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Implementation of neuroreflexotherapy for subacute and chronic neck and back pain within the Spanish public health system: Audit results after one year

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Abstract

Controlled randomized trials have demonstrated the efficacy, safety, effectiveness, and cost-effectiveness of neuroreflexotherapy (NRT) for the management of non-specific back pain. In this audit study, we describe the implementation of NRT into the routine practice of primary care within the Spanish public health service of the Balearic Islands and the results obtained after one year (2004). A referral protocol was made available to all general practitioners (GPs) who could refer eligible patients to specialized units in performing NRT interventions. A total of 1209 patients (median age 52 years, 68% women) were referred to NRT by 412 GPs (80% of all GPs), with a mean (standard deviation (S.D.)) referral rate of 1.57 (0.84) patients per month/10,000 persons affiliated to each practice, and an appropriate referral rate of 95.5%. Pain decreased from a median score (visual analog scale) of 8 at baseline to 1 at discharge, referred pain from 7 to 1, and disability (Roland–Morris Questionnaire) from 12 to 1. NRT was refused by 2.7% of patients. Adverse effects related to the procedure were only a skin reaction in 3.3% of patients. We conclude that it is feasible to implement NRT in the public health service complying with methods and application conditions used in previous randomized controlled trials (RCTs). In such conditions, implementation of this technology obtained positive audit results at one year.

Keywords: Neuroreflexotherapy; Neck pain; Back pain; Audit study; Spanish public health system

1. Introduction

Although acute low back pain improves spontaneously, few treatment modalities have shown effectiveness for patients with subacute and chronic pain

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[1–20], who account for more than 70% of global costs [21–25].

Neuroreflexotherapy (NRT) consists of the temporary subcutaneous implantation of surgical staples and small burins in trigger points in the back at the site of dermatomes clinically involved in each case and at the referred tender points located in the ear. The intervention deactivated neurons are assumed to be involved in the mechanisms of persistence of pain, neurogenic inflammation, and muscle dysfunction and contracture [26–35]. Randomized controlled trials (RCTs) carried out in different primary care and hospital settings by different research teams have shown the efficacy, safety, effectiveness, and cost-effectiveness of NRT [36–38]. Independent reviews from the Cochrane Collaboration and Agencies for Health Technology Assessment have evaluated the quality of those RCTs as high [39–44]. One additional review was performed when only two of those RCTs had been conducted [45], in which language bias led to the exclusion of one of them [46]. Results of this additional review agree on the high quality of the RCT it included [45].

A referral protocol to NRT in routine clinical practice was based on indication criteria used in those RCTs [47,48]. Spanish professional associations of primary care physicians, rehabilitation, orthopedic surgery, and neurosurgery specialists supported the use of NRT, and a pilot test on the implementation of NRT in primary care was performed [49]. Its results showed a rate of appropriate referral over 95%, a high degree of satisfaction among patients and physicians, and clinical results that were consistent with those from previous RCTs [49].

Therefore, in December 2003, the public health service in the Balearic Islands decided to implement NRT for the routine treatment of patients with non-specific subacute and chronic neck, back, and low back pain. This study describes the implementation process and audit results obtained at one year.

2. Materials and methods

2.1. Setting and study characteristics

The study was carried out in the Balearic Islands, an island group in the Mediterranean, east of Spain, including Mallorca, Menorca, Ibiza, and Formentera. The Balearic Health Service (Ib-Salut) is a public organization that belongs to the Spanish national health care system, in which universal tax-funded health care services are provided to every citizen in Spain. The Ib-Salut covers 916,453 inhabitants. It includes five acute-care hospitals and 49 primary care centers with a total of 515 general practitioners (GPs).

A 30-min informative session on NRT was given in each primary care center and at the departments of rheumatology, rehabilitation, orthopedic surgery, and neurosurgery of the hospitals. The presentation included the available evidence on effectiveness, safety, and efficiency of NRT; characteristics of the intervention; and eligibility criteria for patients' referral. All attenders received a copy of the referral protocol (Fig. 1) and were given a toll-free telephone number. Inclusion criteria were as follows: presence of non-specific neck or back pain, with or without referred pain, that lasted for more than 14 days with an intensity ≥ 3 in a 10-cm visual analog scale (VAS) [36], except for patients with symptomatic spinal stenosis or 'red flags' for urgent referral to surgery. Routine work-up studies including laboratory tests, plain radiographs, and magnetic resonance imaging were not recommended unless "red flags" for potential specific conditions were observed (Table 1).

According to the conditions of application in which this technology had proved to be effective, safe, and cost-effective [35–38], specialized units were established in facilities of the Kovacs Foundation, which were separate from the 49 primary care centers and the 5 hospitals belonging to the Ib-Salut. The Kovacs Foundation is a not for profit Spanish institution with its own funding. It is the main Spanish research institution in the field of back pain and it participated with the Spanish National Health Service in the development and assessment of NRT [50]. The investment necessary for developing and running those units was made by the Kovacs Foundation. The fee that the Ib-Salut paid for each patient referred to NRT corresponded with the cost assigned to the technology in the studies in which it has proved to be cost-effective in the Spanish National Health Service [38].

NRT units were established in Mallorca, Menorca, and Ibiza, with the latter covering also referrals from Formentera. Units in Menorca and Ibiza had one specialized physician who applied NRT and one nurse each, while the unit in Mallorca had two specialized

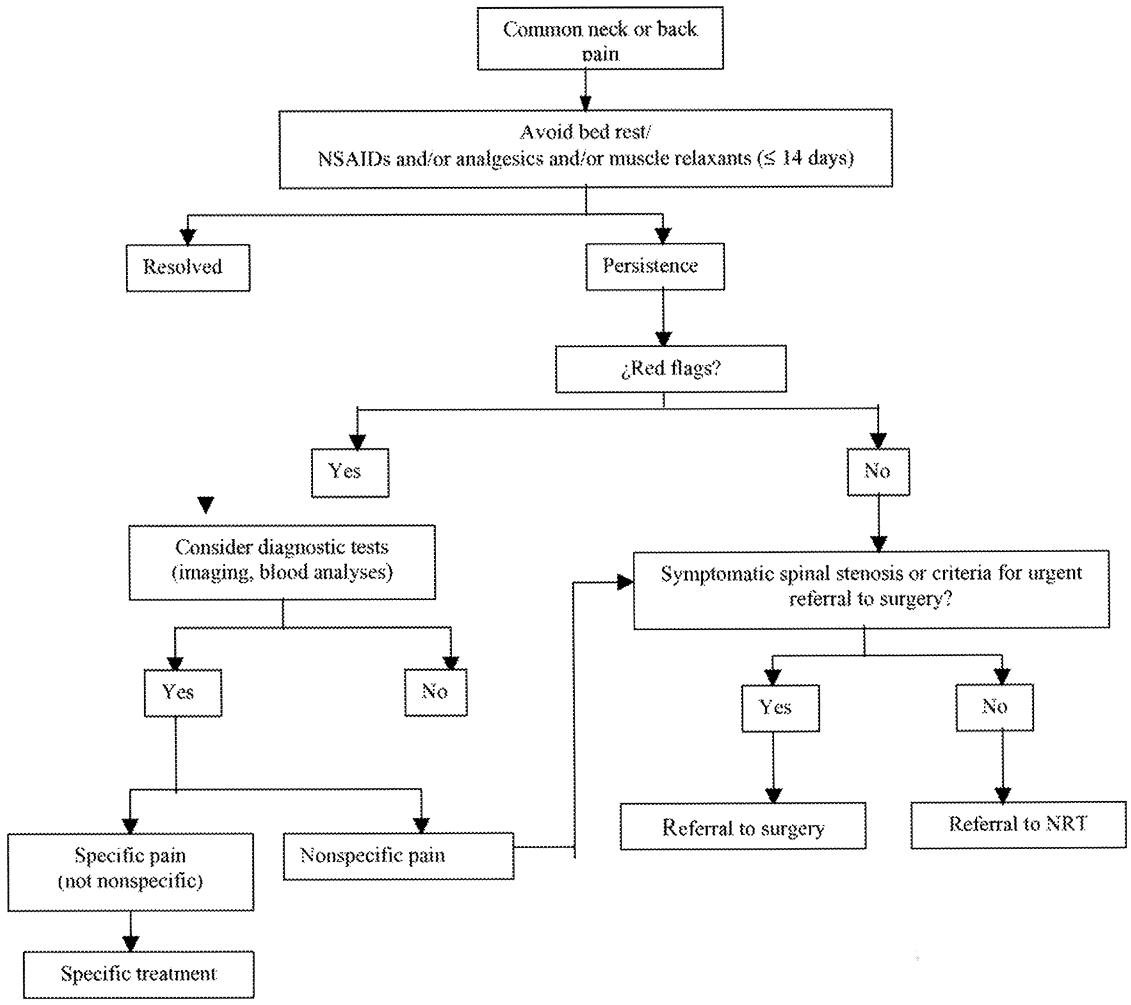

Fig. 1. Referral protocol of patients to neuroreflexotherapy (NRT).

physicians and three nurses. According to conditions of application which had been previously assessed [35–38], the Kovacs Foundation was requested to organize the units and to implement the mechanisms for quality control [35–38,47–49]. General practitioners from the Ib-Salut referred patients to one of the three specialized NRT units. Physicians in hospital services were also allowed to refer patients to NRT, but only through the GPs. Patients were given an informative pamphlet and GPs filled out a standard referral sheet. Telephone appointments to the specialized unit were made by the patients themselves. Specialists at the NRT units assessed appropriateness of patient's referral and performed the NRT intervention. All patients gave their written consent.

2.2. Outcome assessment

The clinical condition of each patient was evaluated by the GP and included duration (days) of pain (since first diagnosis and for the current episode); referred pain (yes/no); reason for consultation (neck, back, or low back pain); intensity of local and referred pain (assessed by the patient alone without assistance using a 10-cm VAS) [51]; disability (only in patients with low back pain) using a Spanish validated version of the

Table 1
Exclusion criteria for referral to neuroreflexotherapy intervention

Signs for urgent referral to surgery (any of the following)
Widespread (>1 nerve root) or progressive motor weakness in the legs or gait disturbance
Sphincter disturbance
Saddle anesthesia
Sensory level
Signs of potential disk herniation with surgical criteria (referral for surgical evaluation)
Relevant motor deficit lasting six weeks or more, or progressive motor deficit
Disabling sciatica for six weeks or more
Compromised nerve root demonstrated by MRI or CAT scan, at the corresponding level
Signs of spinal stenosis (referral for surgical evaluation)
Non-vascular intermittent claudication
Image of spinal stenosis in CT scan or MRI
Red flags for potential specific condition:
Presentation under age 20 years or onset over 55 years
Thoracic pain
Constant, progressive non-mechanical pain
Lumbar flexion < 5 cm
Widespread neurology
Fever
Weight loss
Systemically unwell
A history of
Significant trauma
Systemic steroids
Osteoporosis
Cancer
Drug abuse
HIV

CT scan: computed tomography; MRI: magnetic resonance imaging.

Roland–Morris Questionnaire (RMQ) [52] in which greater levels of disability are reflected by higher numbers on a 24-point scale; diagnostic procedures in the previous six months; current treatment; previous spine surgery because of the current episode; the date of referral to the specialized unit.

In the specialized unit, the date of the patient's visit was recorded and the specialist assessed the appropriateness of the referral (in the latter case, specifying the reason), and if NRT intervention took place or not ("yes", "no", or "being evaluated", indicating the reason in the last two instances). Physicians in the specialized unit had access to patient's self-assessment of pain intensity because results were relevant for appropriateness of the indication of NRT, but only after results were transcribed in the database by administrative staff which was independent of the physician who performed the NRT intervention.

After the intervention, patients were seen 6 weeks later to check the implanted surgical material, and 12 weeks later to extract it. In addition, they were instructed to contact the specialized unit or their primary care center in the presence of any adverse effect. On each visit to the primary care center and to the specialized unit, patients assessed the intensity of local and referred pain using VAS scores and low back pain-related disability with the RMQ as previously described. Diagnostic and therapeutic procedures other than NRT and adverse effects attributable to the intervention were recorded. At the 12 week visit, clinical outcomes and the indication for repeating a NRT intervention were assessed. A patient was considered "asymptomatic" when a score ≤ 1 VAS point or ≤ 4 RMQ points was recorded [53,54]. Improvement was defined as a reduction of at least 1 point on the VAS scale, or 2 points on the RMQ [53–56]. Worsening was defined as any increase (in any size) in the corresponding scale. Any situation between worsening and improvement was considered as "no modification". Criteria for indicating a NRT re-intervention were as follows: having improved after the first intervention (defined as having VAS scores at least 1 point lower than baseline) but still meeting criteria for NRT intervention (i.e., pain ≥ 3 VAS points). Therefore, patients with pain below the limit and those who had not improved after NRT (or had worsened) were discharged. At discharge, an independent assistant asked the patient to define his/her overall condition as "asymptomatic", "improved", "not changed", or "worsened".

Primary endpoints of the study were the following: rates of referral and appropriate referral, and patients' and physicians' satisfaction. Patients' satisfaction was assessed through a questionnaire that was given at the specialized units. The questionnaire was the same one that was previously used in the pilot test

of implementation of this technology. In this questionnaire, responses were in "best to worst" order [49]. Patients filled it out anonymously, alone, and could then deposit it in boxes installed in the specialized unit for that purpose, in places where it was impossible for the staff in the unit to see them. Alternatively, patients could also hand it in at their primary care centers, or mail it in (for free). Additional organizational outcomes were waiting time for NRT; patients' refusal of NRT; complaints; diagnostic and treatment procedures prescribed after referral to NRT; duration of period under NRT; rate of patients in which more than one NRT was performed; number of discharged patients who were again referred to NRT for a new relapse of pain at the same level which was first treated. Phone calls made by the primary care physicians to the toll-free number were registered. At the end of the first year of implementation of NRT, the Ib-Salut Primary Care Division listed all primary care physicians having referred at least two patients who had undergone NRT and had already been discharged, and sent them a survey about their degree of satisfaction, where the responses were in "most favorable to least favorable" order. Physicians completed the survey anonymously.

Lastly, the number of referred patients who never made an appointment at the specialized center was determined ("implicit refusal" of NRT), as well as the number of patients who rejected it when it was proposed in the specialized center ("explicit refusal"), and the number of complaints or claims that were received both at the primary care centers or the specialized units.

2.3. Analysis

A team of biostatisticians that was independent from the physicians who participated in the study and that at no time had any contact with the patients calculated the frequencies for categorical values. Mean and standard deviation (S.D.) were calculated for normally distributed continuous variables and median and interquartile range (IQR) for variables whose distribution departed from normality.

3. Results

Informative sessions in the primary care centers and hospital services started on January 12 and finished on October 15, 2004. From January 1 to December 31, 2004, 412 (80%) primary care physicians referred 1209 patients to NRT. Patients' flow chart during 2004 is shown in Fig. 2. Mean (S.D.) rate of referral was 1.57 (0.84) patients per month, for each 10,000 inhabitants affiliated with each practice. Median (IQR) of time elapsed from request of an appointment to the specialized unit to the visit was 14 (4–24) days.

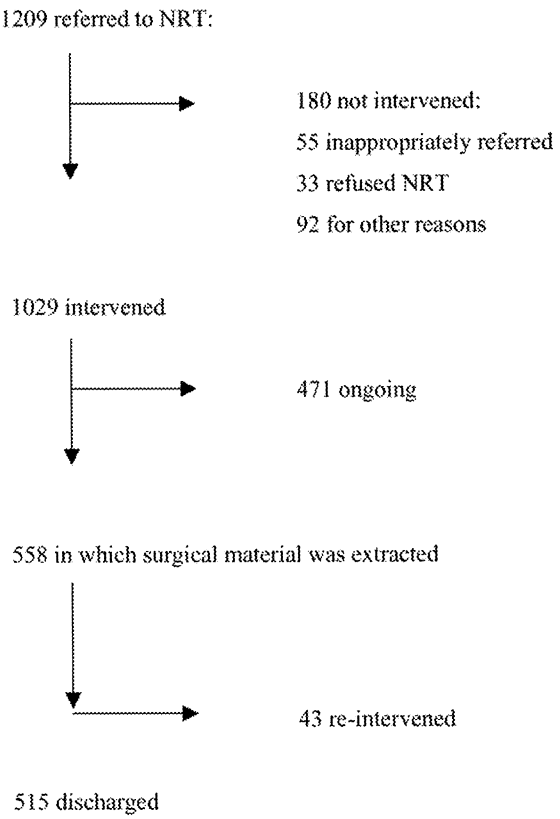

Fig. 2. Patients' flow chart during 2004.

Reasons for referral were neck pain in 426 (35%) cases, thoracic pain in 111 (9%), and low back pain in 672 (56%). Patients had severe local (median, 8 VAS points) and referred pain (median, 7 VAS points). Among low back pain patients, the median value of disability was 12 RMQ points. In 31% of patients ($n = 380$), the pain episode was subacute (less than three months' duration) and chronic in 67% ($n = 829$). Most referred patients had undergone diagnostic procedures and were receiving drug treatments. Approximately

Table 2
Baseline characteristics of referred patients, and prescribed tests, diagnosis, and treatments before referral

Variable	
Age, median (IQR)	52 (42–65)
Sex, *n* (%)	
Males	391 (32.3)
Females	818 (67.7)
Location of pain, *n* (%)	
Neck	426 (35.0)
Thoracic	111 (9.0)
Lumbar	672 (56.0)
Type of pain, *n* (%)	
With no referred pain	408 (33.7)
With referred pain	801 (66.3)
Duration of pain, median (IQR)	
Since diagnosis (days)	2555 (730–5110)
Current episode (days)	180 (60–365)
Intensity of local pain (VAS), median (IQR)	8 (6–9)
Intensity of referred pain (VAS), median (IQR)	7 (5–9)
Low back pain related disability (RM), median (IQR)	12 (8–16)
Diagnostic tests, *n* (%)	
X-ray	494 (40.9)
CAT scan	58 (4.8)
MRI	384 (31.8)
EMG	13 (1.1)
Patients with any previous tests	747 (61.8)
Patients with no previous tests	462 (38.2)
Treatment	
Medication	
NSAIDs	833 (68.9)
Analgesics	832 (68.8)
Muscle relaxants	332 (27.5)
Surgery	112 (9.0)
Other	140 (11.6)
Rehabilitation	126 (10.4)
Patients with any form of treatment	913 (75.5)
Patients with no treatment when referred	296 (24.5)

CT scan: computed tomography; MRI: magnetic resonance imaging; VAS: visual analog scale (0–10); RM: Roland–Morris Questionnaire; EMG: electromyogram; NSAIDS: non-steroidal anti-inflammatory drugs.

9% had undergone unsuccessful spine surgery for the current episode before being referred to NRT. Other baseline characteristics of referred patients are shown in Table 2.

Referrals for NRT were appropriate in 95.5% of cases ($n = 1154$). The procedure was performed in 85.1% ($n = 1029$) of the referred patients. Inappropriate referral was the main reason for not performing and pain intensity <3 VAS point was the main reason for inappropriate referral (Table 3). No case of implicit refusal of NRT was detected, and 33 patients (2.7% of referred patients) explicitly refused the intervention. The main reason for refusal was the desire to delay NRT in order to avoid the implantation of staples during the summer, which accounted for 58% of refusals ($n = 19$).

Table 3
Results of the study

Variable	*n* (%)
Health care demand	
Number of referring physicians	412 (80.0)
Number of referred patients	1209
Monthly rate of referral per 10,000 individuals, mean (S.D.)	1.57 (0.84)
Waiting time (days), median (range)	14 (IQR 4–24)
Workability of referral protocol	
Questions by physicians to consultation telephone	0
Adequate referral	1154 (95.5)
Inadequate referral	55 (4.5)
NRT interventions	
Treated patients	1029 (85.0)
Discharged	515 (50.0)
Ongoing	471 (45.7)
Re-intervened	43 (0.04)
Newly referred post-discharge (19 for same reason)	
For pain at the same level	19 (0.02)
For pain at different level	23 (0.02)
Reasons for not performing NRT at first visit	
No clinical indication	55 (4.5)
Waiting for tests or treatments	45 (3.7)
Patient's refusal	33 (2.7)
Skin allergy to metal	6 (0.5)
Other	41 (3.4)
Patient satisfaction	
Implicitly reject intervention	0
Explicitly reject intervention	33 (2.70)
Reason	
Avoid in summer	19 (57.6)
Other (trips, vacation)	14 (42.4)
Claims or complaints	0

Forty-three of 558 patients (7.7%), in whom the surgical material was extracted, met criteria for a second NRT intervention. The remaining 515 (92.3%) patients were discharged, 19 (3.7%) of which suffered from further pain relapses at the same site and were newly referred for NRT intervention throughout 2004. Other organizational results are shown in Table 3.

Prescription of diagnostic tests and other treatments was sparse after NRT (Table 4). Among the 515 patients who were discharged, median values for local and referred pain were 1 VAS point, and median value for low back pain-related disability was 1 RMQ point. NRT failed to improve or worsened local pain in 40 patients (7.8% of those who were discharged after having been intervened), referred pain in 34 patients (8.2% of those who had it), and disability in 36 patients (7.9% of those with low back pain) (Table 5). Patients in which NRT failed were referred to the appropriate

Table 4
Use of health resources in the 1029 referred patients

Variable	*n* (%)
Test	
X-ray films	3 (0.3)
CT scan	0
MRI	14 (1.4)
Gammagram	4 (0.3)
Bloodwork and other	10 (0.8)
Treatment	
NSAIDs and analgesics	48 (4.0)
Muscle relaxants	6 (0.5)
Others	4 (0.3)
Rehabilitation	25 (2.1)
Surgery	9 (0.7)

NSAIDs: non-steroidal anti-inflammatory drugs; CT scan: computed tomography; MRI: magnetic resonance imaging.

Table 5
Clinical evolution in the 515 intervened patients who were discharged

Variable	*n* (%)	Baseline value	Value at discharge	Improvement (%)
Local pain (VAS), median (IQR)	515 (100)	8 (6–9)	1 (0–4)	87.5
Referred pain (VAS), median (IQR)	415 (80.6)	7 (5–9)	1 (0–3)	85.7
Low back pain related disability (RMQ), median (IQR)	453 (88.0)	12 (8–16)	1 (0–7)	92.0
Low back pain at discharge (in 515 patients)				
Asymptomatic	272 (52.8)			
Improved	203 (39.4)			
Failed to improve	34 (6.6)			
Worsened	6 (1.2)			
Irradiated pain at discharge (in 415 patients)				
Asymptomatic	252 (60.7)			
Improved	129 (31.1)			
Failed to improve	26 (6.3)			
Worsened	8 (1.9)			
Disability (in 453 patients)				
Asymptomatic	297 (65.6)			
Improved	120 (26.5)			
Failed to improve	29 (6.4)			
Worsened	7 (1.5)			
Patients' subjective global assessment (515 patients)				
Asymptomatic	255 (49.5)			
Improved	182 (35.3)			
Failed to improve	73 (14.2)			
Worsened	5 (1.0)			
NRT secondary effects				
Skin reaction	35 (3.3)			
Other	0			

VAS: visual analog scale (range, from best to worst, 0–10); RMQ: Roland–Morris Questionnaire (range, from best to worst, 0–24); IQR: interquartile range.

Table 6
Results of the questionnaire answered by 45 of the 71 eligible physicians

Items in questionnaire	n (%)	Items in questionnaire	n (%)
About the procedure and referral		About the physician's perception of the patients' opinion	
In comparison with other treatments what is your perception about the clinical effectiveness of NRT?		What is your perception about the opinion that referred patients have of the clinical effectiveness of NRT?	
Much more effective	0	They think it's very effective	0
More effective	13 (34.2)	They think it's effective	33 (76.7)
Similar effectiveness	19 (50.0)	They're not clear about it	9 (20.9)
Less effective	1 (2.6)	They think it's not effective	1 (2.4)
		They think it's useless	0
What is your perception about the frequency of the secondary effects of NRT?		What is your perception about the clinical care received at the specialized units?	
Inexistent	6 (14.3)	Are very satisfied	12 (27.9)
Not frequent	29 (69.0)	Are satisfied	25 (58.1)
Frequent	4 (9.5)	Are not satisfied or dissatisfied	3 (7.0)
Very frequent	3 (7.2)	Are dissatisfied	1 (2.4)
Affect almost all patients	0	Are very dissatisfied	2 (4.6)
What is your perception about the usefulness of referring patients to NRT?		About other aspects	
Very useful	5 (11.6)	If in future a relative had a problem similar to your patients', would you recommend referral to NRT?	
Useful	25 (58.2)	Yes, as soon as they had a back problem	6 (15.0)
Not useful or harmful	13 (30.2)	Yes, but only if previous treatment fails	31 (77.5)
Very harmful	0	No	3 (7.5)
In general, are you satisfied by the manner in which NRT specialists have collaborated with you until now?		The prognosis made by the NRT specialists to your referred patients, before intervention, was	
Very satisfied	19 (42.2)	Possibility of great improvement with NRT	2 (5.3)
Satisfied	19 (42.2)	Possibility of improvement with NRT	30 (78.9)
Not satisfied or dissatisfied	6 (13.4)	Without possibility of improvement with NRT	2 (5.3)
Dissatisfied	1 (2.2)	No possibility of improvement with NRT	0
Very dissatisfied	0	Indifferent, or there is no information previous to NRT	4 (10.5)
Do you think the possibility of referring patients to NRT where needed should be maintained?		Had patients been to other specialists previously?	
Yes, without a doubt	24 (53.4)	Yes, once	11 (27.5)
I hope so	11 (24.4)	Yes, several times	21 (52.5)
Indifferent	9 (20.0)	Yes, different specialists, several times	8 (20.0)
I hope not	0	No	0
No, without a doubt	1 (2.2)		

Table 7
Results of the questionnaire filled out by 475 of the 1209 referred patients

Items in questionnaire	*n* (%)	Items in questionnaire	*n* (%)
What do you think of the professional ability of the physician who treated you?		How were you treated when you telephoned to make your appointment?	
Very good	370 (78.6)	Very well	374 (79.2)
Good	93 (19.7)	Well	81 (17.2)
Normal	8 (1.7)	Normal	17 (3.6)
Bad	0	Unpleasantly	0
Very bad	0	Very unpleasantly	0
How long was your wait after arriving and before being seen?		How is this center in regard to cleanliness and maintenance?	
Very short	126 (26.8)	Very good	334 (71.7)
Short	152 (32.3)	Good	113 (24.2)
Normal	177 (37.7)	Normal	19 (4.1)
Long	15 (3.2)	Bad	0
Excessive	0	Very bad	0
How were you treated by non-medical staff?		In general, the health care received has been	
Very pleasantly	374 (78.7)	Very good	316 (68.3)
Pleasantly	74 (15.6)	Good	135 (29.2)
Normal	25 (5.3)	Normal	12 (2.5)
Unpleasantly	0	Bad	0
Very unpleasantly	2 (0.4)	Very bad	0
How were you treated by your physician?		Do you feel that NRT specialists have properly diagnosed your back problem and focused your treatment?	
Very pleasantly	381 (80.6)	Yes	425 (97.5)
Pleasantly	71 (15.0)	No	11 (2.5)
Normal	19 (4.0)		
Unpleasantly	0		
Very unpleasantly	2 (0.4)		
What is the information received like?		If in future a relative had a similar back problem would you recommend referral to NRT?	
The best	223 (47.4)	Yes, as soon as they had a back problem	413 (93.3)
Adequate	215 (45.6)	Yes, but only if other treatments fail	29 (6.5)
Sufficient	31 (6.6)	No	1 (0.2)
Insufficient	2 (0.4)		
Useless	0		

services according to the usual clinical practice in the Ib-Salut, and no further follow-up was made in this study. Organizational and clinical results were similar for neck, back, and low back pain patients (data not shown).

A total of 71 GPs were eligible for the physicians' satisfaction survey, and 45 (63.4%) sent back the questionnaire. As seen in Table 6, 92.5% would recommend referral to NRT to a relative and, in general, their degree of satisfaction was high. No patient made a claim or complaint. A total of 475 of the 1209 referred patients (39.3%) completed the satisfaction questionnaire, and 99.8% would recommend referral to NRT to a relative (Table 7).

4. Discussion

This study shows that it is feasible to implement NRT in routine clinical practice complying with conditions of application which were used in previous RCTs [36–38]. After one year, favorable audit results in terms of clinical outcome, appropriate referrals, and satisfaction among patients and physicians were

observed. These findings are consistent with previous data obtained in previous studies on NRT [35–40,49].

GPs were only given a short lecture and a printed copy of the referral protocol, and none of them used the toll-free number. Although the number of patients who should have been referred to NRT and were not cannot be determined, the rate of appropriate referrals was 95.5%. This percentage in agreement with data of the pilot study [49] further supports that the referral protocol was easy to understand and to follow by GPs.

Clinical evolution of patients was satisfactory, considering that 67% of patients suffered from chronic pain and previous treatments were unsuccessful (including surgery in 9.3%). Only 3.7% of the 515 patients who were discharged had relapses requiring a new referral to NRT, which suggests that improvement after NRT was in general persistent. However, 6.4% patients ($n = 33$) denied any improvement after NRT when asked by administrative staff, in spite of clinically significant improvements in their VAS and RMQ scores (or even total disappearance of pain and disability). Twenty-nine of these patients turned out to be involved in work litigation, suggesting that psychosocial factors might account for this finding.

Ninety-two percent of physicians who answered the survey would recommend referral of a relative to NRT. This figure is consistent with results of the pilot study [49], although in that case, physicians were interviewed by phone. In the present study, the response rate was 63.4% but the reasons for the lack of response were not examined nor was a second mailing of the questionnaire planned. On the other hand, only 39% of patients answered the anonymous survey on their degree of satisfaction, which is a rate higher than the one observed for similar surveys. It is impossible to assess the feeling of non-responders but results on satisfaction are consistent with those from the pilot study, and answers from physicians and patients are also consistent [49]. The main discrepancy is that most physicians would recommend NRT to a relative only after other treatments failed, while most patients would recommend it before trying other treatments. This may be due to the fact that, in accordance with the referral protocol, only patients in which previous treatment had failed (for, at least 14 days, but usually much longer) were referred to NRT.

Assessment of efficacy, safety, and effectiveness of non-pharmacological technologies is usually less rigorous than the one of drugs, and post-marketing surveillance of both drugs and devices may be seen as inadequate [57–60]. In addition, economical interests seem to influence at least the pace and the characteristics of the assessment, approval, and implementation processes [57–61]. However, the case of NRT shows that it is feasible to assess non-pharmacological technologies at least as rigorously as pharmacological ones. In addition, it shows that public and not for profit institutions can also lead the assessment and implementation of new health technologies without pressure from economically driven parties. The Spanish National Health Service has participated from the start in the assessment of the safety [35–38,49], efficacy [36,37], effectiveness [38], and cost-effectiveness [38] of NRT, and such assessment was required before (and not after) implementing the technology in routine clinical practice. The implementation of NRT in routine practice complied with the conditions of application used in previous RCTs [36–38] and was previously test-piloted [49]. Systems for post-marketing surveillance were put in place from the start to assess results in routine practice, and reports such as the current one are planned periodically.

Results obtained in the Health Service of the Balearic Islands have triggered the spread of this technology in other Spanish Health Services. The same referral protocol and systems of implementation and surveillance are used in those Services, suggesting that they are generalizable.

Nowadays, few treatments for back pain have been assessed using a comparable step-by-step process [57–61] and none has shown results that are comparable to this technology, especially for subacute and chronic patients [1–20]. In fact, virtually all others have been developed by for profit companies and are routinely used in practice in spite of the lack of evidence on their effectiveness, safety, or cost-effectiveness [1–20]. However, NRT is only currently used in the Spanish National Health Service. Taking into account the clinical and economical burden that these patients represent and that studies showing the efficacy, effectiveness, or efficiency of NRT have been published since 1993 in indexed publications [36–40,49] this might suggest that factors influencing assessment and approval processes [57–61] might also influence the pace of implementation of technologies in routine clinical practice.

The first systematic review on NRT concluded that it was impossible to draw conclusions since only one high quality RCT was available, after having willingly excluded the other available one at that time [45,46]. The RCTs performed in Spain were supported by the National Health Service and a non-profit specialized institution. To perform those studies elsewhere, similar resources and collaboration would be needed, but as yet no National Health Service has shown any initiative. Lacking the support of multinational for profit companies, large international trials are likely not feasible [59–61]. However, after having acknowledged the high quality of available RCTs, the Cochrane review on NRT suggests to wait until clinical trials are undertaken in other countries before recommending the use of this technology outside Spain [39,40]. This might suggest that usual procedures or standards for assessing the evidence might also be indirectly influenced by usual industry practices [57–61].

In conclusion, the method described allows NRT to be implemented in routine clinical practice within the Spanish National Health System under the conditions in which it was evaluated in previous randomized controlled trials. The referral protocol that was used generates a high rate of appropriate referrals, a high degree of satisfaction among patients and physicians, and clinical results that are consistent with the effectiveness and safety previously demonstrated for this technology.

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