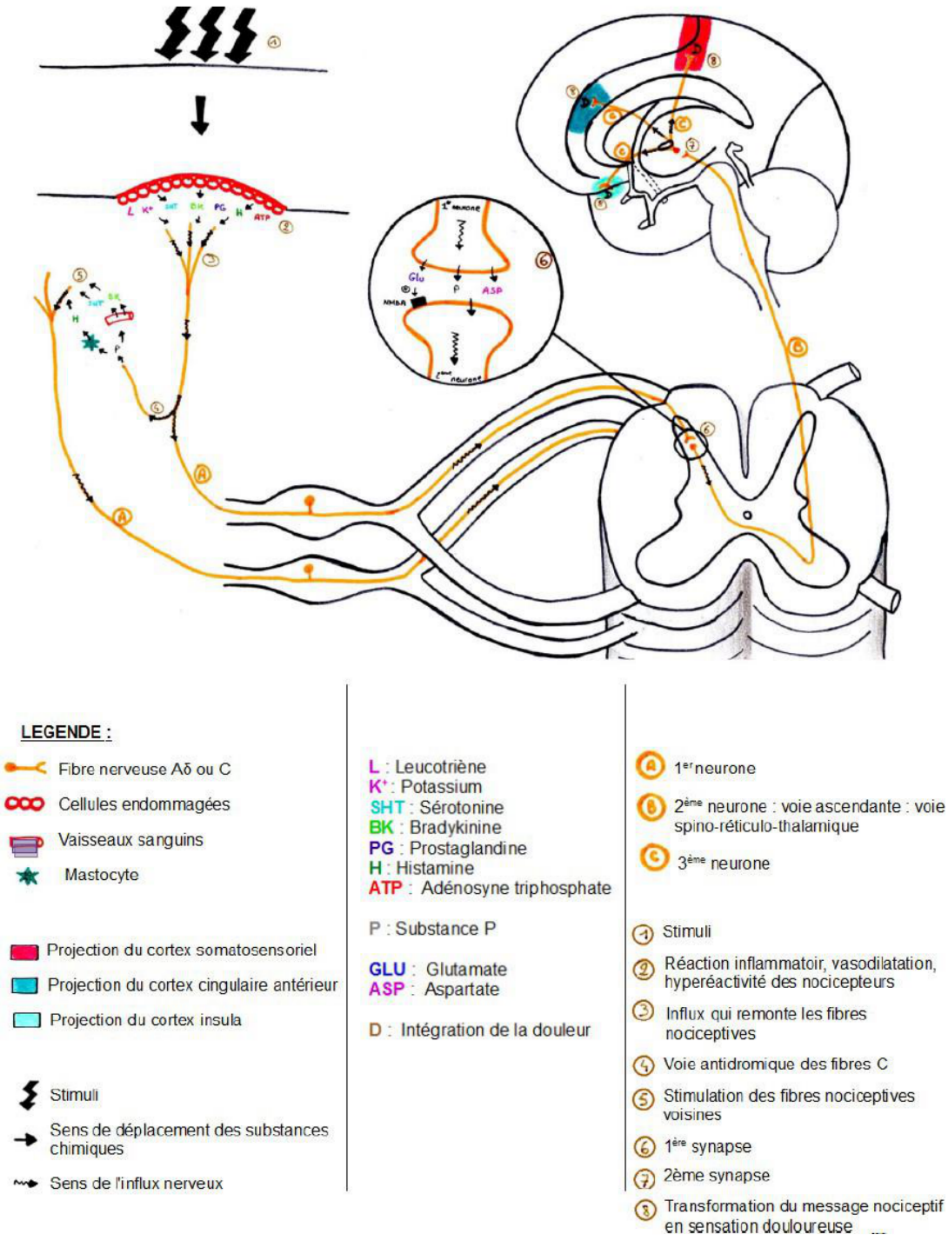

Figure 1. Diagram of pain physiology. (6, 7)

a) Processing of Nociceptive Information

In every type of pain, the painful stimulus originates in anatomical structures such as ligaments, muscles, nerves, joints, bones and the skin surface. Nociception is divided into four stages: transduction, transmission, perception and modulation. (8)

Transduction is the process by which a painful stimulus is converted into an action potential. Transmission and conduction are closely interrelated and refer to the pathway from the painful area to the brain through the spinal cord. Perception occurs when the signal reaches the cerebral cortex.

The complex mechanism by which the pain signal is modified is called modulation. The pain signal follows a route involving three pathways: the afferent pathway ascending to the brain; the integration pathway, which processes the signal in the brainstem, midbrain, diencephalon and cortex; and the efferent pathway returning to the spinal cord.

a.1) Pain Transduction

As already noted, pain is triggered by events occurring at the skin surface or in deeper tissues. The human body contains sensory neurons, or nociceptors, that respond to thermal, mechanical or chemical stimuli. Activation of these neurons releases action potentials and neurotransmitters. These are received by first-order axons travelling towards the dorsal horn of the spinal cord, which subsequently transmits the information to the brain. This is signal transduction, mediated by the local release of potassium, hydrogen ions, bradykinin, serotonin, prostaglandins and leukotrienes.

Nociceptors may release neuromediators as well as substance P, which has a vasodilatory action and promotes the secretion of histamine and serotonin, sensitising neighbouring nociceptors. (10)

a.2) Transmission and Conduction

Once information has been transmitted to the peripheral nerves, three types of fibre conduct it. Anatomically, peripheral fibres converge in the dorsal horn of the spinal cord to form second-order neurons. First-order neurons are of different types and are specialised according to the information received.

A-beta axons have a large diameter and are myelinated. They conduct information rapidly and are specialised in proprioception and discriminative touch. They are not involved in nociceptive pain. A-delta axons are smaller, myelinated and conduct information more slowly; these axons are specialised in mechanoreception. The final type, C fibres, are small and unmyelinated and conduct slowly. They are specialised in thermal, chemical and mechanical sensitivity. (9)

These first-order neurons converge in the dorsal horn of the spinal cord. Local release of neurotransmitters allows information to pass from the first-order neurons to spinal neurons. The principal neurotransmitters are excitatory amino acids, including glutamate and aspartate, and neuropeptides such as substance P. These neuromediators are responsible both for transmission of the nerve impulse and for central sensitisation phenomena that explain secondary hyperalgesia.

At the same time, modulation of the message occurs at spinal level through inhibitory amino acids, including gamma-aminobutyric acid (GABA), and endogenous opioid substances. (10)

The pain information is now present in the spinal neurons. It is transmitted through laminae I and V of the dorsal horn to form the spinothalamic pathway, comprising:

- the neospinothalamic tract, connected to A-delta fibres, which reaches the ventral posterolateral nucleus of the thalamus before travelling to the somatosensory cortex through the anterolateral column of the spinal cord; and
- the paleospinothalamic tract, more closely connected to C fibres, which reaches the medial thalamus and relays to limbic structures and the frontal cortex. (10)

The laminae of the dorsal horn of the spinal cord help explain referred visceral pain through the close relationships between nerve endings from different organs in lamina V of the dorsal horn.

a.3) Perception

This is the phase in which information reaches the cerebral cortices, with each area of the brain corresponding to a specific area of the body. Positron emission tomography (PET) and magnetic resonance imaging (MRI) have made it possible to demonstrate and study this phase. (11)

a.4) Modulation

Signal modulation is explained by several phenomena.

Gate-Control Theory

Gate-control theory is expressed in the dorsal horn of the spinal cord. It was described by Melzack and Wall in 1965 and identifies the first physiological modulation of pain at the point where information enters the dorsal horn.

This first level of modulation is segmental control, occurring at every spinal segment and resulting from interaction between nociceptive afferents (C and A-delta fibres) and non-nociceptive afferents (A-alpha and A-beta fibres). Convergence of all sensory information onto a common projection neuron creates competition between these signals.

Everyone has experienced this competition through the reflex action of rubbing a painful area after an impact: the tactile sensation replaces, or reduces, the painful sensation. A complementary mechanism is also provided by an inhibitory interneuron capable of regulating opening and closing of the gate; this interneuron is itself influenced by nociceptive and non-nociceptive nerve fibres. (12)

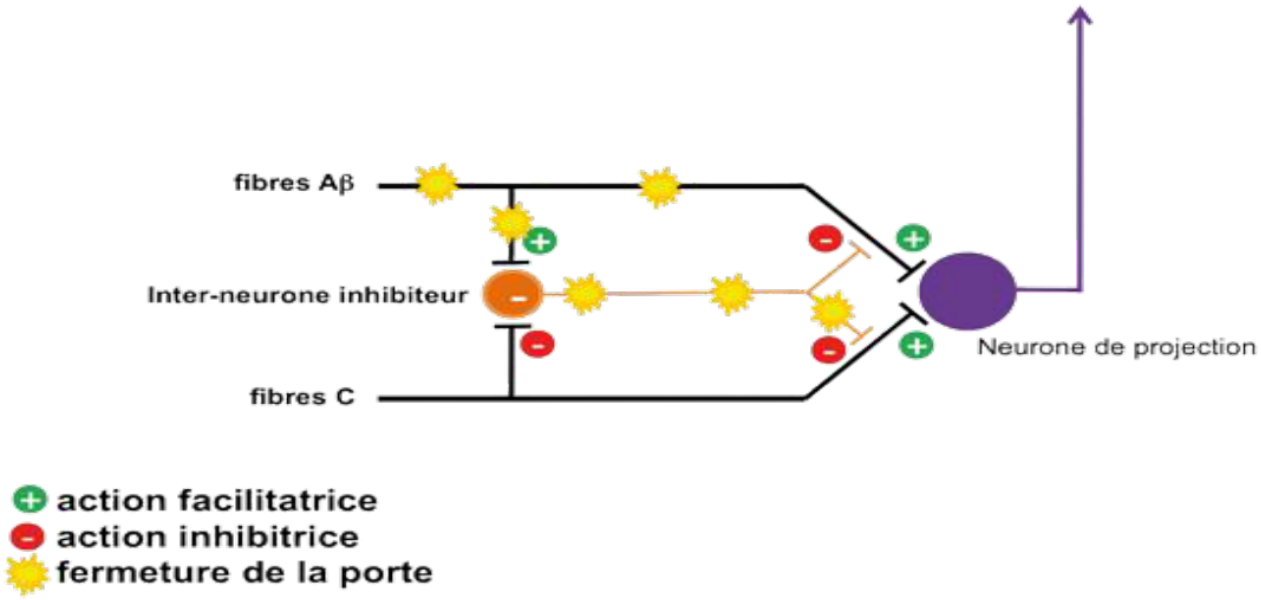

Figure 2. Diagram of gate-control theory.

Descending Inhibitory Controls

Fibres arise from the periaqueductal grey matter (PAG) and the median raphe nucleus (MRN), releasing serotonin, dopamine and noradrenaline within the spinal cord and activating enkephalinergic receptors. Stimulation of the PAG and MRN is thought to produce analgesia by reducing nociceptive afferent activity. (10)

Diffuse Noxious Inhibitory Controls (DNIC)

Described by Le Bars and colleagues in 1979, this concept shows that one pain can mask another; in other words, a strong pain suppresses a weaker one. Nociceptive stimulation activates nociceptive neurons in the spinal segment corresponding to the stimulated area and inhibits all other nociceptive neurons.

In summary, a precise, intense pain locally inhibits a duller, less clearly localised pain by reducing the background activity of nociceptors located outside the acutely painful area. (13)

b) Mechanisms Underlying the Transition to Chronic Pain

Pain becomes chronic when modulation mechanisms are overwhelmed. Pain lasting for more than three months is defined as chronic and may become a complex, multifactorial syndrome combining physical, psychological, behavioural and social manifestations.

Progression to chronic pain is due to structural changes in the central nervous system caused by prolonged painful stimulation. The threshold for triggering pain is lowered, producing hyperalgesia or even allodynia, in which normally non-painful stimuli are perceived as painful. Pain is no longer controlled by modulation mechanisms and is often not relieved by conventional analgesics.

Such pain invades the patient’s psychological, emotional and social world and results in a marked deterioration in quality of life. (10)

c) Different Types of Pain

- **Nociceptive pain** is caused by excessive stimulation of peripheral nociceptors during tissue injury, inflammation or mechanical, thermal or chemical stimulation. It does not follow a defined neuroanatomical distribution and corresponds to the stimulated territory or to the referred-pain territory of the organ concerned.
- **Neuropathic pain** is associated with a clearly localised lesion of a nerve trunk, plexus or root in the peripheral nervous system, or of one side of the body in the central nervous system. It is associated with a sensory deficit in the corresponding territory. Patients may experience electric-shock sensations, allodynia or hyperalgesia. Unlike nociceptive pain, neuropathic pain follows a defined neuroanatomical distribution and is often continuous.
- **Mixed pain** combines nociceptive and neuropathic components. It is frequently encountered in low back pain with dermatomal radicular pain, such as lumbosciatica or femoral neuralgia (cruralgia).
- **Functional or central pain** is related to dysfunction of pain-control systems without an identified lesion. This category includes fibromyalgia syndrome, functional bowel disorders, interstitial cystitis and tension-type headaches. (10)

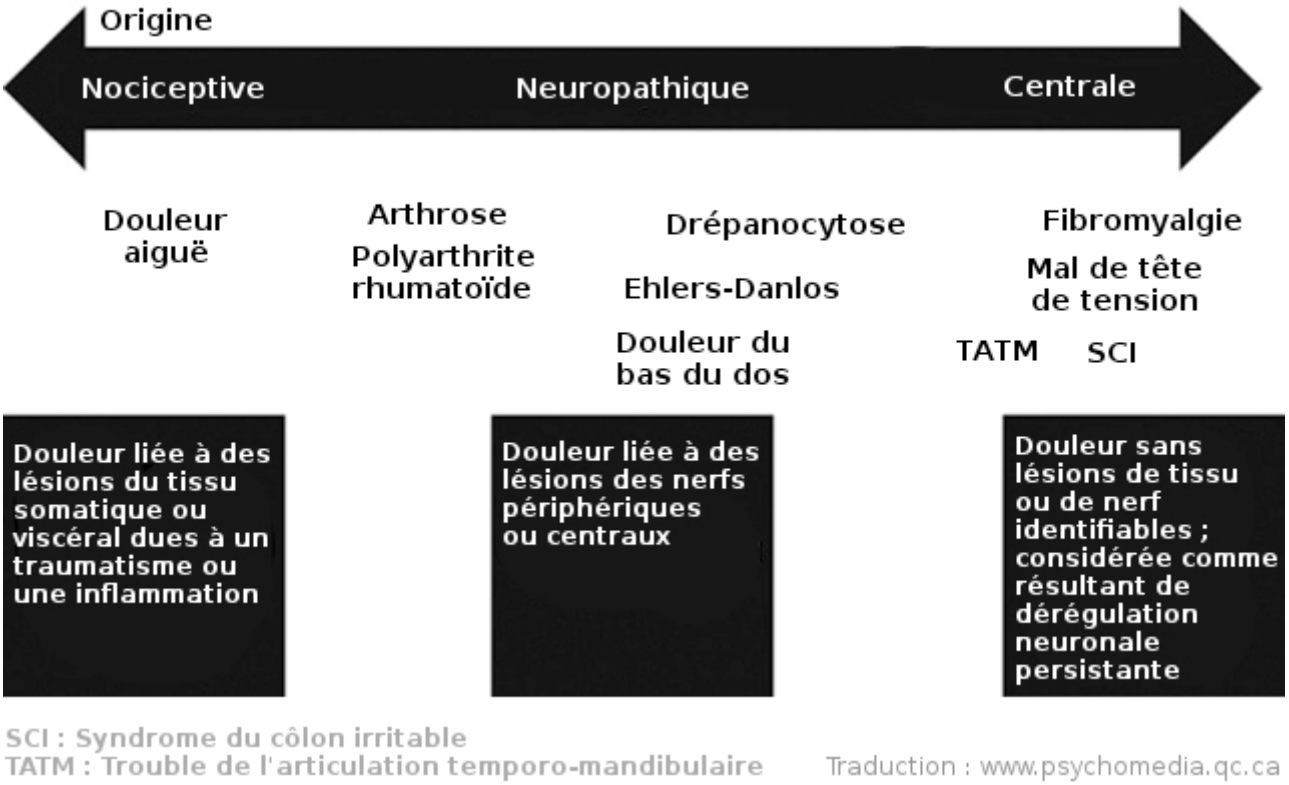

Figure 3. Different types of pain, adapted from Daniel J. Clauw and colleagues (Clinical Journal of Pain, 2016).

IV. Studies of SCENAR in the Literature

Approximately one hundred studies of SCENAR have been conducted worldwide. I selected several that appeared relevant to the continuation of our study, although their levels of evidence vary because of methodological differences.

A first study (14) was a prospective randomised controlled trial involving 60 patients in South Korea between March 2014 and July 2015. All participants had chronic neck pain following trauma, and the study compared SCENAR with TENS. Patients were aged 20 to 50 years and were randomised into two groups: a TENS group of 28 patients (controls) and a SCENAR group of 32 patients (cases). They received 20 minutes of treatment three times per week for four weeks.

The Visual Analogue Scale (VAS) and Neck Disability Index (NDI) were evaluated at weeks 0, 4, 8, 12 and 16. VAS pain decreased more with SCENAR, from 6.3 at week 0 to 2.1 at week 16, than with TENS, from 6.2 at week 0 to 3.7 at week 12. However, the difference was not significant (SCENAR 95% CI [0.119-3.61] versus TENS 95% CI [1.431-5.24]). The reduction in NDI score was significantly greater with SCENAR, falling from 23.75 to 9.5 (95% CI [6.84-12.66]), than with TENS, falling from 24.28 to 14.3 (95% CI [12.797-18.916]) ($p < 0.05$).

Source:
Han J, Han I. A Comparative Study of the Efficacy between Self-controlled Energo-Neuro-Adaptive Regulator and Transcutaneous Electrical Nerve Stimulation for Whiplash Injury. *The Nerve*. 31 Oct 2016;2(2):33-37.

The second study (15) was conducted in Australia in 2007 and compared SCENAR, TENS and placebo in chronic neck pain. It evaluated reductions in VAS pain, the Neck Disability Index (NDI), a Patient-Specific Functional Scale (PSFS) and the SF-36 quality-of-life scale.

The study randomly recruited 24 patients - 10 men and 14 women aged 18 to 50 years. Treatment was single-blind and lasted six weeks: three 15-minute sessions per week for two weeks, followed by two sessions per week for two weeks and then one session per week for two weeks. Assessments were performed at baseline and at weeks 6, 12, 18 and 24. The groups were comparable and comprised nine patients in the SCENAR group, seven in the TENS group and eight in the placebo control group.

Pain decreased significantly in patients treated with SCENAR ($p = 0.001$), whereas the placebo and TENS groups maintained pain levels comparable to baseline. A significant improvement in NDI score was also observed ($p = 0.022$), while little change occurred in the placebo and TENS groups. Patient function improved significantly and durably in the SCENAR group.

Quality-of-life results were again significant in favour of SCENAR ($p = 0.001$). The quality of life of SCENAR-treated patients approached, and tended to become similar to, that of healthy individuals, whereas the TENS and placebo groups showed no improvement over time.

Source:
Vitiello AL, Bonello R, Pollard H. The effectiveness of ENAR® for the treatment of chronic neck pain in Australian adults: a preliminary single-blind, randomised controlled trial. *Chiropr Osteopat*. 9 Jul 2007;15:9.

A third study (16), conducted in Vienna, Austria, was reported as an abstract and included 24 patients with chronic neck pain. It was a randomised controlled study with a SCENAR group of 13 patients and a TENS group of 11 patients. Patients in each group were treated three times per week for two weeks.

VAS pain, neck disability and range of motion - flexion, extension and rotation - were evaluated. Both groups improved in pain, neck disability and mobility, with a significantly greater improvement in neck disability (NDI) in favour of SCENAR ($p < 0.05$).

Source:
Y. Eun, W. Choi. The effect of SCENAR and TENS (Transcutaneous electrical nerve stimulation) on pain relief in patients with chronic neck pain. *EFIC 2015 Abstracts*. Vienna, Austria, 2-5 Sept 2015.

A fourth study (17) was prospective but provided a low level of evidence because it was neither randomised nor controlled. It included 202 patients with chronic myofascial pain syndrome treated with SCENAR three times per week for a mean duration of six months (range 3-16 months). Mean VAS improvement was reported as 89%.

Source:
In Bo Han, Ryoong Huh. SCENAR therapy for myofascial pain syndrome. Abstracts of the WACBE World Congress on Bioengineering 2007, Bangkok, Thailand.

A fifth study (18) was a non-randomised, uncontrolled retrospective evaluation of SCENAR, again in poorly characterised back muscle pain. Treatments were performed between March and December 2006 in the Neurosurgery Department in Seongnam, South Korea, in 340 patients: 138 men and 202 women aged 23 to 76 years, with a mean age of 43.5 years.

Patients were evaluated before treatment, one week after completion of treatment and one month after treatment ended. VAS pain and spinal mobility were assessed. All 340 patients received SCENAR. Overall analysis showed a marked reduction in pain and an improvement in mobility in 296 patients at both one week and one month after treatment.

Two subgroups were analysed: cervical pain (n = 295) and low back pain (n = 45). Effectiveness appeared greater in the cervical-pain subgroup, with pain reduction in 88.7% of patients compared with 83.1% in the low-back-pain subgroup.

Source:
In Bo Han, Ji Young Moon, Ryoong Huh, Hye Young Yoo, Sang Chung. The Efficacy of SCENAR Therapy for Myofascial Pain Syndrome.

V. Low Back Pain: First and Foremost, a Public Health Problem

1. A Public Health Issue

Low back pain is the eighth most frequent consultation result in France, according to a study of general practitioners by the *Observatoire de la Médecine Générale - SFMG*. A total of 4,689 cases of low back pain were recorded, representing 6.88% of consultation results (CRs), among 278 CR categories accounting for 95% of the pathological phenomena encountered by a general practitioner in practice. (19)

Rank	Consultation result	Number	Percentage
1	Routine examinations / prevention	16556	24.28%
2	Febrile state	11849	17.38%
3	Hypertension	8935	13.10%
4	Rhinopharyngitis / common cold	8418	12.34%
5	Vaccination	8224	12.06%
6	Afebrile morbid state	7838	11.49%
7	Hyperlipidaemia	5700	8.36%
8	Low back pain	4689	6.88%
9	Arthropathy / periarthropathy	4063	5.96%
10	Non-characteristic pain	3483	5.11%
11	Tonsillitis / pharyngitis	3175	4.66%
12	Reaction to a distressing situation	3125	4.58%
13	Rhinitis	2944	4.32%
14	Abdominal complaint	2758	4.04%
15	Contraception	2658	3.90%

Figure 4A. Fifteen most frequent consultation results in general practice (all ages).

Rank	Consultation result	Number	Percentage
1	Routine examinations / prevention	1820	20.24%
2	Febrile state	1228	13.66%
3	Afebrile morbid state	966	10.74%
4	Low back pain	949	10.55%
5	Hypertension	938	10.43%
6	Rhinopharyngitis / common cold	859	9.55%
7	Reaction to a distressing situation	722	8.03%
8	Smoking	673	7.48%
9	Vaccination	641	7.13%
10	Non-characteristic pain	589	6.55%
11	Arthropathy / periarthropathy	575	6.39%
12	Hyperlipidaemia	542	6.03%
13	Administrative procedure	463	5.15%
14	Contraception	455	5.06%
15	Rhinitis	404	4.49%

Figure 4B. Fifteen most frequent consultation results among patients aged 40-50 years.

There is no significant difference in the occurrence of low back pain between men and women.

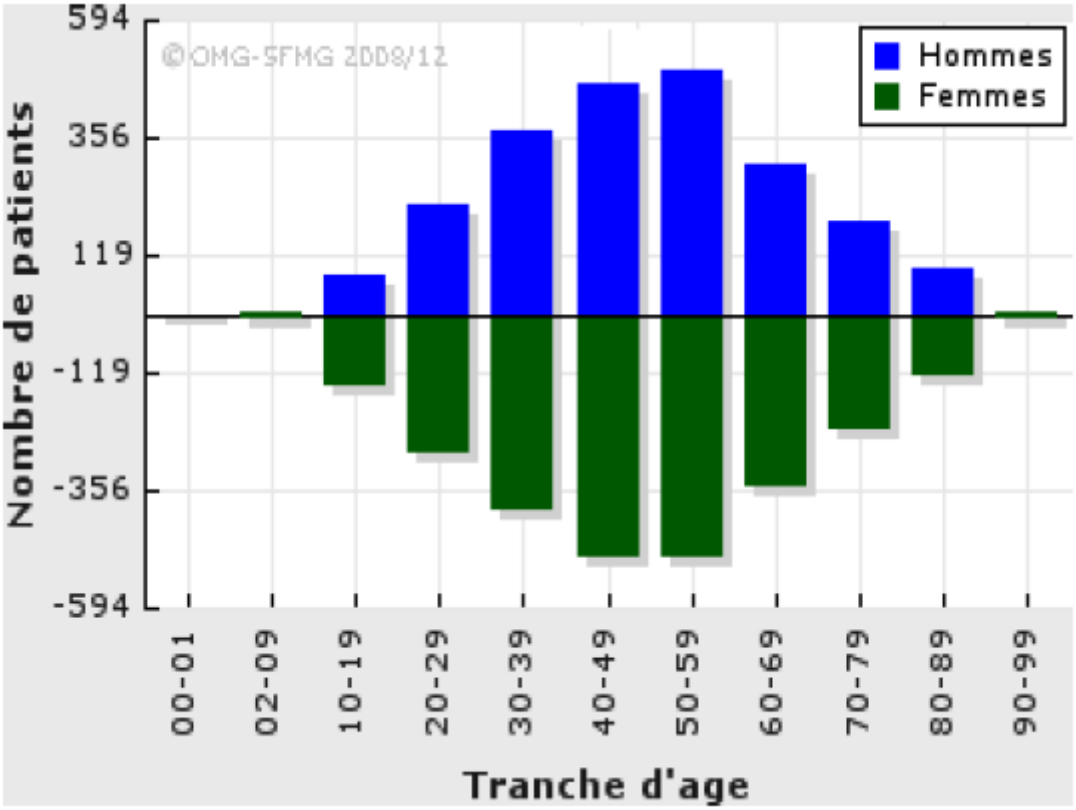

Figure 5. Distribution of patients with low back pain by age group and sex. (19)

The prevalence of low back pain is high. In a working-age population, more than two out of three employees have experienced, or will experience, low back pain. Low back pain accounts for 20% of occupational accidents (OAs) and 7% of occupational diseases (ODs). Almost half of occupational accidents involving low back pain occur while carrying loads. (20)

No study has evaluated the frequency of low back pain in the general population in France. Depending on the study, lifetime prevalence in adults ranges from 66% to 75%. Ninety per cent of episodes resolve without medical consultation. Most episodes resolve rapidly, but 10% to 23% last longer than three months. (21)

Chronic low back pain is a major public health issue because of the disability it may cause. It has increased sharply in industrialised countries over the past ten years. Some risk factors for low back pain - manual handling, falls, collisions, tripping and awkward postures - occur in every occupation, meaning that all employees may be affected. However, the number and duration of periods of sick leave are greater among more highly exposed workers, including material handlers, machinery operators, manual labourers and workers exposed to awkward postures.

The mean duration of sick leave for low back pain is two months and has almost tripled in forty years. The mean duration of sick leave for low back pain recognised as an occupational disease is one year, at a mean cost of EUR 44,000 per year. Each year, almost 11.5 million working days are lost because of occupational accidents and occupational diseases related to low back pain.

Low back pain is responsible for one in six periods of sick leave. It accounts for 30% of absences lasting more than six months and is the third leading cause of recognition of disability status. Overall, work-related low back pain costs the occupational-accident and occupational-disease insurance branch more than EUR 1 billion per year.

The Fifth European Working Conditions Survey (Eurofound) (22) shows that low back pain is a major work-related health problem. Forty-seven per cent of European workers reported that they had “suffered from back pain” during the preceding twelve months. In most cases, low back pain has no major consequences, but it may become chronic. Chronic low back pain is the leading cause of medical unfitness for work among employees under 45 years of age. Sick leave and disability resulting from low back pain are the principal drivers of its economic and social costs.

In England, 25% of people with low back pain account for 90% of the total cost of the condition. In France, direct medical costs represent approximately 1.6% of health-insurance expenditure and 0.1% of gross domestic product. Indirect costs are five to ten times greater than direct costs. (23)

The costs of low back pain are considerable: almost USD 20 billion per year in the United States and EUR 1.5 billion per year in France, where the 7% of cases that remain chronic for more than six months account for over 70% of the total cost of the condition. (22)

Care provided by allied health professionals accounts for 22.9% of costs related to chronic low back pain. (23)

2. Different Types of Low Back Pain

Several types of low back pain are recognised. (24)

Specific (“Symptomatic”) Low Back Pain

Symptomatic low back pain is secondary to an underlying disease. Specific signs or symptoms, known as “red flags”, must be sought because they may require urgent action:

- Age under 20 years or a first episode after 55 years of age
- Major trauma
- Inflammatory or infectious syndrome, or fever
- Prolonged corticosteroid treatment
- Deterioration in general condition
- History or suspicion of cancer, HIV infection or visceral disease
- Progressively increasing pain not related to physical activity
- Pain that increases while lying down or is poorly localised across the back and chest
- Signs of nerve compression, such as sciatica or sphincter disturbance

Non-specific (“Common”) Low Back Pain

This form is not caused by a clearly identified disease and represents the vast majority of cases. It is classified according to duration.

Acute Low Back Pain: Up to Six Weeks

Ninety per cent of cases resolve within a few days, and more than 90% of patients on sick leave because of acute lumbago return to work within one month. Nevertheless, more than one quarter of patients experience recurrence within the following year. Low back pain may occur with or without radicular pain, presenting as sciatica in the L5-S1 distribution or femoral neuralgia (cruralgia) in the L3-L4 distribution.

Subacute Low Back Pain: Six to Twelve Weeks

This affects approximately 3% of patients. It is a transitional period between normal recovery and progression to chronicity. Risk of chronicity is assessed using “yellow flags”, which are psychosocial indicators of an increased risk of chronic pain.

Yellow flags:

- Emotional vulnerability such as depression, anxiety, a tendency towards stress and social isolation
- Withdrawal in relation to the condition, including a passive rather than active attitude towards treatment and the belief that the pain may lead to disability
- Inappropriate pain behaviours, particularly avoidance or reduced activity related to fear
- Work-related problems, such as job dissatisfaction or a work environment perceived as hostile, and compensation-related problems, such as a disability pension

Chronic Low Back Pain: More Than Three Months

This is uncommon: approximately 2% to 7% of acute low back pain becomes chronic. Because of its individual, social, occupational and economic effects, it is the most serious form of non-specific low back pain. The characteristics of the pain frequently change, and chronic low back pain becomes a “chronic pain syndrome”.

Aetiologies of Low Back Pain

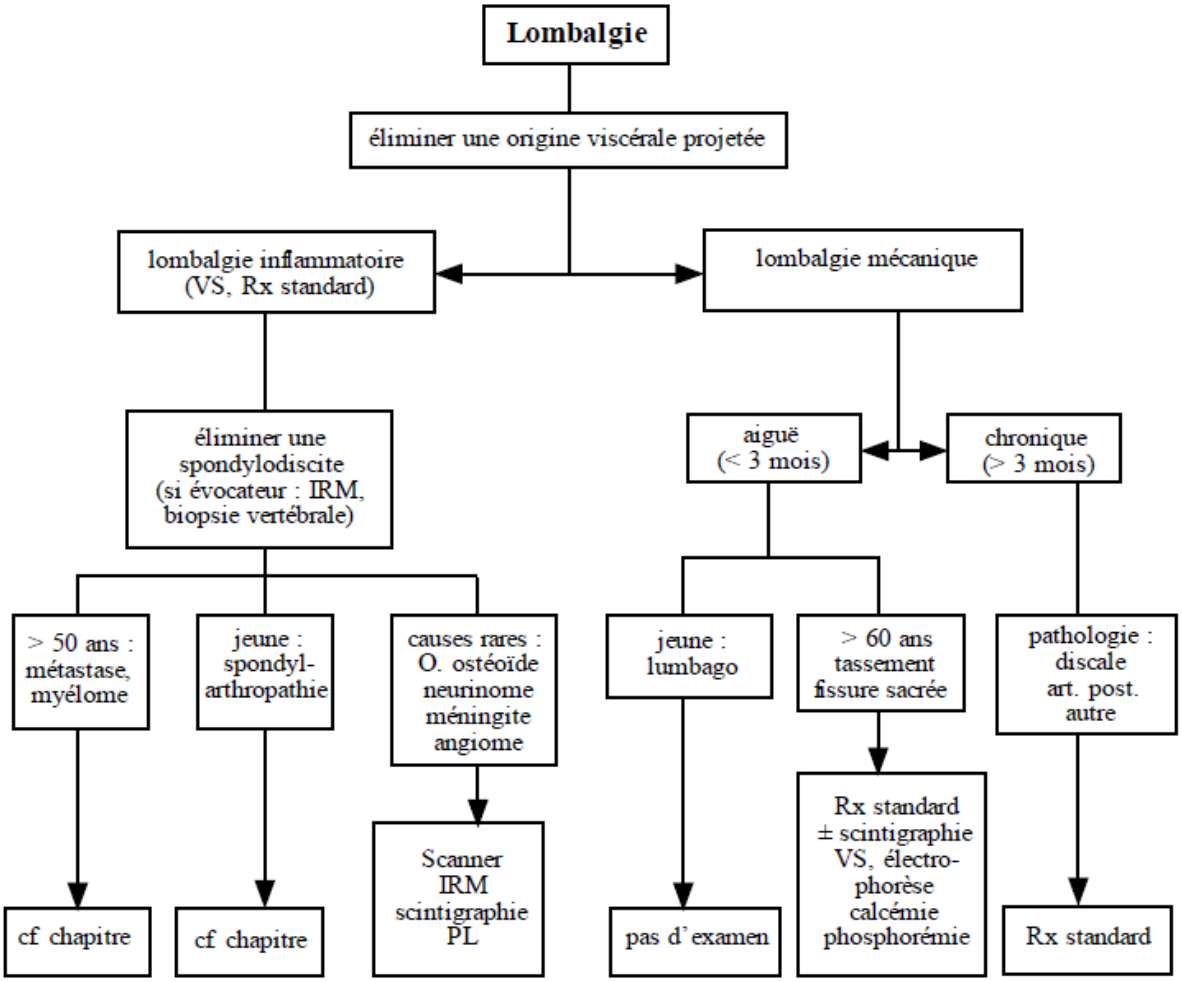

Figure 6. Diagnostic pathway for low back pain, after Dubourg and Wrona (1995). (25)

3. Management of Low Back Pain

A 2019 report by the French National Authority for Health (HAS) summarised available treatments and their place in the management of low back pain. (26)

The following algorithm describes the management of a patient presenting with non-specific low back pain.

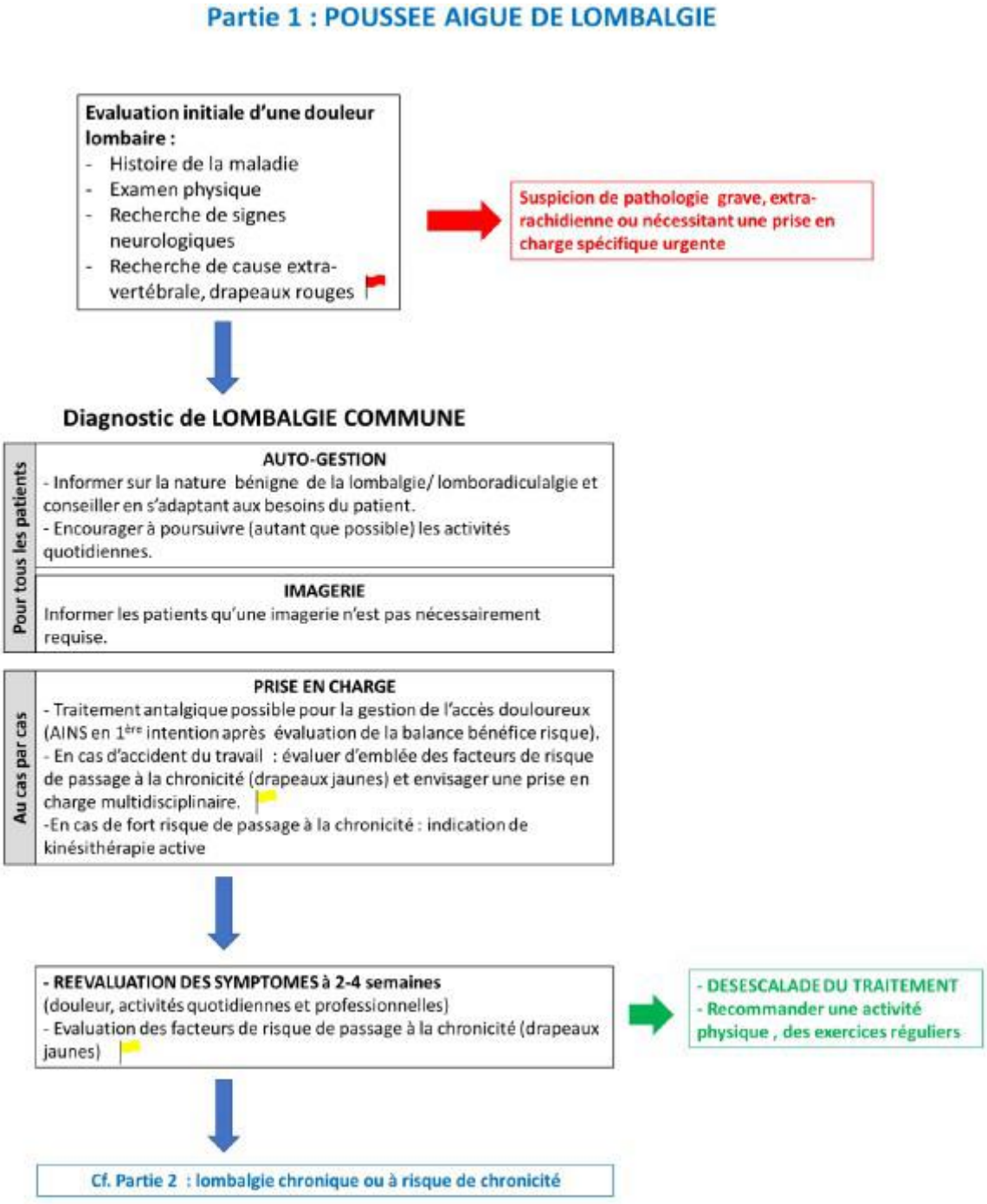

Figure 7. Management of acute low back pain. (26)

In its April 2019 recommendations, the HAS reached new therapeutic conclusions. No medicinal product had demonstrated medium-term efficacy in acute low back pain. Every prescription should therefore be based on an assessment of the benefit-risk balance.

Pharmacological Management

For non-specific low back pain, the HAS recommended paracetamol as first-line symptomatic treatment. It also recommended a non-steroidal anti-inflammatory drug (NSAID), where possible, for the shortest possible duration.

As second-line treatment, the HAS recommended a weak opioid (step 2 of the World Health Organization analgesic ladder), such as paracetamol-codeine (Co-Doliprane®), paracetamol-opium-caffeine (Lamaline®) or tramadol (Topalgic®), again for a short period when an NSAID could not be prescribed.

Tricyclic antidepressants or serotonin-noradrenaline reuptake inhibitors may be indicated in the chronic phase when neuropathic pain is present after assessment with an appropriate questionnaire such as DN4, or when pain is associated with an anxiety-depressive syndrome.

Gabapentinoids may also be prescribed for chronic radicular pain with a neuropathic component. No conclusion could be reached regarding nefopam (Acupan®) or muscle relaxants because of the absence of studies. Antibiotics, vitamin D, anti-TNF-alpha agents and lidocaine patches have no place in the management of low back pain. The HAS considered that corticosteroids might be used during acute flares when no contraindication is present.

Non-pharmacological Management

The HAS recommended resuming adapted activity, particularly sport. It advised self-management of pain and an early return to work. Manual techniques, including physiotherapy and osteopathy, were recommended as second-line interventions.

As third-line management, a physical, psychological and social rehabilitation programme was recommended, particularly in a specialist physical and rehabilitation medicine (PRM) centre. Orthopaedic insoles were not recommended. Patients could use sophrology or hypnosis. A lumbar belt might be considered for a short period to promote an early return to activity.

For pain with a neuropathic component, spinal cord stimulation might be considered after multidisciplinary management. Radiofrequency treatment may be performed in a specialist centre. Physiotherapy is appropriate when the patient is actively involved in care and performs at home the exercises demonstrated by the physiotherapist. The McKenzie method is frequently used in spinal rehabilitation.

Spinal injections have no role in the absence of radicular pain. When radicular pain is present, they may be considered after an adequately conducted course of treatment and after imaging.

Partie 2 : LOMBALGIE CHRONIQUE OU À RISQUE DE CHRONICITÉ

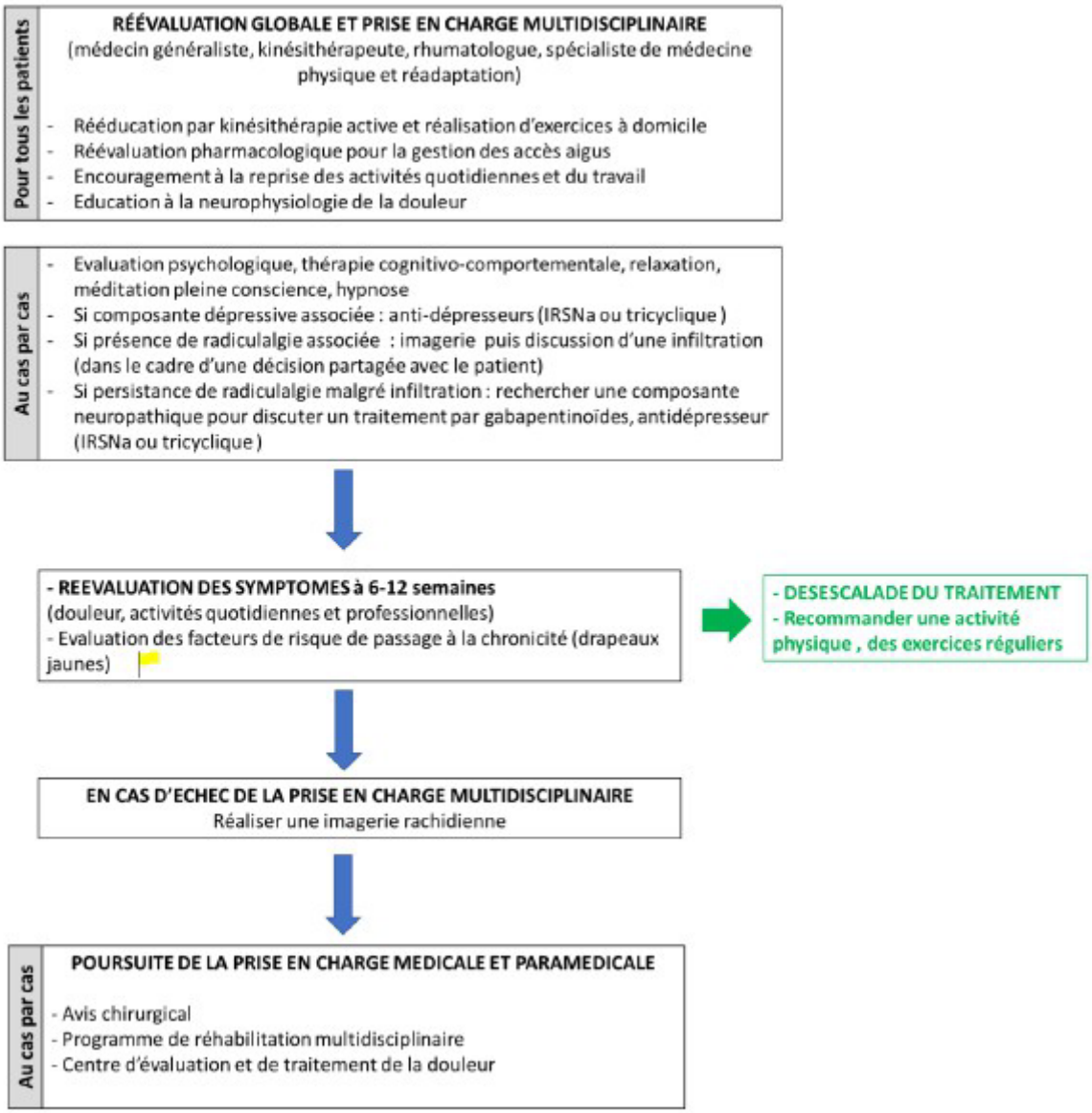

Figure 8. Management of chronic low back pain or risk of chronicity. (26)

VI. SCENAR Results at Poitiers University Hospital

1. Retrospective Study

We know that 90% of acute low back pain resolves spontaneously within one month. What, however, happens in chronic low back pain?

Management of chronic low back pain is more complex because pain may become established and never leave the patient. Surgery can be effective when the indication is appropriate and carefully considered. Nevertheless, many patients must learn to manage their pain in daily life.

The SCENAR device was introduced at Poitiers University Hospital in 2013 by Professor Rigoard and is used in the management of chronic pain, including chronic low back pain. We analysed data from 185 patients treated with SCENAR therapy between 2013 and 2018 after the indication had been established by a spinal surgeon. Treatment was administered by a nurse trained to use the device. Because this was not initially designed as a formal study, only the VAS was assessed (Appendix 5).

The analysis therefore included 185 patients, with or without previous lumbar-spine surgery: 74 men and 111 women aged 19 to 85 years, with a mean age of 50.11 years. There were three indications: 88 cases of low back pain, 16 cases of low back pain with femoral neuralgia (cruralgia), and 81 cases of lumbosciatica. The mean number of sessions was 6.98, with an average frequency of one session per week (Appendix 5).

Mean VAS at the beginning of therapy was 6.18/10, with a median of 6.19/10 and a range from 1/10 to 10/10. Mean VAS at the end of therapy was 3.9/10, with a median of 3.5/10 and a range from 0/10 to 10/10 (Appendix 5).

Closer analysis showed that VAS decreased by more than 50% in 60 patients, representing 32% of the sample. Forty patients experienced a reduction of 30% to 50% (22%), and 34 patients reported a reduction of 1% to 29% (18%). Finally, 47 participants did not improve during the treatment protocol, representing 25% of all patients; 15 of these reported an exacerbation of pain.

> **Source-data clarification:** the four response categories reported in the French narrative total 181 patients (60 + 40 + 34 + 47), whereas the cohort is stated to contain 185 patients. The source does not allocate the remaining four patients to a response category.

Overall, VAS decreased by 37.08% across the 185 analysed patients (Appendix 5).

Following these encouraging results, we proposed a prospective evaluation of effectiveness in terms of pain, medication use and quality of life.

2. Prospective Study

a) Introduction

As shown above, SCENAR appears to provide some benefit for spinal and paraspinal pain and for femoral or sciatic radicular pain. However, neither Poitiers University Hospital nor any other centre in France had quantified changes in medication use or quality of life. I therefore proposed retaining the indications already used at the hospital while introducing a new follow-up questionnaire to address these questions.

b) Methods

This was a prospective observational study including 20 patients treated with the SCENAR device at Poitiers University Hospital between January 2019 and September 2020. Treatment was delivered by nurses trained to use the device for low back pain.

The primary objective was to demonstrate a significant improvement in VAS during SCENAR therapy in patients with chronic pain and to determine whether SCENAR could serve as an adjunctive analgesic modality in primary care, as TENS already does.

The secondary objectives were to evaluate a reduction in analgesic medication use and improvement in quality of life.

Eligible patients were men or women aged 18 years or older, without a contraindication to SCENAR therapy, who had chronic low back pain of 3 to 12 months' duration, with or without radicular symptoms, and no indication for surgery after consultation with spinal specialists at Poitiers University Hospital.

Treatment was delivered in two stages. The first comprised five sessions, each one week apart. This was followed by two additional sessions, each one month apart. The protocol therefore comprised seven sessions over three months. Each session had two components: basic treatment and treatment of the painful area, as explained in Section II.2.b.

Patients were assessed before the protocol, after the first five sessions, at the end of the second month, at the end of the third month and at the end of the fourth month. The fourth-month visit consisted solely of assessment. VAS, quality of life and analgesic medication use were evaluated.

At each session, VAS was recorded before and after treatment, together with analgesic medication use. An arbitrary score was assigned to analgesic medication in order to demonstrate change. One point was assigned to use of WHO step-1 medication and NSAIDs, two points to WHO step-2 medication, three points to gabapentinoids and four points to WHO step-3 medication.

The Saint-Antoine Pain Questionnaire is commonly used, but it is longer and more difficult for patients to understand. After discussion with a multidisciplinary chronic-pain team, we therefore selected the Nottingham Health Profile (NHP). It contains simple questions that are readily understood by patients.

The NHP consists of 38 items grouped into six domains representative of quality of life: emotional reactions, energy level or vitality, pain, sleep, physical mobility and social isolation. Answers are dichotomous (yes/no). Each "yes" answer counts as one point and is multiplied by a coefficient in the corresponding domain. Each domain is scored out of 100. The higher the total NHP score, the poorer the perceived quality of life (Appendix 4).

Patients were instructed to continue taking analgesics when necessary.

c) Results and Discussion

Study Population

We studied 20 patients with chronic low back pain of less than 13 months' duration. All had been examined by spinal specialists and had no indication for surgery, regardless of whether they had previously undergone an operation. The group comprised 10 women and 10 men aged 26 to 84 years; mean age was 52.7 years (Appendix 6).

Six patients were lost to follow-up during treatment, representing 30% of the original sample (Figure 9). The COVID-19 epidemic interrupted three courses of treatment, two patients withdrew because of lack of effectiveness and one left the study after a decision was ultimately made to proceed with surgery (Appendix 6).

Among the 20 initially enrolled patients, there were 11 cases of low back pain, eight cases of lumbosciatica, and one case of low back pain with femoral neuralgia (cruralgia). The small sample prevents conclusions regarding socio-occupational categories or associated comorbidities, although there appeared to be a tendency towards patients who had performed, or continued to perform, manual work, heavy lifting or prolonged sitting.

Comparison of the original 20 patients and the 14 patients who completed the study showed that the two populations were very similar in demographics, VAS, quality of life and baseline medication use.

Mean age in the original population was 52.7 years, with a median of 51 years and a range of 26-84 years. The final population was similar, with a mean age of 52.07 years, a median of 50.5 years and the same range of 26-84 years.

Symptom duration was also similar. In the initial 20 patients, mean duration was 9.75 months, with a median of 10.5 months and a range of 4-12 months. In the 14 remaining patients, mean duration was 9.43 months, with a median of 9.5 months and the same range of 4-12 months (Appendix 6).

VAS values were again similar: mean 5.825 versus 5.82, median 5.75 versus 6.5 and identical ranges of 2-9/10. The 95% confidence intervals overlapped: [4.90-6.75] versus [4.568-7.075] (Appendix 7).

Quality-of-life values were also similar, with a mean number of affirmative responses of 13.3 versus 13.57, medians of 14 versus 15, and ranges of 2-29 in the 20 enrolled patients versus 2-21 in the 14 completers. The 95% confidence intervals overlapped: [10.53-16.07] versus [9.804-17.34] (Appendix 9).

> **Source-data clarification:** the narrative text in the French source reverses these two ranges. The order used here follows the patient-level data in Appendix 9: 2-29 for the full cohort and 2-21 for the completer cohort.

Analgesic-use scores were likewise comparable: mean 1.85 versus 2.14, medians of 1.5 versus 2, and identical ranges of 0-8. The 95% confidence intervals again overlapped: [0.86-2.84] versus [0.768-3.518] (Appendix 11).

This brief analysis indicates that loss of six patients did not change the type of population analysed, although the smaller sample probably reduced the statistical significance of the tests.

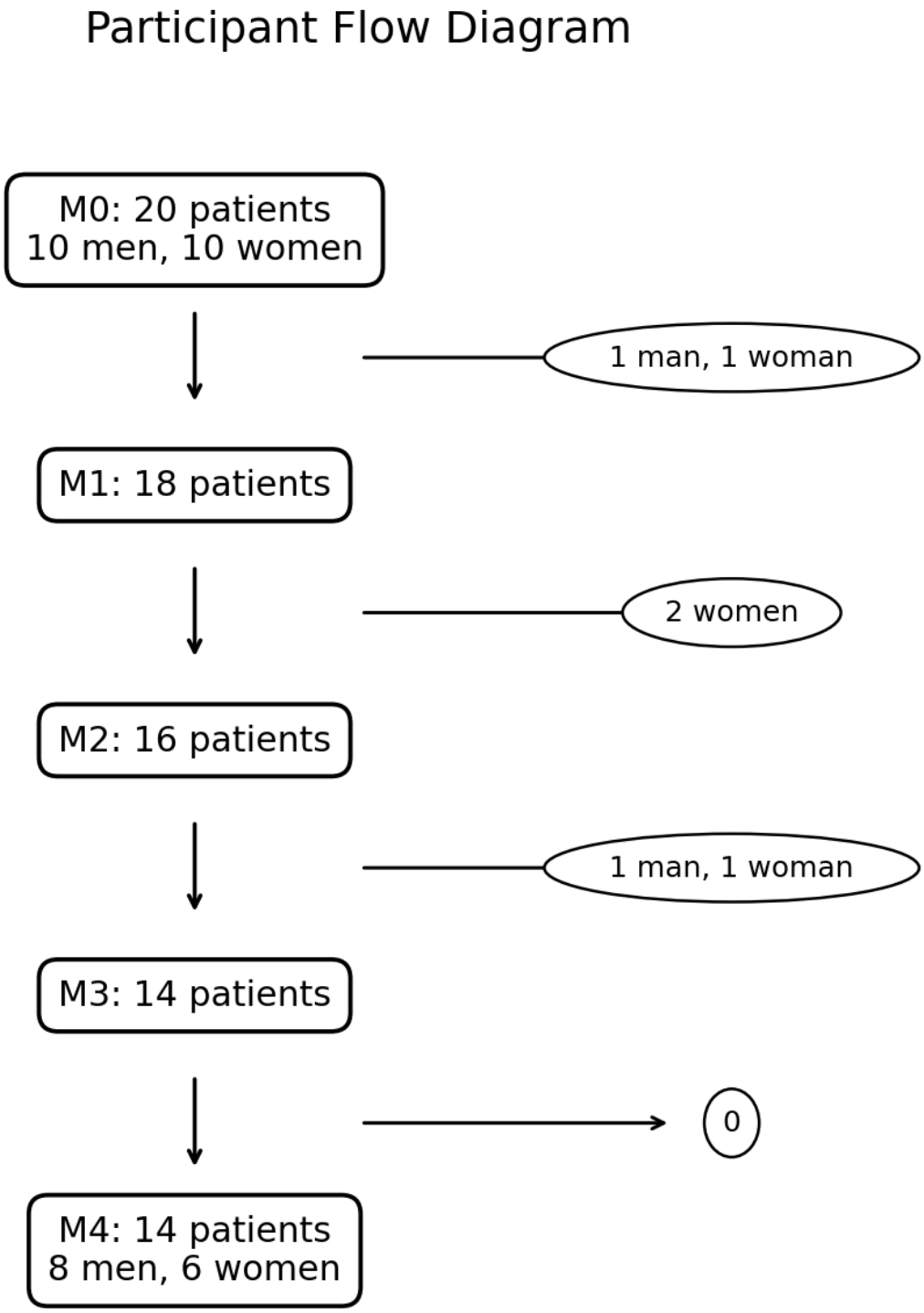

Figure 9. Participant flow diagram.

Pain

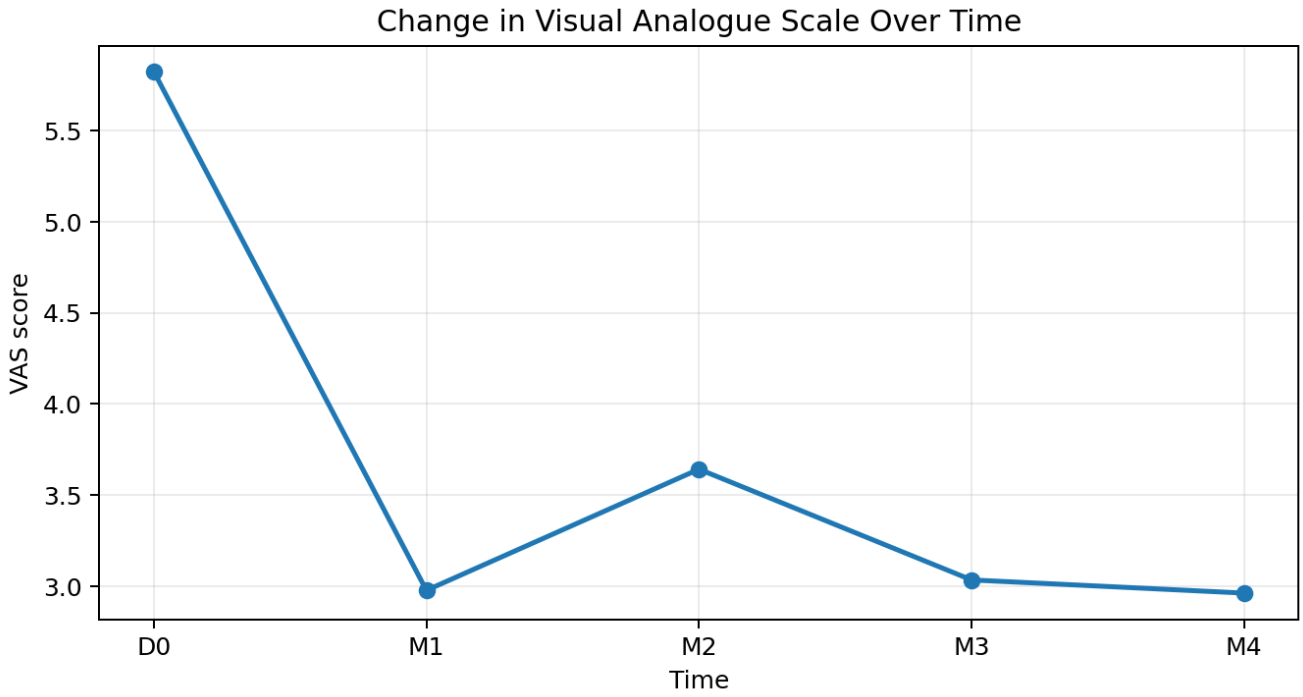

Figure 10. Change in VAS over time.

Statistic	D0	D28 (M1)	M2	M3	M4
n	14	14	14	14	14
Minimum	2	0	0	0	0
25th percentile	3.875	0.875	1.375	0.375	0.375
Median	6.5	1.5	3.5	2.25	3.25
75th percentile	7.625	5.375	5.5	4.875	5.25
Maximum	9	8	8	10	8
Mean	5.821	2.979	3.643	3.036	2.964
Standard deviation	2.172	2.917	2.763	3.171	2.627
Standard error	0.5804	0.7795	0.7383	0.8475	0.7022
Lower 95% CI	4.568	1.295	2.048	1.205	1.447
Upper 95% CI	7.075	4.663	5.238	4.867	4.481
Sum	81.5	41.7	51	42.5	41.5

Figure 11. Main VAS results.

Initial pain ranged from 2 to 9 on the VAS, with a mean of 5.821 (95% CI [4.568-7.075]). At the end of the study, mean VAS among the 14 remaining patients was 2.964 (95% CI [1.447-4.481]), representing a 49% reduction between the first day and the fourth-month assessment (Figures 10 and 11).

Using the Wilcoxon signed-rank test, VAS decreased significantly between D0 and D28 (M1): 5.821, 95% CI [4.568-7.075], versus 2.979, 95% CI [1.295-4.663], $p < 0.001$. The reduction between D0 and M2 was not significant: 5.821, 95% CI [4.568-7.075], versus 3.643, 95% CI [2.048-5.238], $p = 0.0576$. The reduction was significant between D0 and M3: 5.821, 95% CI [4.568-7.075], versus 3.036, 95% CI [1.205-4.867], $p = 0.0315$. At the end of the protocol, VAS was again significantly lower: 5.821, 95% CI [4.568-7.075], versus 2.964, 95% CI [1.447-4.481], $p = 0.0034$.

> **Source-data clarification:** the French narrative gives the M2 mean VAS as 3.543, whereas Figures 11 and 21 and the underlying summary table give 3.643. The tabulated value, 3.643, is retained throughout this translation.

Effectiveness was apparent from the first month and then reached a plateau. This effect was probably related to the treatment schedule and repetition of weekly sessions. Closer examination shows that pain sometimes recurred when sessions were spaced further apart in weak or moderate responders; good responders had similar VAS values at the end of the first month and at the end of the fourth month.

Among the 14 patients who completed the protocol, seven experienced a VAS reduction of more than 50%, two a reduction of 30% to 50%, and two a reduction of less than 30%. Three reported no improvement at all with SCENAR.

Patients lost to follow-up generally did not improve in terms of pain. Overall, among the 20 initial patients, 11 had improved pain and nine had not improved at the time they left the study (Appendix 7).

Session-by-session analysis shows that most patients responded during individual sessions. Of the 20 initial patients, 75% (15/20) reduced their VAS by more than 50%. Some reported no pain at the end of a session despite high VAS values on arrival.

Of the six patients who discontinued, only two were weak or non-responders to treatment; the other four were generally good responders during sessions (Appendix 7). In such a small sample, it is not possible to determine whether effectiveness during the first sessions has predictive value for long-term effectiveness.

The mean duration of the analgesic effect increased as sessions progressed (Appendix 8), followed by a plateau of approximately 10 to 14 days after sessions were spaced further apart. It may therefore be concluded that repeated sessions produce a more marked and durable effect. Continuing weekly sessions throughout the second month might have produced even more convincing results.

However, these means are biased because some patients experienced complete analgesic relief throughout the first week, or throughout the subsequent month, and were assessed while the analgesic effect was still complete. The true duration of effectiveness in these patients is therefore unknown. Among patients lost to follow-up, duration of effectiveness was almost nil in three and only a few days in the other three (Appendix 8).

Quality of Life According to the NHP

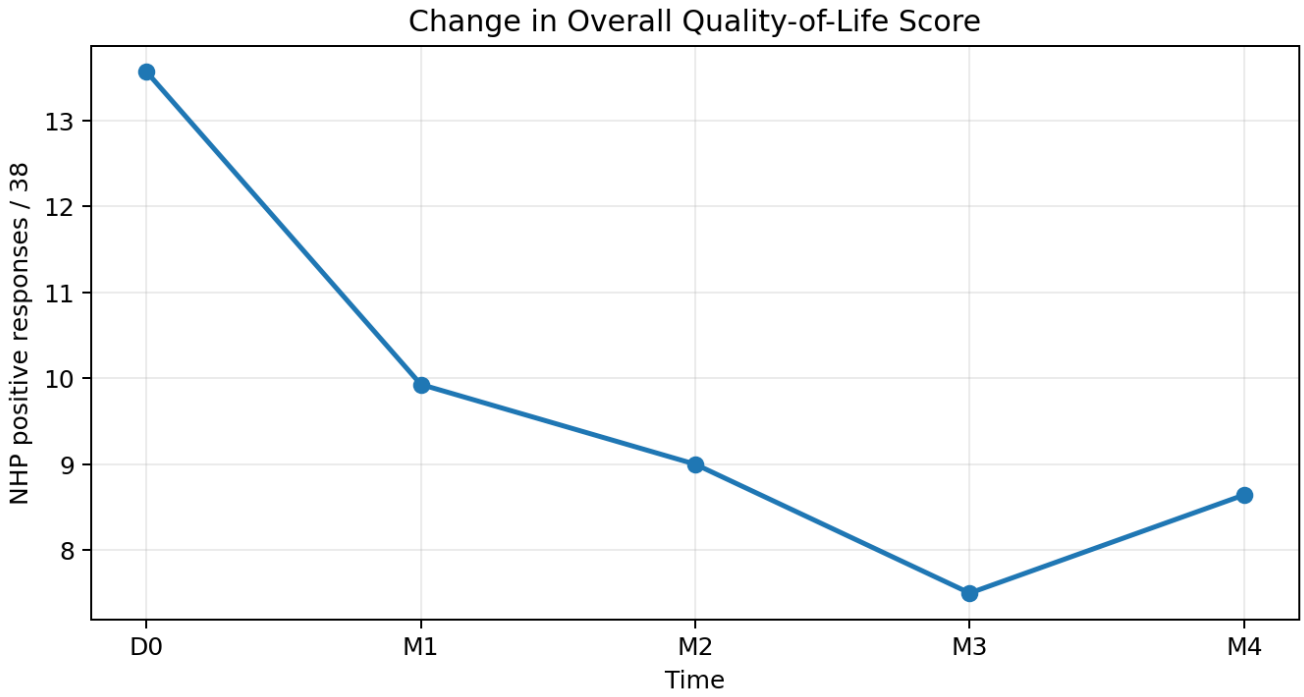

Figure 12. Change in quality-of-life score.

Statistic	D0	M1	M2	M3	M4
n	14	14	14	14	14
Minimum	2	2	1	0	0
25th percentile	9.5	3.75	3.75	2.75	2.25
Median	15	9.5	8	7	7
75th percentile	19.25	14	11.75	11.25	13.25
Maximum	21	22	23	20	23
Mean	13.57	9.929	9	7.5	8.643
Standard deviation	6.525	6.662	6.469	5.841	6.89
Standard error	1.744	1.78	1.729	1.561	1.842
Lower 95% CI	9.804	6.082	5.265	4.128	4.664
Upper 95% CI	17.34	13.77	12.74	10.87	12.62
Sum	190	139	126	105	121

Figure 13. Main overall quality-of-life results.

Quality of life, a cornerstone of health, was assessed using the 38-item Nottingham Health Profile. Each “yes” response is adverse. At the beginning of treatment, patients gave a mean of 13.57 “yes” responses, compared with 8.643 at the end of the protocol, representing a global quality-of-life improvement of 36.3% (Figure 12).

According to the Wilcoxon signed-rank test, the difference between D0 and D28 (M1) was not significant: 13.57, 95% CI [9.804-17.34], versus 9.929, 95% CI [6.082-13.77], p = 0.0552. The difference between D0 and M2 was significant: 13.57, 95% CI [9.804-17.34], versus 9.0, 95% CI [5.265-12.74], p = 0.033. Between D0 and M3, the number of checked boxes decreased significantly, indicating a significant improvement in overall quality of life: 13.57, 95% CI [9.804-17.34], versus 7.5, 95% CI [4.128-10.87], p = 0.0155. At M4, the difference remained

significant, indicating that quality of life was significantly better at the end than at the beginning of treatment: 13.57, 95% CI [9.804-17.34], versus 8.643, 95% CI [4.664-12.62], p = 0.0322.

Detailed analysis shows an improving curve that begins to reverse between M3 and M4, possibly as a consequence of spacing the sessions further apart.

Among the 14 patients still present at the end of the study, quality of life improved by more than 50% in five, by 30% to 50% in one, and by less than 30% in three. Five patients experienced no improvement or a deterioration. Among patients who discontinued after at least participating in the M1 assessment, all four were non-responders in terms of quality of life.

We then examined the individual NHP domains. Social isolation was not discussed in detail because few patients experienced it (Appendix 10). Mobility, pain, emotional reactions, sleep and energy were analysed successively. Each domain is scored from 0 to 100, with a higher score indicating a greater adverse impact.

NHP Physical Mobility Domain

Patient	Sex	D0	M1	M2	M3	M4
1	M	46.41	32.59	21.15	21.15	21.15
2	F	21.15	11.46	0	11.46	0
3	M	33.17	33.17	37.26	37.26	21.15
4	M	33.31	33.17	11.46	11.46	21.15
5	F	72.21	33.17	21.15	9.69	9.69
6	M	78.29	78.29	78.26	45.19	78.29
7	F	22.92	11.46			
8	F	9.69	0	0	0	0
9	M	34.97	48.75	50.5	79.47	60.19
10	M	41.1	32.59	44.61		
11	F	58.43				
12	M	21.71				
13	F	21.15	34.97			
14	M	0	9.69	0	0	0
15	F	34.92	0	11.46	0	0
16	M	41.68	58.43	58.43	34.97	58.43
17	F	44.61	44.61	11.46	11.46	22.9
18	F	0	0	0	0	0
19	M	32.59	21.15	32.59		
20	F	0	0	12.02	21.71	12.02
Baseline statistics for all 20 enrolled patients						
Mean		**32.37578947**				
Median		**33.31**				
Standard deviation		**22.37504272**				
95% CI		**[21.90-42.85]**				
Statistics for the 14 patients who completed follow-up						
Mean		**32.17**	**27.38**	**22.37**	**20.27**	**21.78**
Median		**34.12**	**32.88**	**11.74**	**35.54**	**16.59**
Standard deviation		**24.69**	**24.81**	**24.66**	**22.57**	**25.76**
95% CI		**[17.91-46.43]**	**[13.06-41.71]**	**[8.129-36.61]**	**[7.242-33.3]**	**[6.909-36.66]**

Figure 14. NHP physical-mobility-domain results.

The mean mobility score fell from 32.17 at baseline to 21.78 at M4, representing an unadjusted improvement of 32.3%. According to the Wilcoxon signed-rank test, improvement between D0 and D28 (M1) was not significant: 32.17, 95% CI [17.91-46.43], versus 27.38, 95% CI [13.06-41.71], p = 0.4258.

The score again improved at M2 but remained non-significant: 32.17, 95% CI [17.91-46.43], versus 22.37, 95% CI [8.129-36.61], p = 0.0923. Improvement was greatest at M3, but remained non-significant: 32.17, 95% CI [17.91-46.43], versus 20.27, 95% CI [7.242-33.3], p = 0.0884. At M4, despite an unadjusted improvement of 32.3%, the result was not significant: 32.17, 95% CI [17.91-46.43], versus 21.78, 95% CI [6.909-36.66], p = 0.1475.

A clear trend towards improved mobility was observed, but it was not significant in this sample of 14 patients. Eight of the 14 patients improved over four months, while six did not improve or experienced worse mobility. Of those six, three had no baseline mobility impairment (initial score 0); only one of these developed a higher score. The other three were stable or worsened.

NHP Pain Domain

Patient	D0	M1	M2	M3	M4
1	100	42.36	48.33	48.33	22.42
2	82.34	32.86	43.22	9.69	0
3	70.94	70.94	72.76	72.76	32.86
4	89.56	53.76	42.36	73.67	71.42
5	100	37.41	0	0	9.58
6	41.89	59.55	59.55	41.89	59.55
7	37.71	47.29			
8	40.56	50.44	58.89	22.42	78.16
9	61.84	100	70.46	81.86	100
10	70.94	52.8	100		
11	100				
12	37.41				
13	65.43	58.69			
14	12.73	22.42	12.73	0	0
15	100	22.42	32.78	32	0
16	100	71.9	82.34	71.9	82.34
17	82.34	51.47	60.58	9.58	52.8
18	10.36	0	0	12.73	0
19	88.6	32.78	70.94		
20	27.83	27.83	50.14	50.14	50.14
Baseline statistics for all 20 enrolled patients					
Mean	**64.78526316**				
Median	**70.94**				
Standard deviation	**31.01184711**				
95% CI	**[50.27-79.30]**				
Statistics for the 14 patients who completed follow-up					
Mean	**65.74**	**45.95**	**45.3**	**37.64**	**39.95**
Median	**76.64**	**46.4**	**49.24**	**36.95**	**41.5**
Standard deviation	**33.25**	**25.3**	**25.94**	**29.4**	**35.27**
95% CI	**[46.54-84.94]**	**[31.35-60.56]**	**[30.32-60.27]**	**[20.67-54.61]**	**[19.58-60.31]**

Figure 15. NHP pain-domain results.

An unadjusted improvement of 39.2% was observed in the pain domain, with the mean falling from 65.74 at baseline to 39.95 at M4. According to the Wilcoxon signed-rank test, the difference in perceived pain between D0 and D28 (M1) was not significant: 65.74, 95% CI [46.54-84.94], versus 45.95, 95% CI [31.35-60.56], p = 0.064. The difference between D0 and M2 was likewise non-significant: 65.74, 95% CI [46.54-84.94], versus 45.3, 95% CI [30.32-60.27], p = 0.0942.

At M3, improvement in pain became significant: 65.74, 95% CI [46.54-84.94], versus 37.64, 95% CI [20.67-54.61], p = 0.0398. At M4, however, the difference compared with D0 was no longer significant: 65.74, 95% CI [46.54-84.94], versus 39.95, 95% CI [19.58-60.31], p = 0.1189. A slight deterioration in pain was therefore observed between M3 and M4.

Among the 14 patients present at the end of the study, seven reported an improvement in pain of more than 50%, one an improvement of 30% to 50%, and two an improvement of less than 30%. Four experienced worsening pain.

Comparison of Figure 15 with Appendix 7 shows that, among the four non-responders in the NHP pain domain, two did not improve or had a higher VAS (patients 9 and 20), while two showed partial VAS improvement (patients 6 and 8). Patient 16, who reported no improvement in pain (VAS 3.5), was among those whose NHP pain-domain score improved by less than 30%. There was therefore good correlation between VAS responses and the NHP pain domain.

NHP Emotional Reactions Domain

Patient	D0	M1	M2	M3	M4
1	22.11	0	0	0	0
2	31.57	0	0	0	0
3	12.13	12.13	10.83	10.83	0
4	19.71	0	0	12.13	8.87
5	21	0	0	0	0
6	0	0	0	0	12.13
7	0	12.13			
8	51.57	31.86	42.4	19.44	39.44
9	7.58	40.77	31.86	17.78	8.87
10	8.87	8.87	0		
11	92.46				
12	8.87				
13	0	0			
14	0	0	0	0	0
15	0	8.91	0	0	0
16	8.87	43.15	43.15	43.15	43.15
17	34.24	34.24	0	0	10.57
18	21.29	17.78	8.87	21.29	21.29
19	8.91	0	43.15		
20	0	0	0	0	8.87
Baseline statistics for all 20 enrolled patients					
Mean	**17.459**				
Median	**8.89**				
Standard deviation	**22.45**				
95% CI	**[6.95-27.97]**				
Statistics for the 14 patients who completed follow-up					
Mean	**16.43**	**13.49**	**9.794**	**8.901**	**10.94**

Patient	D0	M1	M2	M3	M4
Median	**15.92**	**4.455**	**0**	**0**	**8.87**
Standard deviation	**15.45**	**16.89**	**16.47**	**12.9**	**14.38**
95% CI	**[7.514-25.35]**	**[3.739-23.24]**	**[0.282-19.31]**	**[1.451-16.35]**	**[2.638-19.25]**

Figure 16. NHP emotional-reactions-domain results.

An unadjusted improvement of 33.4% was observed between the initial and final emotional-reactions scores, from 16.43 to 10.94. Although this is not negligible, statistical analysis did not confirm significance.

According to the Wilcoxon signed-rank test, the reduction between D0 and D28 (M1) was not significant: 16.43, 95% CI [7.514-25.35], versus 13.49, 95% CI [3.739-23.24], p = 0.707. The difference between D0 and M2 remained non-significant despite the continuing perceived improvement: 16.43, 95% CI [7.514-25.35], versus 9.794, 95% CI [0.282-19.31], p = 0.3223. (The French narrative prints the upper confidence limit as 16.35; Figures 16 and 21 give 19.31, which is retained here.) Improvement at M3 was also not significant: 16.43, 95% CI [7.514-25.35], versus 8.901, 95% CI [1.451-16.35], p = 0.25.

At M4, the quality-of-life score was slightly poorer than at M3. Despite an unadjusted improvement of 33.4% between the beginning and end of the protocol, the difference was again non-significant: 16.43, 95% CI [7.514-25.35], versus 10.94, 95% CI [2.638-19.25], p = 0.2129.

Closer examination shows that seven patients improved and seven did not. Among those who improved in emotional reactions, six improved by more than 50% and one by less than 30%. Of those who did not improve, two had no impairment in this domain and remained unchanged. The other five had a higher or stable perception of impaired quality of life in this domain.

In conclusion, although the final mean favoured improvement, only half of patients improved and some experienced deterioration in quality of life. It is not possible to conclude whether this domain was beneficially affected.

NHP Sleep Domain

Patient	D0	M1	M2	M3	M4
1	73.67	34.31	73.67	20.36	57.17
2	20.36	0	0	0	0
3	0	13.95	0	0	0
4	100	100	30.45	100	57.17
5	13.95	0	0	0	0
6	0	0	0	0	0
7	0	0			
8	100	20.36	83.5	69.55	83.5
9	57.17	34.31	50.81	0	13.95
10	0	0	20.36		
11	26.33				
12	0				
13	0	0			
14	20.36	0	0	0	0
15	57.17	20.36	34.31	0	0
16	100	100	83.5	100	100
17	50.81	50.81	30.45	36.86	73.67
18	16.5	0	16.5	16.5	36.86
19	50.81	34.31	34.31		

Patient	D0	M1	M2	M3	M4
20	0	0	0	0	0
Baseline statistics for all 20 enrolled patients					
Mean	**34.3565**				
Median	**20.36**				
Standard deviation	**36.6413612**				
95% CI	**[17.21-51.5]**				
Statistics for the 14 patients who completed follow-up					
Mean	**43.57**	**26.72**	**28.8**	**24.52**	**30.17**
Median	**35.59**	**17.16**	**23.48**	**0**	**6.975**
Standard deviation	**38.49**	**35.04**	**32.4**	**37.69**	**36.95**
95% CI	**[21.34-65.8]**	**[6.489-46.95]**	**[10.09-47.51]**	**[2.758-46.28]**	**[8.831-51.5]**

Figure 17. NHP sleep-domain results.

The mean sleep score was 30.17 at the end of the protocol compared with 43.57 at baseline, representing an unadjusted improvement of 30.75%.

According to the Wilcoxon signed-rank test, sleep score improved markedly between D0 and D28 (M1), falling from 43.57 to 26.72; the difference was significant: 43.57, 95% CI [21.34-65.8], versus 26.72, 95% CI [6.489-46.95], p = 0.0117. Sleep quality again improved significantly between D0 and M2: 43.57, 95% CI [21.34-65.8], versus 28.8, 95% CI [10.09-47.51], p = 0.0039. (The French narrative prints the upper confidence limit as 45.71; the corresponding tables in Figures 17 and 21 give 47.51, which is retained here.) Improvement remained significant between D0 and M3: 43.57, 95% CI [21.34-65.8], versus 24.52, 95% CI [2.758-46.28], p = 0.0078.

Between D0 and M4, improvement in sleep quality was no longer significant: 43.57, 95% CI [21.34-65.8], versus 30.17, 95% CI [8.831-51.5], p = 0.1172.

Among the 14 patients, five experienced an improvement in sleep of more than 50%, one an improvement of 30% to 50%, and two an improvement of less than 30%. Six did not improve. However, three of these six had no sleep impairment at baseline and still had no problem at the end of the protocol; the other three experienced worsening or no change (patients 16, 17 and 18).

Patients enrolled later in the protocol generally improved less, a result that may have been related to the health, economic and social context.

NHP Energy Domain

Patient	D0	M1	M2	M3	M4
1	61.02	0	0	0	0
2	0	0	0	0	0
3	61.02	61.02	26.54	26.54	26.54
4	0	0	0	0	0
5	100	26.54	26.54	0	0
6	0	0	0	0	0
7	65.52	26.54			
8	100	38.98	38.98	0	0
9	100	73.46	100	73.46	73.46
10	0	0	0		
11	100				

Patient	D0	M1	M2	M3	M4
12	0				
13	0	0			
14	0	0	0	0	0
15	26.54	0	65.52	0	0
16	61.02	61.02	26.54	61.02	61.02
17	26.54	65.52	0	0	0
18	26.54	38.98	26.54	65.52	65.52
19	61.02	38.98	100		
20	0	0	0	0	0
Baseline statistics for all 20 enrolled patients					
Mean	**39.461**				
Median	**26.54**				
Standard deviation	**39.83937247**				
95% CI	**[20.82-58.11]**				
Statistics for the 14 patients who completed follow-up					
Mean	**40.19**	**26.11**	**22.19**	**16.18**	**16.18**
Median	**26.54**	**13.27**	**13.27**	**0**	**0**
Standard deviation	**39.87**	**29.53**	**30.05**	**28.35**	**28.35**
95% CI	**[17.17-63.21]**	**[9.059-43.16]**	**[4.842-39.54]**	**[-0.1897-32.55]**	**[-0.1897-32.55]**

Figure 18. NHP energy-domain results.

The mean energy score improved by 59.7%, falling from 40.19 to 16.18. According to the Wilcoxon signed-rank test, improvement between D0 and D28 (M1) was not significant: 40.19, 95% CI [17.17-63.21], versus 26.11, 95% CI [9.059-43.16], p = 0.1406. The reduction between D0 and M2 was also non-significant: 40.19, 95% CI [17.17-63.21], versus 22.19, 95% CI [4.842-39.54], p = 0.1094.

At both M3 and M4, improvement in perceived energy remained non-significant: 40.19, 95% CI [17.17-63.21], versus 16.18, 95% CI [-0.1897-32.55], p = 0.074.

Closer examination showed that six patients improved by more than 50% and one improved by 30% to 50%. Seven patients did not improve, although five of these had no energy impairment either at the beginning or at the end of therapy. Only one patient experienced deterioration in energy during treatment.

Although the results were not significant, the trend was towards improvement among patients who reported low energy at the beginning of the protocol.

Medication Use

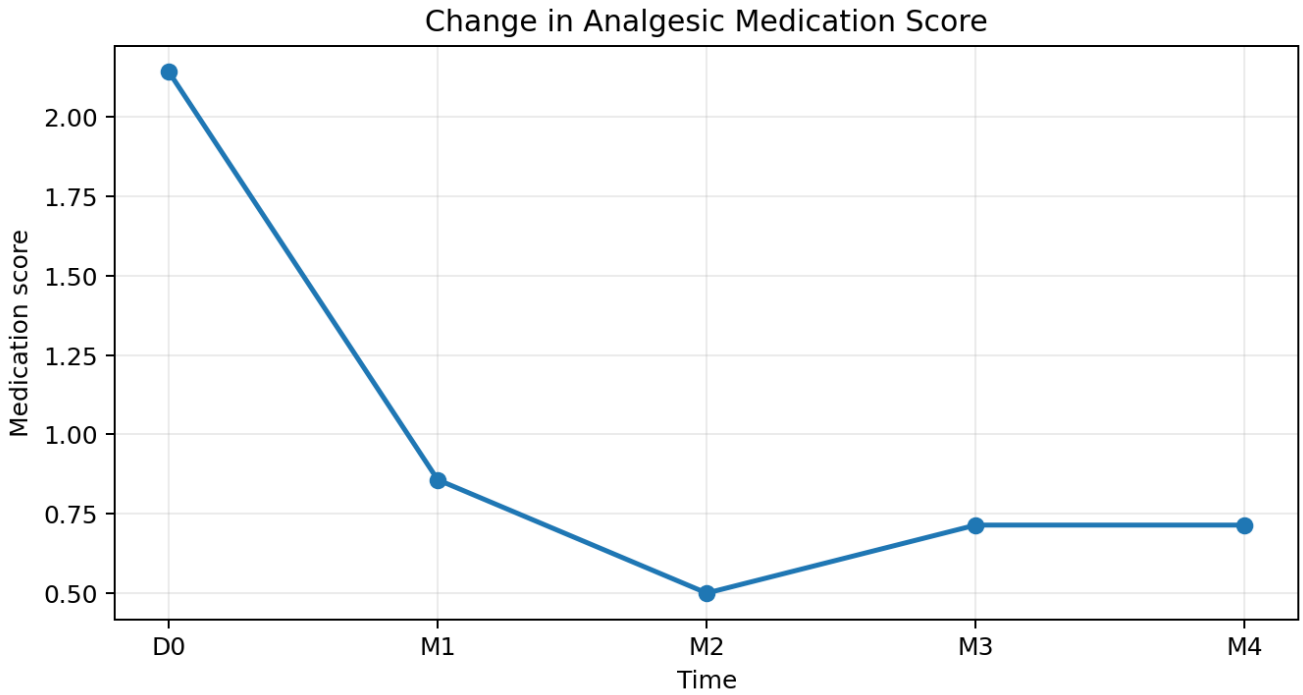

Figure 19. Change in analgesic medication use.

Statistic	D0	D28 (M1)	M2	M3	M4
n	14	14	14	14	14
Minimum	0	0	0	0	0
25th percentile	0	0	0	0	0
Median	2	0	0	0	0
75th percentile	2.5	1.25	1	1	1
Maximum	8	4	3	6	6
Mean	2.143	0.8571	0.5	0.7143	0.7143
Standard deviation	2.381	1.292	0.9405	1.637	1.637
Standard error	0.6364	0.3454	0.2514	0.4376	0.4376
Lower 95% CI	0.768	0.1109	-0.04305	-0.2312	-0.2312
Upper 95% CI	3.518	1.603	1.043	1.66	1.66
Sum	30	12	7	10	10

Figure 20. Main analgesic-use results.

Analgesic use was difficult to analyse and had to be converted into a numerical score. As described above, points were assigned arbitrarily according to medication class: paracetamol and NSAIDs received a coefficient of 1; WHO step-2 agents received 2 points; gabapentinoids received 3 points; and WHO step-3 agents received 4 points. The analysis assessed medication category rather than quantity.

At the beginning of the protocol, mean analgesic score among the 14 patients who completed the study was 2.143 per person. The final mean was 0.7143, representing an overall improvement of 66.7%.

The Wilcoxon signed-rank test showed that improvement between D0 and D28 (M1) was significant: 2.143, 95% CI [0.768-3.518], versus 0.8571, 95% CI [0.1109-1.603], p = 0.0156. Improvement was again significant between D0 and M2: 2.143, 95% CI [0.768-3.518], versus 0.5, 95% CI [-0.04305-1.043], p = 0.0156.

The reduction remained significant between D0 and M3: 2.143, 95% CI [0.768-3.518], versus 0.7143, 95% CI [-0.2312-1.66], p = 0.0156, and between D0 and M4: 2.143, 95% CI [0.768-3.518], versus 0.7143, 95% CI [-0.2312-1.66], p = 0.0313.

After excluding patients lost to follow-up, four patients were taking no analgesic at the beginning of the protocol despite their pain. At the end of therapy, 10 of the 14 patients were taking no medication. No patient increased medication use, although four had the same score as at baseline.

Both patients taking WHO step-3 opioid medication discontinued their step-3 drug, and one of the two patients taking gabapentin stopped it. Improvement in analgesic use was greatest midway through the protocol; a slight increase occurred after sessions were spaced further apart.

Appendix 12 also shows that during the first month, only one patient increased analgesic use; all others reduced or maintained their medication. Among patients who ended the protocol early, only one had no change in medication use (patient 7). The others reduced medication despite generally stable VAS values, which probably contributed to their withdrawal.

d) Conclusion of the Prospective Study

Outcome (mean [95% CI])	D0	D28 (M1)	M2	M3	M4	Improvement D0-M4	Wilcoxon p values: M1 / M2 / M3 / M4
VAS	5.821 [4.568-7.075]	2.979 [1.295-4.663]	3.643 [2.048-5.238]	3.036 [1.205-4.867]	2.964 [1.447-4.481]	49%	<0.001 / 0.0576 / 0.0315 / 0.0034
Global QoL / 38	13.57 [9.804-17.34]	9.929 [6.082-13.77]	9 [5.265-12.74]	7.5 [4.128-10.87]	8.643 [4.664-12.62]	36%	0.0552 / 0.033 / 0.0155 / 0.0322
NHP pain / 100	65.74 [46.54-84.94]	45.95 [31.35-60.56]	45.3 [30.32-60.27]	37.64 [20.67-54.61]	39.95 [19.58-60.31]	39%	0.064 / 0.0942 / 0.0398 / 0.1189
NHP mobility / 100	32.17 [17.91-46.43]	27.38 [13.06-41.71]	22.37 [8.129-36.61]	20.27 [7.242-33.3]	21.78 [6.909-36.66]	32%	0.4258 / 0.0923 / 0.0884 / 0.1475
NHP emotional reactions / 100	16.43 [7.514-25.35]	13.49 [3.739-23.24]	9.794 [0.282-19.31]	8.901 [1.451-16.35]	10.94 [2.638-19.25]	33%	0.707 / 0.3223 / 0.25 / 0.2129
NHP sleep / 100	43.57 [21.34-65.8]	26.72 [6.489-46.95]	28.8 [10.09-47.51]	24.52 [2.758-46.28]	30.17 [8.831-51.5]	31%	0.0117 / 0.0039 / 0.0078 / 0.1172
NHP energy / 100	40.19 [17.17-63.21]	26.11 [9.059-43.16]	22.19 [4.842-39.54]	16.18 [-0.1897-32.55]	16.18 [-0.1897-32.55]	60%	0.1406 / 0.1094 / 0.074 / 0.074
Medication score	2.143 [0.768-3.518]	0.8571 [0.1109-1.603]	0.5 [-0.04305-1.043]	0.7143 [-0.2312-1.66]	0.7143 [-0.2312-1.66]	67%	0.0156 / 0.0156 / 0.0156 / 0.0313

Figure 21. Summary of prospective-study outcomes.

Figure 21 summarises the study. The primary objective was to demonstrate a potential role for SCENAR in the treatment of chronic low back pain with or without radicular symptoms. Despite the small number of participants (14 completers), an overall improvement was observed after SCENAR use.

The primary outcome was change in VAS. VAS decreased significantly between D0 and M4 ($p = 0.0034$).

The NHP analysis also confirmed a significant improvement in overall quality of life ($p = 0.0322$). Analysis of individual NHP domains did not show statistically significant differences at M4, probably because of the small sample size. Nevertheless, substantial improvement between D0 and M4 was observed in each domain.

Analgesic use decreased significantly between D0 and M4 ($p = 0.0313$).

These preliminary findings suggest that SCENAR may be a therapeutic alternative in the management of chronic low back pain. A study involving more patients would be necessary before firm conclusions could be drawn, but the results are encouraging.

VII. Conclusion

Low back pain is a major public health issue in both financial and clinical terms. For example, it represents 7% of consultation results in a general-practice clinic. The real problem is chronic low back pain, which costs approximately EUR 1.05 billion per year in France. No available treatment provides marked relief for all patients.

SCENAR therapy has been used in Poitiers since 2013 to treat these patients. In view of the encouraging results of a retrospective evaluation, it appeared important to conduct a prospective study, particularly because the device could readily be used in general practice.

We therefore analysed VAS, quality of life and medication use in an initial sample of 20 patients. The results were favourable, with statistically significant changes in the principal outcomes.

These findings should be confirmed in a larger patient population. In our opinion, SCENAR therapy deserves further development in France for the management of this type of pain.

Appendices

Appendix 1. CE Certificate

3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE
No. 2017-MDD/QS-014/A

issued in compliance with the Council Directive 93/42/EEC as amended by 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013 Coll. certifies that the medical device of Class IIa,

Impulse therapy medical devices of TENS type (Transcutaneous Electric Nerve Stimulator): CHANS-SCENAR, CHANS-01-SCENAR, CHANS-02-SCENAR, CHANS-SCENAR-M, CHANS-01-SCENAR-M, CHANS-02-SCENAR-M, SCENAR-1-NT (version 01), SCENAR-1-NT (version 02.1), SCENAR-1-NT (version 02.2), SCENAR-1-NT (version 02.3), SCENAR-1-NT (version 03), SCENAR-1-NT (version 01C), SCENAR-1-NT (version 02.1C), SCENAR-1-NT (version 02.2C), SCENAR-1-NT (version 02.3C), SCENAR-1-NT (version 03C)
(for detailed list of trade names and auxiliary electrodes, refer to the Annex pages 1 to 3)

manufactured by the company

RITM OKB ZAO
99, Petrovskaya str., Taganrog, Rostov region, 347900, Russia

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended by 2007/47/EC.

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended by 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 05-006-17, and the Final protocols Nos. 310262/2017 and 310262-A/2017 enclosed to this certificate.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced model of medical device and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until March 7, 2022 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Dr. Katarina Tomin Srdošová
Responsible to act on behalf of NB 2265

In Bratislava, on December 20, 2017
Version A supersedes the EC Certificate No. 2017-MDD/QS-014 issued on March 8, 2017

Appendix 1. CE certificate, page 1 (original certificate already in English).

ANNEX TO EC CERTIFICATE No. 2017-MDD/QS-014/A

issued for the company

RITM OKB ZAO
99, Petrovskaya str., Taganrog, Rostov region, 347900, Russia

List of medical devices covered by the EC Certificate:

Product name: Transcutaneous Electric Nerve Stimulator

CHANS-SCENAR, CHANS-01-SCENAR, CHANS-02-SCENAR, CHANS-SCENAR-M, CHANS-01-SCENAR-M, CHANS-02-SCENAR-M, SCENAR-1-NT (version 01), SCENAR-1-NT (version 02.1), SCENAR-1-NT (version 02.2), SCENAR-1-NT (version 02.3), SCENAR-1-NT (version 03), SCENAR-1-NT (version 01C), SCENAR-1-NT (version 02.1C), SCENAR-1-NT (version 02.2C), SCENAR-1-NT (version 02.3C), SCENAR-1-NT (version 03C)

with add-on electrodes :
Face electrode, Comb electrode, Point electrode, Local electrode, Special Snail electrode, Bent point electrode, Double facial Pawns electrode, Double cosmetic electrode, Double ophthalmic Goggles electrode, Double facial Stamps electrode, Single ophthalmic Monocle electrode, Special double Pencils electrode, Large Comb electrode, Multi-purpose zonal electrode

Page 1 of 3

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Dr. Katarína Tomin Srdošová
Responsible to act on behalf of NB 2265

In Bratislava, on December 20, 2017
Valid until March 7, 2022

Version A supersedes the EC Certificate No. 2017-MDD/QS-014 issued on March 8, 2017

Appendix 1. CE certificate, page 2 (original certificate already in English).

ANNEX TO EC CERTIFICATE No. 2017-MDD/QS-014/A

issued for the company

RITM OKB ZAO
99, Petrovskaya str., Taganrog, Rostov region, 347900, Russia

Trade names of the respective types of the certified medical devices:

Type/Model/Version	Trade (alternative) name
CHANS-SCENAR	RITMSCENAR Home SCENAR Home
CHANS-01-SCENAR	RITMSCENAR Sport SCENAR Sport SCENAR Pain Genie RITMSCENAR Home Device RITMSCENAR Gorfinkel SCENAR Gorfinkel
CHANS-02-SCENAR	RITMSCENAR Basic SCENAR Basic
CHANS-SCENAR-M	RITMSCENAR Home D SCENAR Home D
CHANS-01-SCENAR-M	RITMSCENAR Sport D SCENAR Sport D
CHANS-02-SCENAR-M	RITMSCENAR Basic D SCENAR Basic D

Page 2 of 3

Notified body
NB 2265
NOTIFIKOVANÁ OSOBA

Dr. Katarina Tomin Srdošová
Responsible to act on behalf of NB 2265

In Bratislava, on December 20, 2017
Valid until March 7, 2022

Version A supersedes the EC Certificate No. 2017-MDD/QS-014 issued on March 8, 2017

Appendix 1. CE certificate, page 3 (original certificate already in English).

ANNEX TO EC CERTIFICATE No. 2017-MDD/QS-014/A

issued for the company

RITM OKB ZAO
99, Petrovskaya str., Taganrog, Rostov region, 347900, Russia

Trade names of the respective types of the certified medical devices:

Type/Model/Version	Trade (alternative) name
SCENAR-1-NT (version 01)	RITMSCENAR Pro Prime SCENAR Pro Prime
SCENAR-1-NT (version 02.1)	RITMSCENAR Pro Plus RITMSCENAR Pro + SCENAR Pro Plus SCENAR Pro +
SCENAR-1-NT (version 02.2)	RITMSCENAR Pro Optima SCENAR Pro Optima
SCENAR-1-NT (version 02.3)	RITMSCENAR Pro SCENAR Pro
SCENAR-1-NT (version 03)	RITMSCENAR Pro Essential SCENAR Pro Essential
SCENAR-1-NT (version 01C)	RITMSCENAR Pro Prime C SCENAR Pro Prime C RITMSCENAR Super Pro v.2 bioSCENAR Professional v.2
SCENAR-1-NT (version 02.1C)	RITMSCENAR Pro Plus C RITMSCENAR Pro + C SCENAR Pro Plus C SCENAR Pro + C
SCENAR-1-NT (version 02.2C)	RITMSCENAR Pro Optima C SCENAR Pro Optima C SCENAR Physio
SCENAR-1-NT (version 02.3C)	RITMSCENAR Pro C SCENAR Pro C
SCENAR-1-NT (version 03C)	RITMSCENAR Pro Essential C SCENAR Pro Essential C

Page 3 of 3

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Dr. Katarina Tomin Srdošová
Responsible to act on behalf of NB 2265

In Bratislava, on December 20, 2017
Valid until March 7, 2022

Version A supersedes the EC Certificate No. 2017-MDD/QS-014 issued on March 8, 2017

Appendix 1. CE certificate, page 4 (original certificate already in English).

The certificate and its annexes are reproduced from the source document. They were already issued in English.

Appendix 2. The SCENAR Device

Appendix 2. The SCENAR device.

Appendix 3. Erlanger-Gasser Classification (6)

Fibre type	Diameter (micrometres)	Conduction velocity (m/s)	Myelination	Excitation threshold	Nociceptive role
A-alpha	15-20	90-120, rapid	Myelinated	Low	Non-nociceptive fibre
A-beta	10-15	50-100, rapid	Myelinated	Low	Non-nociceptive fibre
A-gamma	5-10	5-30, slower	Lightly myelinated	Intermediate	Nociceptive fibre
A-delta	1-10	5-30, slower	Myelinated	Intermediate	Nociceptive fibre
B	1-3	3-15, slower	Myelinated	Intermediate	-
C	0.5-1	0.6-2.0, slow	Unmyelinated	High	Nociceptive fibre

Appendix 4. Nottingham Health Profile

Table 1. Nottingham Health Profile Statements

For each statement, the patient selects **Yes** or **No**.

No.	Statement	Yes	No
1	I feel tired all the time.	☐	☐
2	I have pain at night.	☐	☐
3	Things are getting me down.	☐	☐
4	I am in unbearable pain.	☐	☐

No.	Statement	Yes	No
5	I take medication to help me sleep.	☐	☐
6	I have forgotten what it is like to enjoy myself.	☐	☐
7	I feel nervous and tense.	☐	☐
8	I have pain when I change position.	☐	☐
9	I feel lonely.	☐	☐
10	I can only walk indoors, within my home or building.	☐	☐
11	I have difficulty bending forwards, for example to tie my shoes or pick up an object.	☐	☐
12	Everything requires effort.	☐	☐
13	I wake very early in the morning and have difficulty getting back to sleep.	☐	☐
14	I am completely unable to walk.	☐	☐
15	I have difficulty making contact with other people.	☐	☐
16	I feel that the days are endless.	☐	☐
17	I have difficulty going up or down stairs or steps.	☐	☐
18	I have difficulty stretching out my arms to reach objects.	☐	☐
19	I experience pain when I walk.	☐	☐
20	I become angry easily these days.	☐	☐
21	I feel that I have nobody close to me to talk to.	☐	☐
22	I remain awake for a large part of the night.	☐	☐
23	I have difficulty coping with events.	☐	☐
24	I have pain when I am standing.	☐	☐
25	I have difficulty dressing or undressing.	☐	☐
26	I become tired quickly.	☐	☐
27	I have difficulty standing for a long time.	☐	☐

No.	Statement	Yes	No
28	I am in constant pain.	☐	☐
29	It takes me a long time to fall asleep.	☐	☐
30	I feel that I am a burden to other people.	☐	☐
31	Worries prevent me from sleeping.	☐	☐
32	I feel that life is not worth living.	☐	☐
33	I sleep badly at night.	☐	☐
34	I have difficulty getting along with other people.	☐	☐
35	I need help to walk outdoors, such as a cane or another person to support me.	☐	☐
36	I have pain when going up or down stairs or steps.	☐	☐
37	I wake up feeling depressed in the morning.	☐	☐
38	I experience pain when sitting.	☐	☐

Table 2. Coefficients Assigned to Each Item for Calculation of the Nottingham Score

Domain	Item	Coefficient	Domain	Item	Coefficient
Physical mobility	14	19.28	Emotional reactions	32	15.49
Physical mobility	10	13.82	Emotional reactions	6	13.24
Physical mobility	35	13.78	Emotional reactions	23	12.42
Physical mobility	25	12.02	Emotional reactions	3	12.13
Physical mobility	27	11.46	Emotional reactions	37	10.83
Physical mobility	17	11.44	Emotional reactions	31	10.57
Physical mobility	11	9.69	Emotional reactions	16	8.91
Physical mobility	18	8.51	Emotional reactions	7	8.87
Social isolation	30	24.50	Emotional reactions	20	7.58
Social isolation	9	20.43	Energy	1	38.98
Social isolation	21	20.03	Energy	12	34.48
Social isolation	15	18.59	Energy	26	26.54
Social isolation	34	16.36	Sleep	5	26.33
Pain	28	18.14	Sleep	22	22.86

Domain	Item	Coefficient	Domain	Item	Coefficient
Pain	4	17.66	Sleep	33	20.36
Pain	2	12.73	Sleep	29	16.50
Pain	19	11.40	Sleep	13	13.95
Pain	36	10.44			
Pain	24	10.36			
Pain	8	9.69			
Pain	38	9.58			

The coefficients in each domain total 100.

Appendix 5. Retrospective Study

Appendix 5A. Summary statistics reported in the source.

Measure	Source summary
Cohort size	185 patients
Age	Minimum 19 years; maximum 85 years; mean 50.11 years; median 50.15 years
Clinical presentations	Low back pain: 88; lumbocruralgia: 16; lumbosciatica: 81
Symptom duration	Minimum 1 month; maximum 300 months; mean 24.03 months; median 24.17 months
Initial VAS	Minimum 1/10; maximum 10/10; mean 6.18/10; median 6.19/10
Final VAS	Minimum 0/10; maximum 10/10; mean 3.9/10; median 3.5/10
VAS reduction	Minimum 0%; maximum 100%; mean 37.08%
Number of sessions	Mean 6.98; median 6
Sex	74 men; 111 women

Appendix 5B. Patient-level retrospective-study data.

Initials	Age	Clinical presentation	Duration (months)	Initial VAS	Final VAS	Final as % of initial	Change	Sessions	Sex
A/F	50	Low back pain	50	7	3	42.86%	-57.14%	8	F
A/C	40	Low back pain	8	6.3	7	111.11%	11.11%	6	F
A/C	44	Lumbocruralgia	6	7.5	3	40.00%	-60.00%	6	F
A/S	30	Lumbosciatica	10	5	7	140.00%	40.00%	6	M
A/M	62	Lumbosciatica	3	8	2	25.00%	-75.00%	18	F
A/N	55	Lumbocruralgia	6	5	5	100.00%	0.00%	24	F
A/V	43	Low back pain	2.5	6.5	1.5	23.08%	-76.92%	7	F
B/N	55	Lumbosciatica	6	10	10	100.00%	0.00%	5	F
B/I	49	Lumbosciatica	6	7.5	3.6	48.00%	-52.00%	3	F
B/J	80	Low back pain	5	3.5	4	114.29%	14.29%	4	F
B/C	33	Low back pain	3	6.5	5.2	80.00%	-20.00%	5	M
B/JP	57	Low back pain	12	2	3	150.00%	50.00%	11	M
B/P	54	Lumbosciatica	24	8	4	50.00%	-50.00%	10	F
B/M	65	Low back pain	7	8	4	50.00%	-50.00%	12	F
B/B	55	Low back pain	3.5	7.5	1	13.33%	-86.67%	9	F
B/C	51	Low back pain	84	6.9	4.7	68.12%	-31.88%	10	F
B/N	53	Low back pain	36	4.2	2.5	59.52%	-40.48%	15	F
B/C	41	Lumbocruralgia	6	4	4	100.00%	0.00%	5	F
B/C	67	Lumbosciatica	26	6.3	3.5	55.56%	-44.44%	6	F
B/V	46	Lumbosciatica	5	8	8	100.00%	0.00%	3	F
B/M	79	Low back pain	20	8	7	87.50%	-12.50%	4	F
B/M	67	Low back pain	12	4	2	50.00%	-50.00%	6	F

Initials	Age	Clinical presentation	Duration (months)	Initial VAS	Final VAS	Final as % of initial	Change	Sessions	Sex
B/M	53	Low back pain	10	5	1.6	32.00%	-68.00%	5	M
B/G	74	Lumbosciatica	1.5	8	5	62.50%	-37.50%	3	F
B/JC	68	Low back pain	4	6	6	100.00%	0.00%	4	M
B/S	53	Low back pain	4	2	1	50.00%	-50.00%	6	F
B/E	50	Low back pain	24	10	3	30.00%	-70.00%	10	M
B/L	69	Low back pain	9	5	0	0.00%	-100.00%	6	M
B/J	54	Low back pain	18	4	5	125.00%	25.00%	2	M
B/C	39	Low back pain	14	6	2	33.33%	-66.67%	6	M
C/V	57	Low back pain	3	7.4	1.2	16.22%	-83.78%	14	F
C/N	61	Low back pain	54	7	3	42.86%	-57.14%	7	F
C/C	45	Lumbosciatica	2	4	0	0.00%	-100.00%	12	F
C/AC	24	Lumbosciatica	4	6	7	116.67%	16.67%	4	F
C/S	39	Lumbosciatica	36	8	5	62.50%	-37.50%	5	F
C/R	47	Low back pain	120	7	1.5	21.43%	-78.57%	6	M
C/S	38	Low back pain	1.5	4	2	50.00%	-50.00%	12	M
C/P	58	Low back pain	3	7	6	85.71%	-14.29%	7	F
C/AM	50	Low back pain	36	8	6	75.00%	-25.00%	3	F
C/G	77	Lumbosciatica	6	8	3.5	43.75%	-56.25%	2	F
C/I	59	Low back pain	9	7	3.5	50.00%	-50.00%	12	F
C/E	35	Lumbosciatica	24	4	1	25.00%	-75.00%	6	M
C/A	49	Lumbosciatica	60	6	7.5	125.00%	25.00%	7	F
C/D	63	Lumbosciatica	60	3	0	0.00%	-100.00%	3	M
C/D	63	Lumbocruralgia	84	8	4.5	56.25%	-43.75%	16	M
C/J	69	Lumbosciatica	72	5	3	60.00%	-40.00%	10	M
C/P	70	Lumbosciatica	4	7	3.5	50.00%	-50.00%	4	F
C/C	47	Lumbosciatica	8	8	8	100.00%	0.00%	5	F
D/N	45	Low back pain	3	5.5	5	90.91%	-9.09%	5	F
D/B	69	Lumbosciatica	84	8	8	100.00%	0.00%	11	M
D/B	49	Lumbosciatica	25	3.5	3.5	100.00%	0.00%	7	F
D/R	78	Low back pain	4	10	2.5	25.00%	-75.00%	10	F
D/Y	63	Lumbosciatica	6	9	8.5	94.44%	-5.56%	4	F
D/L	24	Low back pain	24	3	0.5	16.67%	-83.33%	4	F
D/C	42	Low back pain	26	8.9	8	89.89%	-10.11%	6	M
D/C	46	Low back pain	36	6	4	66.67%	-33.33%	9	F
D/P	57	Low back pain	12	4	2	50.00%	-50.00%	9	M
D/P	40	Lumbosciatica	5	8	7	87.50%	-12.50%	4	F
E/L	73	Lumbosciatica	15	7	7	100.00%	0.00%	4	F
F/F	42	Lumbosciatica	62	5	2.8	56.00%	-44.00%	6	M
F/C	69	Low back pain	67	8	0	0.00%	-100.00%	9	M

Initials	Age	Clinical presentation	Duration (months)	Initial VAS	Final VAS	Final as % of initial	Change	Sessions	Sex
F/A	33	Lumbosciatica	30	4	2	50.00%	-50.00%	2	M
F/L	53	Low back pain	40	7	6	85.71%	-14.29%	6	F
F/N	41	Low back pain	5	6	3	50.00%	-50.00%	8	F
F/JM	58	Low back pain	96	4	2	50.00%	-50.00%	6	M
F/V	55	Lumbosciatica	9	8.5	6	70.59%	-29.41%	2	F
F/R	79	Lumbosciatica	42	5	5.5	110.00%	10.00%	10	F
F/G	36	Low back pain	17	5	2.5	50.00%	-50.00%	6	M
F/C	26	Lumbosciatica	10	7	0	0.00%	-100.00%	16	F
F/J	31	Lumbosciatica	36	7.5	9	120.00%	20.00%	6	F
G/C	45	Lumbosciatica	12	9	9	100.00%	0.00%	13	F
G/R	61	Lumbosciatica	48	7	4	57.14%	-42.86%	4	F
G/A	38	Lumbosciatica	48	10	10	100.00%	0.00%	4	F
G/F	59	Lumbosciatica	66	2	0	0.00%	-100.00%	6	M
G/A	46	Low back pain	11	9	9	100.00%	0.00%	9	F
G/C	50	Lumbosciatica	20	8	5.5	68.75%	-31.25%	5	F
G/E	41	Lumbosciatica	11	7.5	9	120.00%	20.00%	10	F
G/C	61	Lumbosciatica	12	7.5	8	106.67%	6.67%	7	F
G/A	35	Lumbosciatica	13	6	1.5	25.00%	-75.00%	6	F
G/M	65	Lumbosciatica	31	7	2	28.57%	-71.43%	20	F
G/JP	44	Lumbosciatica	84	5.5	5.5	100.00%	0.00%	2	M
G/Y	64	Low back pain	6	6.5	1	15.38%	-84.62%	9	F
G/A	40	Lumbosciatica	24	5	5	100.00%	0.00%	9	F
G/MF	50	Low back pain	4	10	5	50.00%	-50.00%	8	F
G/K	49	Lumbosciatica	12	9	8	88.89%	-11.11%	5	F
GM/P	39	Lumbocruralgia	2	8	3	37.50%	-62.50%	18	M
G/J	42	Low back pain	3	3	3	100.00%	0.00%	5	M
G/MC	68	Low back pain	36	3	0	0.00%	-100.00%	15	F
G/C	41	Lumbocruralgia	12	4	6	150.00%	50.00%	6	F
G/F	45	Lumbocruralgia	4	2.5	2.2	88.00%	-12.00%	5	F
G/I	42	Low back pain	18	7	3.5	50.00%	-50.00%	5	F
G/JM	52	Lumbosciatica	48	7	7	100.00%	0.00%	4	M
G/MT	64	Low back pain	1	10	8	80.00%	-20.00%	3	F
G/F	47	Low back pain	12	9	5	55.56%	-44.44%	3	M
HH/MC	57	Lumbosciatica	96	4.5	0	0.00%	-100.00%	3	F
H/E	24	Lumbosciatica	11	4.2	3.7	88.10%	-11.90%	4	M
H/JY	60	Low back pain	15	6.5	2	30.77%	-69.23%	9	M
H/C	66	Lumbocruralgia	6	7	6	85.71%	-14.29%	3	F
H/JM	59	Low back pain	48	10	8	80.00%	-20.00%	4	M
J/F	70	Low back pain	7	7	6.5	92.86%	-7.14%	4	F

Initials	Age	Clinical presentation	Duration (months)	Initial VAS	Final VAS	Final as % of initial	Change	Sessions	Sex
J/S	40	Lumbosciatica	24	6	0	0.00%	-100.00%	7	F
J/D	48	Lumbocruralgia	1.5	4	7	175.00%	75.00%	4	M
J/Y	73	Low back pain	50	7.5	4	53.33%	-46.67%	6	M
K/C	59	Lumbocruralgia	11	5	3	60.00%	-40.00%	5	F
K/G	67	Low back pain	72	3	2	66.67%	-33.33%	13	M
K/I	45	Lumbocruralgia	300	7	7	100.00%	0.00%	6	F
L/D	78	Lumbosciatica	60	8	8	100.00%	0.00%	10	F
L/R	85	Lumbosciatica	12	9	4	44.44%	-55.56%	5	M
L/A	41	Lumbosciatica	10	8	4	50.00%	-50.00%	17	F
L/JY	63	Low back pain	12	2	0	0.00%	-100.00%	6	M
L/A	32	Low back pain	6	2.5	3.5	140.00%	40.00%	5	F
L/L	44	Low back pain	16	5.5	0.7	12.73%	-87.27%	15	M
L/A	43	Lumbosciatica	7	8	1.5	18.75%	-81.25%	8	M
L/M	72	Low back pain	24	5	2	40.00%	-60.00%	7	M
L/C	25	Lumbosciatica	60	7.4	0.2	2.70%	-97.30%	8	F
LR/F	74	Low back pain	40	8	7.5	93.75%	-6.25%	4	F
L/M	58	Lumbosciatica	12	6.5	5	76.92%	-23.08%	6	M
L/B	55	Lumbocruralgia	1	3	3	100.00%	0.00%	3	M
M/JC	73	Low back pain	18	8	1	12.50%	-87.50%	10	M
M/M	61	Lumbosciatica	3	5.5	1.9	34.55%	-65.45%	6	F
M/R	46	Low back pain	3	4.5	1	22.22%	-77.78%	6	F
M/C	39	Low back pain	2.5	6	3	50.00%	-50.00%	6	F
M/P	24	Lumbosciatica	1.5	4.5	3.5	77.78%	-22.22%	3	M
MF/S	45	Lumbosciatica	4	3	3	100.00%	0.00%	6	F
M/C	55	Lumbosciatica	72	10	5	50.00%	-50.00%	4	F
M/G	57	Low back pain	89	3.5	2.5	71.43%	-28.57%	8	M
M/R	30	Lumbosciatica	12	4	4	100.00%	0.00%	3	M
MJ/S	41	Lumbosciatica	24	4	3	75.00%	-25.00%	10	M
M/N	50	Low back pain	60	1	1	100.00%	0.00%	5	F
M/JF	54	Low back pain	24	7	6	85.71%	-14.29%	4	M
M/A	37	Lumbosciatica	13	8	4	50.00%	-50.00%	5	M
M/C	25	Lumbosciatica	3	7	4	57.14%	-42.86%	3	F
M/AS	31	Lumbosciatica	12	6.5	6.5	100.00%	0.00%	4	F
M/C	56	Low back pain	6	6.5	5.5	84.62%	-15.38%	14	F
M/JM	83	Low back pain	18	3.5	3	85.71%	-14.29%	11	M
M/H	23	Low back pain	2	7.5	2.5	33.33%	-66.67%	11	F
M/S	46	Lumbosciatica	4	7	4.5	64.29%	-35.71%	3	F
M/M	49	Lumbosciatica	28	9	2.7	30.00%	-70.00%	6	F
M/E	48	Low back pain	36	5	5	100.00%	0.00%	3	M

Initials	Age	Clinical presentation	Duration (months)	Initial VAS	Final VAS	Final as % of initial	Change	Sessions	Sex
M/C	44	Low back pain	39	9	6	66.67%	-33.33%	4	M
P/K	49	Lumbosciatica	8	9	5	55.56%	-44.44%	8	F
P/G	50	Low back pain	5	7	7	100.00%	0.00%	6	M
P/N	41	Low back pain	9	7	6.5	92.86%	-7.14%	5	M
P/A	28	Lumbosciatica	8	3	4	133.33%	33.33%	8	F
P/D	45	Lumbocruralgia	72	7	1	14.29%	-85.71%	22	M
P/L	30	Lumbocruralgia	1	4.5	4.5	100.00%	0.00%	5	M
P/E	38	Low back pain	8	1	0.3	30.00%	-70.00%	4	M
P/E	67	Low back pain	7	5	0.7	14.00%	-86.00%	13	F
P/FX	39	Lumbosciatica	1.5	3	0.2	6.67%	-93.33%	6	M
R/E	45	Low back pain	12	5	7	140.00%	40.00%	2	M
R/L	45	Low back pain	108	2.5	2.5	100.00%	0.00%	2	F
R/S	41	Low back pain	6	2.9	0.8	27.59%	-72.41%	3	M
R/A	39	Low back pain	48	8.9	0.3	3.37%	-96.63%	5	F
R/D	66	Lumbosciatica	7	8	0	0.00%	-100.00%	6	F
R/F	41	Lumbosciatica	1	6	6	100.00%	0.00%	10	F
R/MA	62	Low back pain	7	5.5	0	0.00%	-100.00%	6	F
R/M	54	Low back pain	12	9	1	11.11%	-88.89%	7	F
R/B	49	Lumbosciatica	6	7.5	7	93.33%	-6.67%	7	M
R/M	36	Lumbosciatica	12	7	7	100.00%	0.00%	4	F
R/Y	38	Lumbocruralgia	36	10	0.5	5.00%	-95.00%	6	M
R/C	49	Lumbosciatica	24	5	5	100.00%	0.00%	17	F
S/L	45	Lumbosciatica	6	8.7	5.4	62.07%	-37.93%	6	F
S/E	44	Lumbosciatica	12	7.8	6.6	84.62%	-15.38%	5	M
S/C	48	Low back pain	8	1.5	0.3	20.00%	-80.00%	9	F
S/S	44	Low back pain	3	2	0	0.00%	-100.00%	7	M
S/C	52	Lumbosciatica	2	8	7.5	93.75%	-6.25%	4	F
S/J	63	Low back pain	14	6.5	2.3	35.38%	-64.62%	9	F
T/S	34	Low back pain	4	5	0.5	10.00%	-90.00%	3	F
T/PH	34	Lumbocruralgia	36	7.5	6	80.00%	-20.00%	10	M
T/L	23	Lumbosciatica	24	8	8	100.00%	0.00%	7	F
T/J	30	Low back pain	6	1	0	0.00%	-100.00%	3	F
T/M	62	Low back pain	12	5	3	60.00%	-40.00%	8	M
T/F	38	Low back pain	4	2	1	50.00%	-50.00%	7	M
T/L	50	Low back pain	4	9	3	33.33%	-66.67%	7	F
V/J	64	Lumbosciatica	7	7	0.2	2.86%	-97.14%	10	M
V/C	48	Low back pain	144	5.4	4.3	79.63%	-20.37%	4	F
V/N	42	Lumbosciatica	18	5.4	2	37.04%	-62.96%	6	M
V/D	48	Lumbosciatica	5	5	1	20.00%	-80.00%	11	M

Initials	Age	Clinical presentation	Duration (months)	Initial VAS	Final VAS	Final as % of initial	Change	Sessions	Sex
V/S	38	Lumbosciatica	98	9	9	100.00%	0.00%	3	F
V/O	41	Lumbosciatica	2	8	6	75.00%	-25.00%	2	M
V/H	79	Lumbosciatica	7	4	0	0.00%	-100.00%	6	F
V/E	48	Low back pain	18	7	6	85.71%	-14.29%	6	M
W/S	45	Lumbosciatica	12	6.2	4.6	74.19%	-25.81%	8	F
WN/G	19	Low back pain	12	9.2	8	86.96%	-13.04%	2	M
W/S	49	Low back pain	36	6.5	3.5	53.85%	-46.15%	9	M

All 185 patient rows from the source table are reproduced. The source codes sex as 1/2; the codes have been rendered as F/M because code 1 occurs 111 times and code 2 occurs 74 times, matching the source totals of 111 women and 74 men. No numerical value was altered.

Appendix 6. Study Population

Appendix 6A. Population summary reported in the source.

Measure	All enrolled patients (n=20)	Completers (n=14)
Patients	20	14
Sex	10 men; 10 women	7 men; 7 women
Mean age	52.7 years	52.0714286 years
Median age	51 years	50.5 years
Age range	26-84 years	26-84 years
Clinical presentations	Low back pain: 11; lumbosciatica: 8; lumbocruralgia: 1	Not reported separately
Mean symptom duration	9.75 months	9.428571429 months
Median symptom duration	10.5 months	9.5 months
Symptom-duration range	4-12 months	4-12 months
Symptom-duration standard deviation	2.403396719	2.440500759
95% CI for mean symptom duration	[8.63-10.87]	[8.02-10.84]

Appendix 6B. Prospective-study population.

Patient	Sex	Age	Occupation	Comorbidity / history	Clinical presentation	Duration (months)	Reason for withdrawal
1	M	68	Retired (DDE)	Hypertension	Low back pain	12	
2	F	49	Administration	None	Right L5 lumbosciatica	7	
3	M	84	Retired (EDF)	Parkinson disease; atrial fibrillation	Low back pain	7	
4	M	58	Heavy-goods vehicle driver	Hypercholesterolaemia	Right L5 lumbosciatica	12	
5	F	47	Hospital representative	None	Right L5 lumbosciatica	8	
6	M	59	Upholsterer/decorator	Cervical and lumbar disc hernia; hepatitis B; liver transplant; chronic kidney disease	Right L5 lumbosciatica	11	
7	F	82	Retired secretary	Treated hypertension	L5 low back pain	12	
8	F	53	Nursing assistant, Poitiers University Hospital	Zopiclone for sleep	Low back pain	12	Withdrawal: inefficacy
9	M	59	Security officer	Treated obstructive sleep apnoea	Bilateral lumbosciatica	11	
10	M	44	House manager	None	Low back pain	8	
11	F	52	Hospital services assistant in nursing home	Bipolar disorder	Low back pain	7	COVID-19 interruption
12	M	58	Lorry driver	Previous L4-L5 disc surgery	Low back pain	12	COVID-19 interruption
13	F	38	Nursing assistant in nursing home	None	Low back pain	12	Surgical management
14	M	36	Disability-accessibility service / unemployed	Asthma; disc surgery in 2011	Low back pain	10	COVID-19 interruption
15	F	42	Medico-psychological assistant (work accident)	Treated hypothyroidism	Right lumbar cruralgia	8	
16	M	47	Carpenter/roofer (work accident)	Treated hypothyroidism; treated hypertension	Left lumbosciatica	12	

Patient	Sex	Age	Occupation	Comorbidity / history	Clinical presentation	Duration (months)	Reason for withdrawal
17	F	51	Nursing assistant	Treated hypercholesterolaemia	Left lumbosciatica	9	
18	F	26	Retail drive-through service	None	Low back pain	4	
19	M	51	Factory worker	None	Low back pain	12	
20	F	50	Registered nurse	None	Low back pain	9	Withdrawal; reason unknown

Blank withdrawal fields indicate that the patient remained in follow-up.

Appendix 7. Change in VAS Across Sessions

Appendix 7A. Baseline VAS statistics for all enrolled patients.

Statistic	D0 (all 20 enrolled patients)
n	20
Mean	5.825
Median	5.75
Minimum	2
Maximum	9
Standard deviation	1.98199129
95% CI	[4.90-6.75]

Appendix 7B. VAS statistics for the 14 completers.

Statistic	D0	D28 (M1)	M2	M3	M4
n	14	14	14	14	14
Mean	5.821428571	2.978571429	3.642857143	3.035714286	2.964285714
Median	6.5	1.5	3.5	2.25	3.25
Minimum	2	0	0	0	0
Maximum	9	8	8	10	8
Standard deviation	2.171556893	2.91657823	2.762583597	3.171169923	2.627255703
95% CI	[4.568-7.075]	[1.295-4.663]	[2.048-5.235]	[1.205-4.867]	[1.447-4.481]

Appendix 7A. VAS before and after the five weekly sessions.

Patient	Sex	D0 pre	D0 post	D7 pre	D7 post	D14 pre	D14 post	D21 pre	D21 post	D28 pre	D28 post
1	M	4	6	6	3.5	2	1	2	0	1	0
2	F	9	0	5	0	3	0	2	0	1	0
3	M	7	0	6	0	6	3	5	2	6.5	1
4	M	7.5	0	7.5	2.5	5	0	6	0	5	0
5	F	8	2.5	1	0	3	0	1	0	1	0
6	M	6	4.5	6	3	5	4	5	4	5	3
7	F	5.5	0	5.5	0	5.5	0	5.5	0	5.5	0
8	F	7	0	6.5	1	5	1	6	1	8	0
9	M	8	3	7	3.5	8	3	10	8	8	6
10	M	5	5	5.5	4.5	5.5	4	6.5	5	6.5	5
11	F	9	9	9	9	9	9	9	9		

Patient	Sex	D0 pre	D0 post	D7 pre	D7 post	D14 pre	D14 post	D21 pre	D21 post	D28 pre	D28 post
12	M	4.5	8	1.5	0	3	1.5				
13	F	5	0	2.5	0	7	0	2	0	3	3
14	M	2	0	2.5	0	3	0.5	1	0	0.5	0
15	F	5.5	1.5	4	0	3	0	3	0	0.2	0
16	M	3.5	0	3.5	0	2.5	0	3.5	0	2	0
17	F	7	0	5	0	1.5	0	1	0	2.5	0
18	F	3	0	1.5	0	1	0	0	0	0	0
19	M	6	0	4	4	8	5	2	1	3	0
20	F	4	0	5	0	7	1.5	1	0	1	0

Appendix 7B. VAS at the monthly follow-up sessions and final assessment.

Patient	Sex	M2 pre	M2 post	M3 pre	M3 post	M4 assessment
1	M	2	0	1	0	1
2	F	0	0	0	0	0
3	M	7	3	4.5	2	3.5
4	M	4.5	0	3.5	1.5	6
5	F	1	0	1	0	3
6	M	5	3.5	4.5	3	5
7	F					
8	F	0	0	0	0	4
9	M	8	5	10	7	8
10	M	6	4			
11	F					
12	M					
13	F					
14	M	2	0	0.5	0	0.5
15	F	2.5	0	0	0	0
16	M	8	0	3.5	1	3.5
17	F	1.5	0	0.5	0	1
18	F	4.5	0	7.5	0	0
19	M	7	1			
20	F	5	0	6	0	6

Blank cells indicate that the patient was no longer available for that assessment. The Appendix 7 source table gives the M2 upper 95% confidence limit as 5.235; Figure 11 gives 5.238. Each value is preserved in the location in which it appears in the source.

Appendix 8. Duration of SCENAR Effectiveness

Appendix 8. Duration of the analgesic effect of SCENAR (days).

Patient	Sex	D0-D7	D7-D14	D14-D21	D21-D28	M1-M2	M2-M3	M3-M4
1	M	0	3	6	4	7	7	7
2	F	0.0625	0.33	1.5	3	30	30	30
3	M	0.33	0.83	0	16	14	14	16
4	M	0.8	0.5	1	0.083	2	0.5	1
5	F	3	0.5	1.5	2	4.5	30	30
6	M	2	2	2	2	2.5	2.5	2.5
7	F	2	2	0.16	0.16			
8	F	3	2	0.5	4	21	18	15
9	M	0.41	0.41	0	0	0	0.41	0.41
10	M	0	0	1	1	4		
11	F	0	0	0				
12	M	0	0					
13	F	0.145	1	7	5			
14	M	7	5	3.5	5	21	30	7
15	F	7	0.1	3	5	9	30	30
16	M	0.0014	1	2	0.1	3	7	7
17	F	0.5	5	7	4	21	30	15
18	F	0.5	7	7	7	15	3	7
19	M	0.2	0	2.5	5	3		
20	F	0.5	0.5	0.5	2	4	2	2
Mean		1.37	1.56	2.43	3.63	10.1	14.6	12.14

Blank cells indicate unavailable follow-up. The final row reproduces the means reported in the source.

Appendix 9. Overall Quality of Life

Appendix 9A. Baseline NHP statistics for all enrolled patients.

Statistic	D0 (all 20 enrolled patients)
n	20
Mean	13.3
Median	14
Minimum	2
Maximum	29
Standard deviation	5.913317196
95% CI	[10.53-16.07]

Appendix 9B. NHP statistics for the 14 completers.

Statistic	D0	M1	M2	M3	M4
n	14	14	14	14	14
Mean	13.57142857	9.928571429	9	7.5	8.642857143
Median	15	9.5	8	7	7
Minimum	2	2	1	0	0
Maximum	21	22	23	20	23
Standard deviation	6.524678427	6.661765598	6.468860321	5.840837664	7.154879991
95% CI	[9.804-17.34]	[6.082-13.77]	[5.265-12.74]	[4.128-10.87]	[4.664-12.62]

Appendix 9C. Patient-level overall quality-of-life data.

Patient	D0 / 38	M1 / 38	M2 / 38	M3 / 38	M4 / 38
1	20	9	10	7	7
2	13	4	2	2	0
3	12	13	10	11	7
4	17	13	7	12	12
5	20	7	3	1	3
6	11	11	11	8	12
7	7	7			
8	19	10	14	7	14
9	15	21	20	17	17
10	11	9	13		
11	29				
12	6				
13	7	7			
14	2	3	1	0	0
15	15	4	8	3	0
16	21	22	23	20	23
17	18	17	8	4	13
18	5	3	4	7	6
19	16	8	17		
20	2	2	5	6	7

Blank cells indicate unavailable follow-up. Appendix 9 reports the M4 standard deviation as 7.154879991, whereas Figure 13 reports 6.89; both source values are retained in their respective tables.

Appendix 10. Social Isolation Domain

Appendix 10A. Social-isolation summary statistics reported in the source.

Statistic	D0 (all 20)	D0 (14 completers)	M4 (14 completers)
n	20	14	14
Mean	8.375	4.537142857	0
Median	0	0	0

Appendix 10B. Patient-level NHP social-isolation data.

Patient	D0	M1	M2	M3	M4
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0
5	0	0	0	0	0
6	24.5	0	0	0	0
7	20.43	0			
8	39.02	0	0	0	0
9	0	0	0	0	0
10	0	0	0		
11	83.55				
12	0				
13	0	0			
14	0	0	0	0	0
15	0	0	0	0	0
16	0	0	36.39	0	0
17	0	0	0	0	0
18	0	0	0	0	0
19	0	0	0		
20	0	0	0	0	0

Blank cells indicate unavailable follow-up.

Appendix 11. Analgesic Use

Appendix 11A. Baseline analgesic-score statistics for all enrolled patients.

Statistic	D0 (all 20 enrolled patients)
n	20
Total score	37
Mean	1.85
Median	1.5
Minimum	0
Maximum	8
Standard deviation	2.109502311
95% CI	[0.86-2.84]

Appendix 11B. Analgesic-score statistics for the 14 completers.

Statistic	D0	M1	M2	M3	M4
n	14	14	14	14	14
Mean	2.142857143	0.857142857	0.5	0.714285714	0.714285714
Median	2	0	0	0	0
Minimum	0	0	0	0	0
Maximum	8	4	3	6	6
Standard deviation	2.381245403	1.292412345	0.940539943	1.637473261	1.637473261
95% CI	[0.768-3.518]	[0.1109-1.603]	[-0.04305-1.043]	[-0.2312-1.66]	[-0.2312-1.66]

Appendix 11C. Patient-level analgesic medication use.

Patient	Sex	Time point	Analgesic treatment	Score
1	M	D0	Izalgi, 2/day	2
1	M	M1	0	0
1	M	M2	0	0
1	M	M3	0	0
1	M	M4	0	0
2	F	D0	0	0
2	F	M1	0	0
2	F	M2	0	0
2	F	M3	0	0
2	F	M4	0	0

Patient	Sex	Time point	Analgesic treatment	Score
3	M	D0	Paracetamol 2 g/day	1
3	M	M1	Paracetamol 1 g/day, 2 days/week	1
3	M	M2	Paracetamol 2 g/day	1
3	M	M3	Paracetamol 2 g/day	1
3	M	M4	Paracetamol 2 g/day	1
4	M	D0	Ibuprofen 1,200 mg/day + paracetamol 4 g/day	2
4	M	M1	Ibuprofen 1,200 mg/day + paracetamol 3 g/day	2
4	M	M2	Ibuprofen 1,200 mg/day + paracetamol 3 g/day	2
4	M	M3	Ibuprofen 1,200 mg/day + paracetamol 3 g/day	2
4	M	M4	Ibuprofen 1,200 mg/day + paracetamol 3 g/day	2
5	F	D0	Ibuprofen 800 mg/day + paracetamol 4 g/day	2
5	F	M1	Paracetamol 3 g/day	1
5	F	M2	0	0
5	F	M3	0	0
5	F	M4	0	0
6	M	D0	0	0
6	M	M1	0	0
6	M	M2	0	0
6	M	M3	0	0
6	M	M4	0	0
7	F	D0	Tramadol 100 mg/day + paracetamol 3 g/day	3
7	F	M1	Tramadol 100 mg/day + paracetamol 3 g/day	3
7	F	M2		
7	F	M3		
7	F	M4		
8	F	D0	Paracetamol 3 g/day	1
8	F	M1	Paracetamol 1 g/day	1
8	F	M2	Paracetamol 1 g/day	1
8	F	M3	0	0
8	F	M4	Paracetamol 2 g/day	1
9	M	D0	0	0
9	M	M1	0	0
9	M	M2	0	0
9	M	M3	0	0
9	M	M4	0	0
10	M	D0	Prolonged-release tramadol 100 mg every other day	2
10	M	M1	0	0

Patient	Sex	Time point	Analgesic treatment	Score
10	M	M2	0	0
10	M	M3		
10	M	M4		
11	F	D0	0	0
11	F	M1		
11	F	M2		
11	F	M3		
11	F	M4		
12	M	D0	Ketoprofen 100 mg/day, 5 days/week	1
12	M	M1		
12	M	M2		
12	M	M3		
12	M	M4		
13	F	D0	0	0
13	F	M1	0	0
13	F	M2		
13	F	M3		
13	F	M4		
14	M	D0	Prolonged-release tramadol 150 mg during very painful attacks, about twice/month	2
14	M	M1	0	0
14	M	M2	0	0
14	M	M3	0	0
14	M	M4	0	0
15	F	D0	Codeine-containing Klipal 600/50, 4/day during attacks, 2 days/month	2
15	F	M1	0	0
15	F	M2	0	0
15	F	M3	0	0
15	F	M4	0	0
16	M	D0	Paracetamol 3 g/day + gabapentin 300 mg at night + tramadol 100 mg morning and evening	6
16	M	M1	Paracetamol 2 g/day + tramadol 100 mg morning and evening	3
16	M	M2	Paracetamol 3 g/day + tramadol 100 mg morning and evening	3
16	M	M3	Gabapentin 200 mg/day + tramadol 100 mg morning and evening + paracetamol 2 g/day	6
16	M	M4	Same as M3	6
17	F	D0	Gabapentin 1,200 mg/day + Doliprane 2 g/day ± morphine	8
17	F	M1	Gabapentin every other day + Doliprane once/day	4
17	F	M2	0	0
17	F	M3	0	0

Patient	Sex	Time point	Analgesic treatment	Score
17	F	M4	0	0
18	F	D0	Skenan LP 20 mg/day + Actiskenan 5 mg as needed	4
18	F	M1	0	0
18	F	M2	0	0
18	F	M3	Paracetamol 2 g/day during the last week	1
18	F	M4	0	0
19	M	D0	Paracetamol 3 g/day	1
19	M	M1	0	0
19	M	M2	Paracetamol 3 g/day	1
19	M	M3		
19	M	M4		
20	F	D0	0	0
20	F	M1	0	0
20	F	M2	0	0
20	F	M3	0	0
20	F	M4	0	0

Arbitrary score used in the source: WHO step 1 and NSAIDs = 1 point; WHO step 2 = 2 points; gabapentinoids = 3 points; WHO step 3 = 4 points. The wide source table has been reformatted into a longitudinal layout for legibility; no values were changed.

Appendix 12. Change in Analgesic Use During the First Month

Appendix 12A. Baseline analgesic-score statistics for all enrolled patients.

Statistic	D0 (all 20 enrolled patients)
n	20
Total score	37
Mean	1.85
Median	1.5
Minimum	0
Maximum	8
Standard deviation	2.109502311
95% CI	[0.86-2.84]

Appendix 12B. First-month analgesic-score statistics for the 14 completers.

Statistic	D0	D28 (M1)
n	14	14
Mean	2.142857143	0.857142857
Median	2	0
Minimum	0	0
Maximum	8	4
Standard deviation	2.381245403	1.292412345
95% CI	[0.768-3.518]	[0.1109-1.603]

Appendix 12C. Patient-level change in analgesic use during the first month.

Patient	Sex	Time point	Analgesic treatment	Score
1	M	D0	Izalgi, 2/day	2
1	M	D7	Izalgi, 1/day	2
1	M	D14	0	0
1	M	D21	0	0
1	M	D28 (M1)	0	0
2	F	D0	0	0
2	F	D7	0	0
2	F	D14	0	0
2	F	D21	0	0
2	F	D28 (M1)	0	0

Patient	Sex	Time point	Analgesic treatment	Score
3	M	D0	Paracetamol 2 g/day	1
3	M	D7	Paracetamol 1 g/day, 5 days/week	1
3	M	D14	Paracetamol 1 g/day, 4 days/week	1
3	M	D21	Paracetamol 1 g/day, 3 days/week	1
3	M	D28 (M1)	Paracetamol 1 g/day, 2 days/week	1
4	M	D0	Ibuprofen 1,200 mg/day + paracetamol 4 g/day	2
4	M	D7	Same	2
4	M	D14	Same	2
4	M	D21	Ibuprofen 1,200 mg/day + paracetamol 3 g/day	2
4	M	D28 (M1)	Same	2
5	F	D0	Ibuprofen 800 mg/day + paracetamol 4 g/day	2
5	F	D7	Paracetamol 1 g/day	1
5	F	D14	Ibuprofen 400 mg/day + paracetamol 1 g/day	2
5	F	D21	Ibuprofen 800 mg/day	1
5	F	D28 (M1)	Paracetamol 3 g/day	1
6	M	D0	0	0
6	M	D7	0	0
6	M	D14	0	0
6	M	D21	0	0
6	M	D28 (M1)	0	0
7	F	D0	Tramadol 100 mg/day + paracetamol 3 g/day	3
7	F	D7	Same	3
7	F	D14	Same	3
7	F	D21	Same	3
7	F	D28 (M1)	Same	3
8	F	D0	Paracetamol 3 g/day	1
8	F	D7	Paracetamol 1 g/day	1
8	F	D14	Paracetamol 2 g/day	1
8	F	D21	Paracetamol 1 g/day	1
8	F	D28 (M1)	Paracetamol 1 g/day	1
9	M	D0	0	0
9	M	D7	0	0
9	M	D14	0	0
9	M	D21	0	0
9	M	D28 (M1)	0	0
10	M	D0	Prolonged-release tramadol 100 mg every other day	2
10	M	D7	0	0

Patient	Sex	Time point	Analgesic treatment	Score
10	M	D14	0	0
10	M	D21	0	0
10	M	D28 (M1)	0	0
11	F	D0	0	0
11	F	D7	0	0
11	F	D14	0	0
11	F	D21	0	0
11	F	D28 (M1)		
12	M	D0	Ketoprofen 100 mg/day, 5 days/week	1
12	M	D7	Ketoprofen 100 mg/day, 4 days/week	1
12	M	D14	0	0
12	M	D21		
12	M	D28 (M1)		
13	F	D0	0	0
13	F	D7	0	0
13	F	D14	0	0
13	F	D21	0	0
13	F	D28 (M1)	0	0
14	M	D0	Prolonged-release tramadol 150 mg during very painful attacks, about twice/month	2
14	M	D7	0	0
14	M	D14	0	0
14	M	D21	0	0
14	M	D28 (M1)	0	0
15	F	D0	Codeine-containing Klipal 600/50, 4/day during attacks, 2 days/month	2
15	F	D7	0	0
15	F	D14	0	0
15	F	D21	0	0
15	F	D28 (M1)	0	0
16	M	D0	Paracetamol 3 g/day + gabapentin 300 mg at night + tramadol 100 mg morning and evening	6
16	M	D7	Paracetamol 3 g/day + tramadol 100 mg morning and evening	3
16	M	D14	Paracetamol 2 g/day + tramadol 100 mg morning and evening	3
16	M	D21	Same	3
16	M	D28 (M1)	Same	3
17	F	D0	Gabapentin 1,200 mg/day + Doliprane 2 g/day ± morphine	8
17	F	D7	Gabapentin 1,200 mg/day + Doliprane 2 g/day	4
17	F	D14	Gabapentin 1,200 mg/day	3
17	F	D21	Gabapentin 600 mg/day	3

Patient	Sex	Time point	Analgesic treatment	Score
17	F	D28 (M1)	Gabapentin every other day + Doliprane once/day	4
18	F	D0	Skenan LP 20 mg/day + Actiskenan 5 mg as needed	4
18	F	D7	Paracetamol 1 g as needed (2 days/week)	1
18	F	D14	0	0
18	F	D21	0	0
18	F	D28 (M1)	0	0
19	M	D0	Paracetamol 3 g/day	1
19	M	D7	Co-Doliprane once	2
19	M	D14	Paracetamol 500 mg once/day	1
19	M	D21	0	0
19	M	D28 (M1)	0	0
20	F	D0	0	0
20	F	D7	0	0
20	F	D14	0	0
20	F	D21	0	0
20	F	D28 (M1)	0	0

Arbitrary score used in the source: WHO step 1 and NSAIDs = 1 point; WHO step 2 = 2 points; gabapentinoids = 3 points; WHO step 3 = 4 points. The wide source table has been reformatted into a longitudinal layout for legibility; no values were changed.

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Medical Oath

In the presence of the teachers of this school, my dear fellow students and the image of Hippocrates, I promise and swear to remain faithful to the laws of honour and integrity in the practice of medicine. I shall provide free care to the indigent and shall never demand payment beyond the value of my work. When admitted into people’s homes, my eyes shall not see what occurs there; my tongue shall keep the secrets entrusted to me, and my profession shall not be used to corrupt morals or facilitate crime. Respectful and grateful towards my teachers, I shall pass on to their children the instruction I received from their fathers.

May people grant me their esteem if I remain faithful to my promises. May I be covered in disgrace and despised by my colleagues if I fail to keep them.

Abstract

Introduction: Chronic low back pain is a major public health problem in the twenty-first century in physical, psychological, economic and social terms. The latest 2019 HAS recommendations describe multidisciplinary management. Treatment is complex and depends above all on the patient. No therapy has demonstrated optimal effectiveness in improving VAS, reducing analgesic use or improving quality of life. We therefore conducted a prospective study of a nerve-stimulation device known as SCENAR (Self-Controlled Energo-Neuro Adaptive Regulation), invented in the USSR in 1983, granted CE marking in 2001 and authorised for marketing in France in 2012. The device has been used at Poitiers University Hospital since 2013.

Method: Twenty patients with chronic low back pain of 3 to 12 months' duration and no indication for surgery were recruited after medical consultation with a spinal specialist. Treatment was delivered according to the following schedule: D0, D7, D14, D21, D28, M2 and M3, with 30-minute sessions. The primary outcome was change in VAS from D0 to D28 (M1), M2, M3 and M4. Secondary outcomes were changes in analgesic use and quality of life, measured with the Nottingham Health Profile, from D0 to D28 (M1), M2, M3 and M4.

Results: Six patients were lost to follow-up: one underwent surgery, three had treatment interrupted by the COVID-19 crisis, and two left the protocol because they considered treatment ineffective. Fourteen patients were analysed using the Wilcoxon signed-rank test, a non-parametric paired-sample test selected for the small sample. Unadjusted VAS improvement was 49% between D0 and M4. VAS improvement was significant between D0 and D28 ($p < 0.001$), D0 and M3 ($p = 0.0315$), and D0 and M4 ($p = 0.0034$). Unadjusted quality-of-life improvement was 36% between D0 and M4. Quality of life improved significantly between D0 and M2 ($p = 0.033$), D0 and M3 ($p = 0.0155$), and D0 and M4 ($p = 0.0322$). Unadjusted improvement in analgesic use was 67% between D0 and M4. Analgesic use improved significantly between D0 and D28 ($p = 0.0156$), D0 and M2 ($p = 0.0156$), D0 and M3 ($p = 0.0156$), and D0 and M4 ($p = 0.0313$).

Discussion: Improvements in individual quality-of-life domains between D0 and M4 were not statistically significant. Analgesic use increased slightly after sessions were spaced further apart. Both patients receiving morphine discontinued it.

Keywords: SCENAR; chronic low back pain; Visual Analogue Scale; Nottingham Health Profile; analgesic medication use; Wilcoxon signed-rank test; Poitiers; France.