Author's response to reviews

Title: Avoidable costs of physical treatments for chronic back, neck and shoulder pain within the Spanish National Health Service: A cross-sectional study

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Version: 2 Date: 9 November 2011

Author's response to reviews: see over
Dear Editors of *BMC Musculoskeletal Disorders*

I am re-submitting the revised version of the manuscript “*Avoidable costs of physical treatments for chronic back, neck and shoulder pain within the Spanish National Health Service: a cross-sectional study*” (no. 4915369405835320) for your consideration.

The authors thank the reviewers for their comments and valuable suggestions, which have contributed to improving the quality of the manuscript and have been taken into account for the updated version.

As previously stated there are no financial or other relationships between the authors and other third parties which might lead to conflicts of interest. The revised manuscript has been read and approved by all of the authors, the requirements for authorship have been met, and each author believes that the manuscript represents honest work. Besides, written permission has been obtained from all persons named in the Acknowledgments.

As indicated in the manuscript, correspondence regarding this submission may be directed to me at the following address:

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Thank you very much for your attention to our submission.

Sincerely,  
Pedro Serrano, MD, PhD
Avoidable costs of physical treatments for chronic back, neck and shoulder pain within the Spanish National Health Service: a cross-sectional study

The authors thank the reviewers for their comments and valuable suggestions, which have contributed to improving the quality of the manuscript and have been taken into account for the updated version.

Point by point reply to these comments (in italics) is as follows:

Reviewer's report

Title: Avoidable costs of physical treatments for chronic back, neck and shoulder pain within the Spanish National Health Service: A cross-sectional study

Version: 1 Date: 24 August 2011

Reviewer: Chung-Wei Christine Lin

Reviewer's report:

This study contains a literature search to identify systematic reviews and clinical guidelines on treatments for low back, neck and shoulder pain, and a cost of illness study in which costs attributed to the treatments for low back, neck and shoulder pain were collected from a health service database. The authors described the costs attributed to treatments that were either effective, ineffective or had uncertain effectiveness.

The study was well-written and highlighted costs which may have unnecessarily incurred, but needs to be clearer on the identification and valuation of costs and does not present the latest evidence on effectiveness. My comments are below.

MAJOR COMPULSORY REVISIONS

1. Clarification of types of health services/costs collected – On page 5 under methods it is stated: “It [the database] includes data on the patients who are referred to private practices, including referrals for physical treatment”, and later (page 10) “it does not factor in data on the costs deriving from physical treatments administered in hospitals and primary care practices”. The distinction between private practice and primary care practice is not clear. Hence it would be useful to list the type of health services included in the database.

Following the reviewer’s comment, the manuscript has been modified and the updated version reads:

- Second paragraph under “Background”

The Spanish National Health Service is a public health insurance system with universal coverage which provides free health care to every resident in Spain. Within the Spanish National Health Service (SNHS), primary care practices and hospitals are owned and managed by the
government. Private hospitals and private primary care practices which are owned and managed by private entities exist in parallel to the SNHS, and operate independently. In 2008, 72.5% of total health care expenditure in Spain came from governmental funding [15]. The SNHS can choose to refer patients to private practices in order to shorten waiting times, usually for non-urgent, non-life-threatening conditions, such as physical therapy for musculoskeletal complaints, or surgery for cataract or abdominal hernia. In such cases, the SNHS fully covers the cost of procedures performed by the private practices on the patients it refers. The SNHS is managed at the regional level, and fully financed by national taxes, although some regional governments add local taxes to provide additional funding. The Spanish National Health Service in the Canary Islands (SNHSCI) covers a population of two million individuals, and outsources approximately 70% of physical treatments to the private sector. Physicians at the SNHSCI make the diagnosis and treatment recommendations, but clinicians employed by the private practices have the ability to adjust or change treatments according to each patient’s clinical response. The clinical management of shoulder, neck or back pain is not regulated by compulsory clinical guidelines, and clinicians are free to choose whether or not to follow the European and Spanish evidence-based clinical guidelines for low back pain [16,17]. (Current references 16th and 17th corresponds to previous 42th and 43th references. So references numbers from 16th to 43th were reordered)

- **First paragraph under “Identification of the forms of physical treatments used” (within the “Methods” section)**

  The Information System for private Hospital contracts (ISHC), is a governmental database which includes data from patients in the SNHSCI, who were referred to private practice. In the case of patients with musculoskeletal problems who are referred for physical therapy, the database gathers demographic data, patient’s diagnosis (ICD-9-CM) and the type and number of physical therapies received.

- **Two first paragraphs of the “Discussion” section**

  These results show that as much as 60% of the resources spent by the SNHSCI on physical treatments for non-specific chronic NP, BP and SP between 2004 and 2007, were allocated to treatments that had been found to be either ineffective or for which there was no evidence of effectiveness. This means that, in that period, over 3 million Euros from taxpayers’ contributions was handed over to private centres which had been awarded contracts by the government to apply treatments which lacked any evidence of effectiveness, or which had shown to be ineffective.

  This is a very conservative estimation of the total cost, as it does not factor in data on the costs deriving from physical treatments administered in public hospitals and primary care practices run by the SNHSCI; only data from patients who were referred to private practice were included, representing 70% of patients receiving physical treatment for these conditions. In addition, it was sufficient for a therapy to be considered effective in a single CPG or SR, to be categorised as such in
this study. Any form of treatment labelled as “exercise” was considered to be effective, irrespective of the type of exercise, number of sessions, patients’ compliance or whether it was administered appropriately or inappropriately. Exercise was considered to be effective irrespective of its effect size, whereas previous studies suggest that improvements in pain or disability of less than 30% of baseline value, are clinically irrelevant for patients with NP and BP [50-52]. Moreover, only the provider’s personnel and equipment costs directly related to physical therapies used for SP, NP and BP were taken into account, disregarding other costs (e.g., other provider’s costs –facilities, financial costs, etc.- and profit), societal costs (work absenteeism associated with receiving physical therapy sessions, etc.), costs incurred by patients (transport, loss of earnings, etc.) and other costs for other institutions (insurance companies dealing with work-related accidents, private healthcare, etc.).

2. A main criticism I have is that the literature search for guidelines and systematic reviews is from 2003 to 2007, and therefore dated. It is possible that the authors have done this to coincide with the period of cost data collection. However this means that the evidence is not current and hence the results on avoidable cost do not reflect the latest evidence. For example in Table 1 the authors have stated that there is no data on massage for back pain. But a Cochrane systematic review was published in 2010 (Furlan et al), whose results would change the results of the current manuscript. I would suggest that the search needs to be updated to reflect the latest evidence.

The authors fully agree with the reviewer in that, if the 2010 Cochrane review on massage had been available back in 2007, the classification of “massage” in this study would have been different, despite some uncertainties affecting conclusions from that review.*


In fact, new studies conducted in the future could change the evidence available for all procedures included in this study, by either clarifying their effectiveness (i.e., for those classified as “insufficiently assessed”, or for which the evidence is “inconclusive”), or supporting their classification as “effective” or “ineffective”. Therefore, the authors feel that it would be inappropriate to evaluate the decision-making retroactively, based on new evidence which was not available when the decision was made; this would be a never ending task of limited practical value.

Consequently, the objective of this study was to quantify the cost of procedures which were used in practice, despite the lack of evidence supporting their effectiveness at that point in time.

As a result, at the design phase of this study, the authors felt that the most appropriate course of action would be to classify all procedures as; “effective”, “ineffective”, “insufficiently assessed” or of “inconclusive effectiveness”, based on the evidence available at the time of application. The rationale supporting this decision was that decision makers can only be expected to make decisions based on information available at the time; it is impossible to foresee what the evidence will show in the future. For instance, even if future studies show that exercise is ineffective (contrarily to what is nowadays considered to be the “truth”, based on the currently existing
Following the reviewer’s comment, this issue has been further clarified in the updated version of the manuscript, which reads:

- **“Background” section of the “Abstract”**

  ...The objective of this study was to estimate the cost of physical treatments which, despite the absence of evidence supporting their effectiveness, were used between 2004 and 2007 for chronic and non-specific neck pain (NP), back pain (BP) and shoulder pain (SP), within the Spanish National Health Service in the Canary Islands (SNHSCI).

- **“Methods” section of the “Abstract”**

  Chronic patients referred from the SNHSCI to private physical therapy centres for NP, BP or SP, between 2004 and 2007, were identified. The costs of providing physical therapies to these patients was estimated. Systematic reviews (SRs) and clinical practice guidelines (CPGs) for NP, BP and SP available in the same period were searched for and rated according to the Oxman and AGREE criteria, respectively.

- **Sixth paragraph under “Discussion”:**

  The search for SRs and CPGs was restricted to the 2003-2007 period. It is possible that studies published afterwards may have changed, or will change, the evidence supporting the use of procedures included in this study. However, this study focused on quantifying the costs of procedures used in routine practice, despite the lack of supporting evidence at the time of use. In this regard, even if the evidence were to change based on future research, the use of these technologies in the 2004-2007 period would continue to be inappropriate.

3. Methods for valuation of cost are not clear. Page 7 – the health service pays private clinics a fixed fee per condition, irrespective of the types and numbers of treatment. However the description on how the costs were broken down to cost individual treatments is not clear.

Following the reviewer’s comment, this has been further clarified in the updated version of the manuscript:

- **Four paragraphs under “Cost-Estimation”, within the “Methods section”:**

  The fees paid by the SNHSCI to private practices cover 35 sessions of physical therapy for SP patients, and 30 for NP and BP. These fees remain constant irrespectively of the type of physical treatment actually provided during each session. In fact, the physicians in private practices can modify the physical treatment dispensed, depending on patient’s clinical evolution and their own clinical criteria. In practice, most patients included in this study actually received several forms of physical treatment (Table 1). Since the SNHSCI pays for a “package” of 30-35 sessions, and the type of physical therapies actually performed during these sessions varies from one patient to
the other, it was impossible to estimate the amount paid by the SNHS for each particular form of physical treatment.

Therefore, the costs were estimated using data provided by the private subcontractor to which SP, NP and BP patients were referred from the SNHSCI. These data only included personnel and equipment costs incurred by the private practices in order to provide each form of physical treatment to SP, NP and BP patients referred from the SNHSCI (Table 1). For treatments which are provided to several patients simultaneously (e.g., thermotherapy or some forms of exercise), the conservative assumption that each group comprised two patients, was made. Therefore, for such treatments, unit cost per patient was estimated by dividing the cost of treatment by two.

Total cost for each therapy was obtained by multiplying the unit cost by number of sessions and by number of patients (Table 1). For example, the costs associated with exercises for NP patients were obtained as follows: unit cost per patient per session (€1.25) x number of sessions per patient (30) x number of different types of exercises applied (10,440) in all included cases.

Avoidable costs were defined as costs of treatments which had been classified as “Ineffective”, “of Inconclusive Effectiveness” or “Insufficiently Assessed”. All costs are expressed in inflation-adjusted, 2008 Euros (€).

- Second paragraph of the “Discussion” section

This is a very conservative estimation of the total cost, as it does not factor in data on the costs deriving from physical treatments administered in public hospitals and primary care practices run by the SNHSCI; only data from patients who were referred to private practice were included, representing 70% of patients receiving physical treatment for these conditions. In addition, it was sufficient for a therapy to be considered effective in a single CPG or SR, to be categorised as such in this study. Any form of treatment labelled as “exercise” was considered to be effective, irrespective of the type of exercise, number of sessions, patients’ compliance or whether it was administered appropriately or inappropriately. Exercise was considered to be effective irrespectively of its effect size, whereas previous studies suggest that improvements in pain or disability of less than 30% of baseline value, are clinically irrelevant for patients with NP and BP [50-52]. Moreover, only the provider’s personnel and equipment costs directly related to physical therapies used for SP, NP and BP were taken into account, disregarding other costs (e.g., other provider’s costs –facilities, financial costs, etc.- and profit), societal costs (work absenteeism associated with receiving physical therapy sessions, etc.), costs incurred by patients (transport, loss of earnings, etc.) and other costs for other institutions (insurance companies dealing with work-related accidents, private healthcare, etc.).

4. An essential issue in this area is that most of the evidence on conservative treatments for neck, low back and shoulder pain shows no evidence when one treatment is compared to another. Yet most treatments show some evidence of effectiveness when compared to no treatment. This manuscript suggests that currently the healthcare system spends 60% of its budget on treatments of no effectiveness. But it would be useful in the discussion to take into account the
nature of evidence and possible alternatives to current treatments being funded to allow health dollars to be utilized wisely.

Following the reviewer’s comment, the manuscript has been modified and the updated version reads:

- Seventh to ninth paragraph under “Discussion”

The results of this study illustrate the rationale for recommending disinvestment in specific health technologies. Disinvestment refers to the processes of reducing or discontinuing utilization of selected procedures and treatments [56]. Proactive disinvestment requires prior analyses of inappropriate variation in clinical practice, development of valid CPGs designed to update clinicians’ education and practice, adequate information for patients, in order to improve consumer behaviour, organisational support within the health services for implementing these changes, economic incentives for providers, and incentives for improving the efficiency of purchasing decisions, including the elimination of funding for technologies which are ineffective and/or unsafe. Clinicians, consumers and providers of potentially discarded technologies may feel threatened by disinvestment, while beneficiaries, such as taxpayers and patients themselves, may be less aware of the advantages of such decisions. As a result, incentives to perpetuate the status quo may override the call for change [57].

However, disinvestment in technologies which are not evidence-based, would make funds available for implementing technologies which are not currently available in the SNHSCI despite having proven effective and cost/effective for NP and BP within the SNHS, such as neuro-reflexotherapy, [65-67] and for further expanding the use of technologies proven effective for the conditions reviewed in this study, such as exercise (Table 1, Fig 1). Funds made available through disinvestment could also be used for supporting further research on the effectiveness and cost/effectiveness of physical procedures, which is sparse and of low scientific validity (Table 2).

In fact, results from this study suggest that there is a need for high-quality studies assessing the effectiveness and cost/effectiveness of different forms of physical therapy, individually and in combination. These should be randomized controlled clinical trials, with homogenous and sufficiently large samples, in which validated instruments should be used to assess clinically meaningful variables, and in which randomization, patients’ assessment and data analysis should be masked. These trials should analyze both the statistical significance and clinical relevance of results. Since data on comparative effectiveness of different procedures are difficult to interpret when neither has previously shown superiority versus “sham” or placebo, these studies should compare different forms of physical treatment to the appropriate “sham” procedures as well as to other interventions. Taking into account that some treatments formerly believed to be useful for patients with acute BP proved to actually be harmful, when appropriate, these studies should consider including groups without any intervention (58). The assessment of the results should also be made from the patient’s point of view [54,59,60].

- Second to last paragraph under “Discussion”
No studies quantifying the amount of resources potentially wasted on non evidence-based physical therapies for SP, NP and BP in other countries have been found. However, approximately 50%, 65% and 94% of physiotherapists in the UK, US and Canada, respectively, use procedures which were classified in this study as non-evidence based (Table 2).[68] In addition, approximately 55% of primary care practitioners in the US, recommend those forms of treatment.[69] In fact, only in the US more than 200 treatments are offered only for BP, most of which are not evidence-based.[70,71] With this non-evidence based approach, the cost of health care provided to low back pain patients in the US increased by 65% (constant dollars) from 1997 to 2005, without generating any improvements in outcomes.[72] In contrast to this, in The Netherlands, yearly costs derived from low back pain represented 1.7% of the Gross Domestic Product in 1995, and were reduced to 0.9% in 2002 and to 0.6% in 2007. This decrease was achieved without noticing deterioration in outcomes, and is attributed to the progressive implementation of an evidence-based clinical management.[8,73] Although available data do not reveal the exact amount of potential savings which could be made in other countries, results from this study are likely to be generalisable to other industrialised countries, suggesting that disinvesting in not-evidence based physical therapies for SP, NP and BP, would reduce costs without worsening patients’ evolution, thus substantially improving efficiency.

MINOR ESSENTIAL REVISIONS

The study is conducted in a specific region in Spain and may have limited generalisability, as discussed by the authors. Although the authors discussed the generalisability as applied to the rest of Spain, it would be useful for the international readership of this journal to have some discussion on how the study results would apply to another country/different healthcare setting.

Following the reviewer’s comment, the manuscript has been modified and the updated version reads (second to last paragraph under “Discussion”):

No studies quantifying the amount of resources potentially wasted on non evidence-based physical therapies for SP, NP and BP in other countries have been found. However, approximately 50%, 65% and 94% of physiotherapists in the UK, US and Canada, respectively, use procedures which were classified in this study as non-evidence based (Table 2).[68] In addition, approximately 55% of primary care practitioners in the US, recommend those forms of treatment.[69] In fact, only in the US more than 200 treatments are offered only for BP, most of which are not evidence-based.[70,71] With this non-evidence based approach, the cost of health care provided to low back pain patients in the US increased by 65% (constant dollars) from 1997 to 2005, without generating any improvements in outcomes.[72] In contrast to this, in The Netherlands, yearly costs derived from low back pain represented 1.7% of the Gross Domestic Product in 1995, and were reduced to 0.9% in 2002 and to 0.6% in 2007. This decrease was achieved without noticing deterioration in outcomes, and is attributed to the progressive implementation of an evidence-based clinical management.[8,73] Although available data do not reveal the exact amount of potential savings which could be made in other countries, results from this study are likely to be generalisable to other industrialised countries, suggesting that disinvesting in not-evidence based physical therapies for SP,
NP and BP, would reduce costs without worsening patients’ evolution, thus substantially improving efficiency.

Reviewer's report

Reviewer: Heikki M Hemmilä

Reviewer's report:

General remarks

The work is an important addition to the present data on the use of different physiotherapy methods on musculoskeletal disorders. It reveals that a large portion of public financing is spent in Spain on therapies that on the basis of current knowledge are regarded as unfounded. This is probably true for other countries as well, and it could be discussed a bit more. The original study was evidently aimed at policy makers to motivate changes in the contracts with the private physiotherapy units as well as to change the customs of the doctors and therapists responsible for the practices.

A considerable part of the paper is dedicated to the analysis of available evidence of effectiveness of the different therapy methods. Dozens of systematic reviews and clinical practice guidelines were searched, analyzed and rated to judge whether each therapy method currently compensated by the Spanish National Health Service was regarded as effective, not effective, or insufficiently studied to enter a conclusion. In my mind adding a fourth level on the analysis does not add to the certainty of judgement. In the end, only few references were actually used for the rating - and only exercise and manual therapy with mobilization were assessed as effective. In stead the national or European guidelines could have been employed and the main focus aimed at the actual findings and possible explanations to the status quo.

Possible solutions to improve the current practices could have been discussed, as well as published experiences from other countries. Or if the second purpose of the paper was to formulate a new Spanish National Clinical Practice Guideline, it should have been based on the analysis of all the available RCT:s – a much more cumbersome task, though.

Several issues were discussed properly but more emphasis could have been put on the description and analysis of the current practices. Also the obvious weakness of the cost analysis was not sufficiently treated: The unit costs of the specific therapy methods were based on information given by a single subcontractor, the ICOT Group. It was not clear whether that data was actually employed by the company in its internal accounting or was it just a random estimate. It did not become clear, either, what was the count of total expenditure based on: official statistics or a multiplication of the given, largely theoretic, figures.

Major Compulsory Revisions

Abstract/ Methods: Explaining at first how the criteria for rating the different therapies were adopted obscures the main purpose of the paper. In stead, the info on collecting the data should be first and the principles of rating the therapy
methods should be referred to rather shortly thereafter. The same applies to the Abstract/ Results section

Following the reviewer’s comment, the manuscript has been modified and the updated version reads:

- “Methods” section of the Abstract:

Chronic patients referred from the SNHSCI to private physical therapy centres for NP, BP or SP, between 2004 and 2007, were identified. The cost of providing physical therapies to these patients was estimated. Systematic reviews (SRs) and clinical practice guidelines (CPGs) for NP, BP and SP available in the same period were searched for and rated according to the Oxman and AGREE criteria, respectively. Those rated positively for ≥70% of the criteria, were used to categorise physical therapies as Effective; Ineffective; Inconclusive; and Insufficiently Assessed. The main outcome was the cost of physical therapies included in each of these categories.

- “Results” section of the Abstract:

8,308 chronic cases of NP, 4,693 of BP and 5,035 of SP, were included in this study. Among prescribed treatments, 39.88% were considered Effective (physical exercise and manual therapy with mobilization); 23.06% Ineffective; 13.38% Inconclusive, and 23.66% Insufficiently Assessed. The total cost of treatments was € 5,107,720. Effective therapies accounted for € 2,069,932.

Main article/Background/paragraph 2: In order to satisfy the international readership better the regulations of Spanish health care contracts with private physiotherapy clinics should be explained in more detail. Must all the therapy sessions be prescribed by a doctor, including the selection of forms of therapy, or is the choice of therapy(ies) left to the private physiotherapist? Is the use of different methods regulated by compulsory guidelines or restrictions on reimbursement? Is the therapists invoice totally paid by the public insurance or is there an own liability to the patient? These matters would help to make international comparisons.

Following the reviewer’s comment, the manuscript has been modified and the updated version reads (second paragraph under “Background”):

The Spanish National Health Service is a public health insurance system with universal coverage which provides free health care to every resident in Spain. Within the Spanish National Health Service (SNHS), primary care practices and hospitals are owned and managed by the government. Private hospitals and private primary care practices which are owned and managed by private entities exist in parallel to the SNHS, and operate independently. In 2008, 72.5% of total health care expenditure in Spain came from governmental funding [15]. The SNHS can choose to refer patients to private practices in order to shorten waiting times, usually for non-urgent, non-life-threatening conditions, such as physical therapy for musculoskeletal complaints, or surgery for cataract or abdominal hernia. In such cases, the SNHS fully covers the cost of procedures performed by the private practices on the patients it refers. The SNHS is managed at the regional level, and fully financed by national taxes, although some regional governments add local taxes to provide additional funding. The Spanish National Health Service in the
Canary Islands (SNHSCI) covers a population of two million individuals, and outsources approximately 70% of physical treatments to the private sector. Physicians at the SNHSCI make the diagnosis and treatment recommendations, but clinicians employed by the private practices have the ability to adjust or change treatments according to each patient’s clinical response. The clinical management of shoulder, neck or back pain is not regulated by compulsory clinical guidelines, and clinicians are free to choose whether or not to follow the European and Spanish evidence-based clinical guidelines for low back pain [16,17]. (Current references 16th and 17th corresponds to previous 42th and 43th references. So references numbers from 16th to 43th were reordered)

Main article/Methods/Evidence of effectiveness. I suggest thinking again to dedicate that much space to finally entering to a simple conclusion based on a couple of references. This kind of analysis could be the subject of another article with emphasis on the possible differences between some national and international CPGs. Could their judgements be influenced by different local traditions and national interests.

The authors thank the reviewer for this comment and agree that the information gathered for this study could be used to initiate another one comparing differences across CPGs and their potential causes.

The objective of this study was to estimate costs derived from the use of physical therapies for SP, NP and BP, and especially from the use of physical therapies which were not supported by the available evidence when they were used in routine practice. At the design phase of this study, the authors decided to use a comprehensive approach and define “effective” procedures as those categorised as such by a high quality Systematic Review (SR) or Clinical Guideline (CG). To this end, all evidence-based SRs and CGs available during the study period had to be searched for, analyzed and rated, so that conclusions from the “high quality” ones could be taken into account. The rationale for this decision was that, if the classification as “effective” were to be based on an arbitrarily, pre-hoc, selected set of CGs, conclusions might have been seen as biased; not based on all the evidence available.

As the reviewer points out, the selected approach implied a painstaking task, but the authors felt that it was appropriate for ensuring the (international) validity of the classification of physical therapies and, therefore, of results from this study. For the sake of transparency, the description of the process followed was duly included in the article.

Main article/Methods/Cost estimation/Paragraph 1: the third sentence states that NHS pays a fixed fee per treated condition. This needs more clarification: Does the patient pay the rest? Or is the physiotherapist bound to adapt his/her expenses into those diagnosis-based limits of income? These matters might explain the motivation of either the patient or the therapist to modify the therapy scheme prescribed by a doctor.

Following the reviewer’s comment, the manuscript has been modified to clarify this issue, and the updated version reads:

- Second paragraph under “Background”:
The Spanish National Health Service is a public health insurance system with universal coverage which provides free health care to every resident in Spain. Within the Spanish National Health Service (SNHS), primary care practices and hospitals are owned and managed by the government. Private hospitals and private primary care practices which are owned and managed by private entities exist in parallel to the SNHS, and operate independently. In 2008, 72.5% of total health care expenditure in Spain came from governmental funding [15]. The SNHS can choose to refer patients to private practices in order to shorten waiting times, usually for non-urgent, non-life-threatening conditions, such as physical therapy for musculoskeletal complaints, or surgery for cataract or abdominal hernia. In such cases, the SNHS fully covers the cost of procedures performed by the private practices on the patients it refers. The SNHS is managed at the regional level, and fully financed by national taxes, although some regional governments add local taxes to provide additional funding. The Spanish National Health Service in the Canary Islands (SNHSCI) covers a population of two million individuals, and outsources approximately 70% of physical treatments to the private sector. Physicians at the SNHSCI make the diagnosis and treatment recommendations, but clinicians employed by the private practices have the ability to adjust or change treatments according to each patient’s clinical response. The clinical management of shoulder, neck or back pain is not regulated by compulsory clinical guidelines, and clinicians are free to choose whether or not to follow the European and Spanish evidence-based clinical guidelines for low back pain [16,17]. (Current references 16th and 17th corresponds to previous 42th and 43th references. So references numbers from 16th to 43th were reordered)

- First and second paragraphs under “Cost Estimation”, within “Methods”:

The fees paid by the SNHSCI to private practices cover 35 sessions of physical therapy for SP patients, and 30 for NP and BP. These fees remain constant irrespectively of the type of physical treatment actually provided during each session. In fact, the physicians in private practices can modify the physical treatment dispensed, depending on patient’s clinical evolution and their own clinical criteria. In practice, most patients included in this study actually received several forms of physical treatment (Table 1). Since the SNHSCI pays for a “package” of 30-35 sessions, and the type of physical therapies actually performed during these sessions varies from one patient to the other, it was impossible to estimate the amount paid by the SNHS for each particular form of physical treatment.

Therefore, the costs were estimated using data provided by the private subcontractor to which SP, NP and BP patients were referred from the SNHSCI. These data only included personnel and equipment costs incurred by the private practices in order to provide each form of physical treatment to SP, NP and BP patients referred from the SNHSCI (Table 1). For treatments which are provided to several patients simultaneously (e.g., thermotherapy or some forms of exercise), the conservative assumption that each group comprised two patients, was made. Therefore, for such treatments, unit cost per patient was estimated by dividing the cost of treatment by two.
Main article/Methods/Cost estimation/Paragraph 2: Question: How does the calculated total sum of the individual therapy costs relate to the actual payment by the NHS?

Only data from some direct costs were provided by the internal accounting of ICOT, explaining that the relationship between these costs and actual payment is approx. 75%. That is another reason that explains the conservative estimation of avoidable costs, as is explained in the discussion section (2nd paragraph).

Following the reviewer’s comment, the manuscript has been modified and the updated version reads:

- First and second paragraphs under “Cost Estimation”, within “Methods”:

  The fees paid by the SNHSCI to private practices cover 35 sessions of physical therapy for SP patients, and 30 for NP and BP. These fees remain constant irrespectively of the type of physical treatment actually provided during each session. In fact, the physicians in private practices can modify the physical treatment dispensed, depending on patient’s clinical evolution and their own clinical criteria. In practice, most patients included in this study actually received several forms of physical treatment (Table 1). Since the SNHSCI pays for a “package” of 30-35 sessions, and the type of physical therapies actually performed during these sessions varies from one patient to the other, it was impossible to estimate the amount paid by the SNHS for each particular form of physical treatment.

  Therefore, the costs were estimated using data provided by the private subcontractor to which SP, NP and BP patients were referred from the SNHSCI. These data only included personnel and equipment costs incurred by the private practices in order to provide each form of physical treatment to SP, NP and BP patients referred from the SNHSCI (Table 1). For treatments which are provided to several patients simultaneously (e.g., thermotherapy or some forms of exercise), the conservative assumption that each group comprised two patients, was made. Therefore, for such treatments, unit cost per patient was estimated by dividing the cost of treatment by two.

- Second paragraph under “Discussion”:

  This is a very conservative estimation of the total cost, as it does not factor in data on the costs deriving from physical treatments administered in public hospitals and primary care practices run by the SNHSCI; only data from patients who were referred to private practice were included, which only represents 70% of patients receiving physical treatment for these conditions. In addition, it was sufficient for a therapy to be considered effective in a single CPG or SR, to be categorised as such in this study. Any form of treatment labelled as “exercise” was considered to be effective, irrespective of the type of exercise, number of sessions, patients’ compliance or whether it was administered appropriately or inappropriately. Exercise was considered to be effective irrespectively of its effect size, whereas previous studies suggest that improvements in pain or disability of less than 30% of baseline value, are clinically irrelevant for patients with NP and BP [50-52]. Moreover, only the provider’s personnel and equipment costs directly related to physical therapies used for SP, NP and BP were taken into account, disregarding other costs (e.g., other provider’s costs –facilities, financial
costs, etc.- and profit), societal costs (work absenteeism associated with receiving physical therapy sessions, etc.), costs incurred by patients (transport, loss of earnings, etc.) and other costs for other institutions (insurance companies dealing with work-related accidents, private healthcare, etc.).

Discussion/Paragraph 7: Results from this study suggest... Do they? Or is it obvious already from other studies? Think again, is the whole paragraph essential. If so, I would also add the need to compare the therapies with natural history, meaning control group with no therapy. The possibility of all studied therapies being harmful was illustrated by the Finnish study on acute LBP where the control group fared best (Malmivaara A, et al: The treatment of acute low back pain - bed rest, exercises, or ordinary activity? NEJM 332: 351-355, 1995).

As the reviewer points out, previous studies had already suggested that clinical practice involving physical therapy for chronic SP, NP and BP is not always evidence based. The current study builds on this evidence by quantifying the percentage of public funds spent on physical therapy for these patients, identifying the proportion being spent on procedures which are not evidence-based.

The authors fully agree with the reviewer in that RCTs conducted in the future should gather data on the possibility that all therapies included may actually be harmful.

To further clarify this, following the reviewer’s comment, the manuscript has been modified and the updated version reads (ninth paragraph under “Discussion”):

In fact, results from this study suggest that there is a need for high-quality studies assessing the effectiveness and cost/effectiveness of different forms of physical therapy, individually and in combination. These should be randomized controlled clinical trials, with homogenous and sufficiently large samples, in which validated instruments should be used to assess clinically meaningful variables, and in which randomization, patients’ assessment and data analysis should be masked. These trials should analyze both the statistical significance and clinical relevance of results. Since data on comparative effectiveness of different procedures are difficult to interpret when neither has previously shown superiority versus “sham” or placebo, these studies should compare different forms of physical treatment to the appropriate “sham” procedures as well as to other interventions. Taking into account that some treatments formerly believed to be useful for patients with acute BP proved to actually be harmful, when appropriate, these studies should consider including groups without any intervention (58). The assessment of the results should also be made from the patient’s point of view [54,59,60].

Discussion/Paragraph 11: Check ref [63]: To my understanding the reference deals with the recommended treatment of HIV, not physical therapies and rehabilitation.

The authors apologize for the reference mistakenly included in the previous version of the manuscript.

Following the reviewer’s comment, the appropriate reference is now included (Nº 64 in the updated version of the manuscript)

Discussion/Paragraph 12 (last Pgf): This important section of the Discussion looks like it came from another paper. While it may be relevant to discuss the criteria of dividing therapies into sheep and goats, a more relevant issue might be the line of demarcation and what would be the consequences of approaching each end. Also some reference could be made into experiences from other countries, which is now totally absent.

The criteria used in this study for classifying the treatments as evidence-based or not (i.e., “effective”, “ineffective”, “of inconclusive effectiveness” and “insufficiently assessed”), derive from international systematic reviews and evidence-based clinical guidelines. Therefore, the authors feel that the “line of demarcation” is internationally valid.

The authors have failed to find any other studies quantifying the resources assigned to funding not-evidence based treatments for SP, NP and BP in other countries. This makes it difficult to estimate the potential impact of implementing the strategy they propose for Spain (i.e., disinvesting in non-evidence based physical therapies used in clinical practice for SP, NP and BP), in other countries. However, international data on the evolution of costs associated with BP suggest that savings can also be very significant in other countries.

Following the reviewer’s comment, the manuscript has been modified and the updated version reads (second to last paragraph under “Discussion”):

No studies quantifying the amount of resources potentially wasted on non-evidence-based physical therapies for SP, NP and BP in other countries have been found. However, approximately 50%, 65% and 94% of physiotherapists in the UK, US and Canada, respectively, use procedures which were classified in this study as non-evidence based (Table 2).[68] In addition, approximately 55% of primary care practitioners in the US recommend those forms of treatment.[69] In fact, only in the US more than 200 treatments are offered only for BP, most of which are not evidence-based.[70,71] With this non-evidence based approach, the cost of health care provided to low back pain patients in the US increased by 65% (constant dollars) from 1997 to 2005, without generating any improvements in outcomes.[72] In contrast to this, in The Netherlands, yearly costs derived from low back pain represented 1.7% of the Gross Domestic Product in 1995, and were reduced to 0.9% in 2002 and to 0.6% in 2007. This decrease was achieved without noticing deterioration in outcomes, and is attributed to the progressive implementation of an evidence-based clinical management.[8,73] Although available data do not reveal the exact amount of potential savings which could be made in other countries, results from this study are likely to be generalisable to other industrialised countries, suggesting that disinvesting in non-evidence based physical therapies for SP, NP and BP, would reduce costs without worsening patients’ evolution, thus substantially improving efficiency.
Competing interests: Several of the authors are employed by the Spanish state organization responsible for financing the therapies under study. Should this connection not be explicitly expressed?

Following the reviewers’ comment we have clarified this issue in a new paragraph in the updated version of the manuscript, which reads (“Competing Interest” section):

The authors have no conflicts of interest to report. No benefits in any form have been or will be received by the authors or their institutions from any party harbouring economic interests related directly or indirectly to the subject of this article. Funds for this study came from governmental and not-for-profit scientific institutions, and no funds were received from any for-profit institution or entities linked to the health industry. While this study was designed and conducted, José María Cabrera-Hernández was involved in planning, assessing and financing treatments performed by private practices on patients referred from the Spanish National Health Service at the Canary Islands (SNHSCI). However, he had no links—either financial or otherwise— with any private practice or contractor, or incentives to increase or reduce the amount of payments made by the SNHSCI.

Minor Essential Revisions (Issues not for publication)

Main article/Background/Paragraph 1/ third sentence These musculoskeletal disorders are usually non-specific. “Non-specific” is not regarded as a distinct diagnosis, it rather means that no underlying pathology has been found with current diagnostic tools to explain the symptoms. I also suggest checking the references. According to their headlines ref [11] and [14] sound to suit here better than [9].

Reference # 9 focuses on the most common (musculoskeletal) health problems among the general and the working populations (which include SP, NP and BP), and reviews their causes according to the available evidence. The definition of “non-specific” mentioned in the “background” section, derives from this reference. Therefore, the authors feel that it is appropriate and would like to keep it as the citation.

Following the reviewer’s comment, the manuscript has been modified to further clarify the meaning of “non-specific”, and the updated version reads as follows (first paragraph under “Background”):

Back, neck and shoulder problems are the most common causes of pain and occupational disability [1-3]. They reduce health-related quality of life (HRQL) and have a significant economic impact [4-8]. These musculoskeletal disorders are usually non-specific, which means that pain cannot be attributed to any specific structural cause and is believed to originate from soft tissues [9]. Their lifetime prevalence is 50-70% and they are among the most common reasons for primary care visits in Spain [10-14].

Main article/Background/paragraph 3: Question: Does the coding of Spanish National Health Service statistics allow separation of chronic from acute musculoskeletal conditions? If not, word chronic should be omitted from sentence 2. The above mentioned also applies to the first sentence in Methods paragraph 2

The coding system does not distinguish acute from chronic conditions. However, among the cases with selected ICD codes, only those who initiated treatment at least
12 weeks after date of initial complaint were included in the analysis. Therefore, only patients with pain for >12 weeks (i.e. chronic cases) were included in this study. Accordingly, this study (and the literature review we performed to assess whether the treatments the patients received were or were not evidence-based), focused only on chronic patients.

**Following the reviewer’s comment**, the manuscript has been modified to further clarify this issue, and it now reads as follows (third paragraph under “Identification of the forms of physical treatments used”, within the “Methods” section):

The type and number of physical treatments funded by the Spanish National Health Service in the Canary Islands from January 1st, 2004 to December 31st, 2007, for patients over 18 years for non-specific chronic NP, BP and SP (ICD-9-CM-723.1, ICD-9-CM-724.2 and ICD-9-CM-726.1) were identified using the ISHC database. Chronic NP, BP or SP was defined as an episode lasting 12 or more weeks,[18] Only patients who initiated treatment at least 12 weeks after seeking care for SP, NP or BP (i.e., chronic cases) were included in the study. Treatments for other conditions were not considered.

**Main article/Methods/Evidence of effectiveness../Paragraph 2/third sentence**: It consists of 23 key items... Which of them? Evidently the AGREE instrument, please add it.

**Following the reviewer’s comment**, the manuscript has been modified and the updated version reads (second paragraph under “Evidence on the effectiveness of the different forms of physical treatment”, within the “Methods” section):

CPGs and SRs focusing on chronic nonspecific NP, BP and SP, and covering any form of physical treatment, were selected. Their quality was assessed independently by two assessors, and disagreements between them were discussed and resolved by the first author. Quality assessment was based on the AGREE instrument for CPGs and the Oxman scale criteria for SRs. The AGREE instrument consists of 23 key items organised in six domains, to capture separate dimensions of CPG quality [17]. These domains are:....

**Main article/Results/Paragraph 3/last sentence**: Thirty four in stead of Thirty-four.

Please, excuse the typo in the previous version of the manuscript, which has been corrected in the updated one.

**Main article/Results/Paragraph 4/third sentence**: ..., of inclusive effectiveness... correct: inconclusive

Please, excuse the typo in the previous version of the manuscript, which has been corrected in the updated one.

**Main article/Results/Paragraph 6: ...between 2004 and 2007, paid for... correct: was paid for...**

Please, excuse the typo in the previous version of the manuscript, which has been corrected in the updated one.
Discussion/Paragraph 3/second sentence: The main shortcomings affected the randomization... Should be better expressed, eg. ...The main shortcomings were related to...

Following the reviewer’s comment, the manuscript has been modified and the updated version reads (third paragraph under “Discussion”):

All the SRs and CPGs reviewed conclude that the quality of most clinical trials on physical treatments was low. The main shortcomings were related to...

Discussion/Paragraph 4/first sentence: ...of the different type of ... correct: types...

Please, excuse the typo in the previous version of the manuscript, which has been corrected in the updated one.

Discussion/Paragraph 6/first sentence: These results illustrate the rational... preferably: The results of this study..., and correct: rationale

Following the reviewer’s comment, the manuscript has been modified and the updated version reads (7th paragraph under “Discussion”):

The results of this study illustrate the rationale for recommending disinvestment in specific health technologies. Disinvestment refers to ...

Discussion/Paragraph 11/second sentence: aging rate - do you mean age distribution. And health expectancy – should it be life expectancy.

Following the reviewer’s comment, the manuscript has been modified and the updated version reads (third to last paragraph under “Discussion”):

These results were obtained from a single Spanish region, so generalisation of these findings should be discussed. The Canary Islands has a population of approximately 2 million, and a similar demographic structure, populations’ age distribution, life expectancy and infant mortality to the average values of Spain [61]...

Ref 57: University of Technology Sidney. correct Sydney.

Please, excuse the typo in the previous version of the manuscript, which has been corrected in the updated one.

Discretionary Revisions Conclusions (Issues not for publication)

Abstract/Results second sentence: They included medium and low... This expression arises the question if the high quality studies were excluded. Pls formulate better.
Following this and a previous reviewer’s comment, the manuscript has been modified and the updated version reads:

- **“Methods” section of the Abstract:**

  Chronic patients referred from the SNHSCI to private physical therapy centres for NP, BP or SP, between 2004 and 2007, were identified. The costs of providing physical therapies to these patients was estimated. Systematic reviews (SRs) and clinical practice guidelines (CPGs) for NP, BP and SP available in the same period were searched for and rated according to the Oxman and AGREE criteria, respectively. Those rated positively for ≥70% of the criteria, were used to categorise physical therapies as Effective; Ineffective; Inconclusive; and Insufficiently Assessed. The main outcome was the cost of physical therapies included in each of these categories.

- **“Results” section of the Abstract:**

  8,308 chronic cases of NP, 4,693 of BP and 5,035 of SP, were included in this study. Among prescribed treatments, 39.88% were considered Effective (physical exercise and manual therapy with mobilization); 23.06% Ineffective; 13.38% Inconclusive, and 23.66% Insufficiently Assessed. The total cost of treatments was € 5,107,720. Effective therapies accounted for € 2,069,932.

Following this and a previous reviewer’s comment, the manuscript has been modified and the updated version reads (Results section of the Abstract):

8,308 chronic cases of NP, 4,693 of BP and 5,035 of SP, were included in this study. Among prescribed treatments, 39.88% were considered Effective (physical exercise and manual therapy with mobilization); 23.06% Ineffective; 13.38% Inconclusive, and 23.66% Insufficiently Assessed. The total cost of treatments was € 5,107,720. Effective therapies accounted for € 2,069,932.

Abstract/Conclusions last sentence ..., or are ineffective. sounds to refer to the allocated resources in stead of the treatments. Should it read ..., or are proven ineffective.

Following the reviewer’s comment, the manuscript has been modified and the updated version reads (“Conclusions” section of the Abstract):

Sixty percent of the resources allocated by the Spanish National Health Service to fund physical treatment for NP, BP and SP in private practices, are spent on forms of treatment proven to be ineffective, or for which there is no evidence of effectiveness.

Main article/Discussion/Paragraph 1/first sentence: is chronic an entitled term here?
The authors feel that the term is appropriate, since only chronic patients were included in this study.

Following the reviewer’s comment, the manuscript has been modified and the updated version reads (third paragraph under Identification of the forms of physical treatments used, within the “Methods” section):

The type and number of physical treatments funded by the Spanish National Health Service in the Canary Islands from January 1st, 2004 to December 31st, 2007, for patients over 18 years for non-specific chronic NP, BP and SP (ICD-9-CM-723.1, ICD-9-CM-724.2 and ICD-9-CM-726.1) were identified using the ISHC database. Chronic NP, BP or SP was defined as an episode lasting 12 or more weeks.[18] Only patients who initiated treatment at least 12 weeks after seeking care for SP, NP or BP (i.e., chronic cases) were included in the study. Treatments for other conditions were not considered.

Conclusions: Given the vague basis of the unit costs of different therapies it seems inappropriate to present the results with two decimals of a percent!

Following the reviewer’s comment, the manuscript has been modified and the updated version reads (“Conclusions” section of the Abstract):

The average physical treatment applied in private practice to patients with chronic non-specific neck, back and shoulder pain referred from the Spanish National Health Service in the Canary Islands, includes 4.5 forms of treatment applied in 30-35 sessions. Between 2004 and 2007, only 40% of the treatments applied had previously shown to be effective, namely exercise and mobilization for certain cases. A conservative estimate suggests that treatments lacking any evidence of effectiveness represented 60% of total expenditure and accounted for approximately 3 million Euros. Over one million Euros were spent for treatments which had previously been shown to be ineffective.

References: As being addressed to an English readership the headlines of all the Spanish references should be translated into English (Refs 10, 43, 60, 61, 62, and 63). Also it is regarded as unnessesary to list the Spanish translations of originally English references (Refs 20, 21, 26, 27, 28, and 29).

Following the reviewer’s comment, all references have been translated to English, and the list of Spanish translation of originally English references, has been deleted.