

BMJ Open Development of a clinical prediction model to inform clinical decision making for classification of patients with sciatica, based on their clinical characteristics, in the Greek health system: protocol for a prospective predictive exploratory study

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ABSTRACT

Introduction Sciatica is one of the most common reasons for seeking healthcare for musculoskeletal pain. Sciatica is primarily considered as neuropathic in nature when neural tissue in the low back is compromised, but sometimes other non-neural structures may be involved. Appropriate assessment and management are important for patients with sciatica. Therapists use several outcome measures to assess patients to inform selection of the most suitable treatment. There is limited evidence for the best treatment of sciatica, and this is likely contributed to by having no reliable algorithm to categorise patients based on their clinical characteristics to inform physiotherapy treatment. The purpose of this study is to develop a clinical prediction model to categorise patients with sciatica, in terms of early clinical outcome, based on their initial clinical characteristics.

Methods and analysis A prospective observational multicentre design will recruit consecutive patients (n=467) with sciatica referred for physiotherapy. Each patient will be evaluated to determine whether or not they will be accepted into the study by answering some questions that will confirm the study's eligibility criteria. Patients' basic characteristics, patient-reported outcome measures and performance-based measures will be collected at baseline from multiple sites in the Greek territory using this same protocol, prior to commencement of treatment. The main researcher of this study will be responsible for data collection in all sites. On completion of the standard referred physiotherapy treatment after 3 weeks' time, participants will be asked by telephone to evaluate their outcome using the Global Perceived Effect Scale. For the descriptive statistical analysis, the continuous variables will be expressed in the form of 'mean' and 'SD'. In order to assess the prognostic value of each predictor, in terms of the level of improvement or worsening of the symptoms, multiple variable regression analysis will be used.

Strengths and limitations of this study

- This will be the first research study in Greece to categorise patients with sciatica, in terms of clinical outcome, based on their clinical characteristics. It will generate a fast and reliable algorithm for every day clinical practice for healthcare professionals that can predict the early outcome of the patients after physiotherapy treatment based on their clinical characteristics.
- Candidate predictive factors selected from a systematic review, other published studies and experts' opinions.
- This prospective predictive study will be conducted according to the TRIPOD checklist (Prediction Model Development), PROGRESS framework and PROBAST.
- For reliability reasons, the main researcher will conduct all data collection to all participants to ensure standardised procedures of data collection.
- The outcome will be dichotomised and that may lead to loss of information and risk of misclassification.
- Due to COVID-19 restrictions during the planned period of the study, this may create difficulties for gathering a larger sample.

Ethics and dissemination This study is approved from the Ethics and Deontology Committee of the University of West Attica, Athens, Greece, protocol number: 38313-09/06/2020, 10226-10/02/2021. The study's findings will be published in a peer-reviewed journal and disseminated at national and international conferences and through social media.

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INTRODUCTION

In primary care, a large proportion of patients with low back pain (LBP), approximately 60%,

also report low back-related leg pain (LBLP).¹ This pain is commonly referred to as sciatica and is often described as pain radiating to the buttocks, thighs and below the knee, foot and/or toes. LBLP is generally clinically diagnosed as sciatica (lumbar radicular) or referred pain (involving non-neural structures); sciatica is considered neuropathic in nature whereas referred pain is considered nociceptive.² It may be accompanied by physical findings of nerve root entrapment, such as decreased sensitivity, alteration in reflex and/or muscle weakness in entrapped nerve root distribution.³ However, there is evidence to suggest the coexistence of both pain mechanisms in LBLP,⁴ and evidence for sciatica presenting without neuropathic pain and referred pain presenting with neuropathic pain.⁵ The prevalence of neuropathic pain reported in a recent study by Harrison *et al.*⁹ estimates of neuropathic pain in LBLP ranged from 19% to 80%, although these findings must be observed with caution as the review itself is at moderate risk of bias. LBLP compared with LBP alone is associated with increased disability, pain and poorer quality of life.⁶ Sciatica is a relatively common and often a persistent 'nuisance'⁷ that leads to the use of health services,⁸ prolonged sick leave⁹ and has considerable economic consequence in terms of healthcare resources and lost productivity.¹⁰ Although prognosis is good for most patients, a significant proportion (up to 30%) still have pain for a year or more.¹¹

The aetiology of sciatica varies as described above, as well as lumbar radiculopathy and referred pain. It may be due to severe vertebral pathology as well as other non-vertebral diseases.¹² In a large proportion of cases, it is caused by an intervertebral disc herniation resulting in nerve root irritation,³ but yet in these cases the management is not straight forward. Sciatica is, therefore, a broad term encompassing multiple diagnoses that require different management.³ Evaluation of aetiology often involves the use of expensive imaging methods (MRI) which can lead to wrong conclusions regarding the causes of pain.¹² The diagnosis and management of sciatica varies considerably within and between countries,³ which may reflect treatment availability, clinician preference and socioeconomic variables rather than evidence-based practice. Previous systematic reviews (including meta-analyses) have evaluated the effectiveness of various individual treatment approaches for sciatica, including conservative treatments,^{11 13–15} epidural steroid injections^{11 14 16 17} and surgical procedures.¹⁸ However, numerous treatments have not been directly compared with other interventions and the results have not been statistically or clinically significant. In order to compare interventions, it would be helpful if study populations had the same clinical characteristics. Populations in the studies are commonly heterogeneous owing to the multiple diagnoses and aetiopathological parameters within sciatica. It is thus easily understood that research interest is increasingly focused on exploring more effective evaluation tools to categorise these patients based on their clinical characteristics with the aim of prediction the outcome of the patients after physiotherapy treatment.

Although there is worldwide research interest in possible classification prediction models for these patients, there is an urgent need to develop a clinical and research application algorithm for Greek society for clinical and research use. In the international physiotherapy community, some evaluation tools for sciatica have been proposed with sometimes poor, controversial and/or conflicting results.¹² Although the sample of these research was sufficient the results cannot be generalised to other health systems such as the Greek. There are psychosocial differences in patients of different nationalities in terms of pain and its treatment.¹⁹ and international systems may not be appropriate. Culture across countries also varies. Culture according to Helman²⁰ is a set of guidelines that individuals inherit as members of a particular society that tells them how to see the world, how to experience it emotionally and how to behave in relation to other people. There is evidence that there are cultural differences in medical, physical and psychosocial findings among patients with pain in the low lumbar region.^{19 21} and research based on intracultural comparisons could provide valuable information on the development of features to be included in a classification system.²² In Greece, no study has yet investigated the evaluation and categorisation of patients with sciatica in terms of early clinical outcome, based on their initial clinical characteristics.

Objective

To develop a clinical prediction model to categorise patients with sciatica in terms of early clinical outcome, based on their initial clinical characteristics.

METHODS AND ANALYSIS

Source of data

This research is a prospective predictive exploratory observational multicentre study for clinical prediction model development within the Greek health system. Patients with sciatica referred for physiotherapy will be recruited. The study will be started on June 2021 with anticipated completed date on September 2022. Self-reported and physical examination potential predictive data items will be collected at baseline prior to treatment, which will commence immediately following recruitment. Following collection of potential predictive data items, patients will undergo physiotherapy treatment. At the end of their standard physiotherapy treatment, at 3 weeks postbaseline, outcome will be evaluated. Outcome will be assessed using Global Perceived Effect Scale (GPES). This protocol is written in line with the transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD) statement of items that should be included in reports of prediction model development and validation.²³ Prognosis research strategy (PROGRESS) framework²⁴ and prediction model risk of bias assessment tool (PROBAST)²⁵ were used for the plan analysis of this study.

Participants and eligibility

Consecutive eligible patients will be recruited in order not to introduce bias. Participants will be patients with diagnosed sciatica, referred from spinal surgeons for standard physiotherapy provided by their public insurance and will contribute to our understanding of the findings from the systematic review informing this application. Patients may have with them X-ray and/or MRI results of investigations of their back. Participants will be recruited from private physiotherapy clinics in Greece. Physiotherapists, owners of these clinics, will be invited to participate as a clinical site in the research. All consecutive eligible patients will be approached for recruitment into the study by the clinic owner who will be responsible to book the appointment for the assessment. The special musculoskeletal physiotherapist that is the main researcher of this study will be informed for the appointment and will go to each clinic for the data collection. Based on feasibility data, it is estimated that 30 eligible participants will be available for recruitment in a 1-month period across sites. Initially, each patient will be evaluated to determine whether or not they will be accepted into the study by answering some simple questions that will confirm the study's eligibility criteria. All patients will be asked to provide written informed consent for participating to the study, they will consent for publication of the results and they will be informed that they allowed to withdraw from the study at any time they wish without impact on their management. A lay summary of the study report will be written for patients and disseminated through social media, conferences and publication to raise awareness of the study and future research plans.

Inclusion criteria:

- ▶ Patients with sciatica diagnosed by a spine specialist in a private or public hospital/clinic and referred to standard physiotherapy using their public health insurance.
- ▶ Pain in the buttock region that refers into the lower extremity in any distribution.
- ▶ Aged 18–75 years old.
- ▶ Ability to read and communicate in Greek.

Exclusion criteria:

- ▶ Suspected serious spinal pathology or clinical red-flags such as cauda equina syndrome, suspicion of spinal tumours, infection, fractures and inflammatory spondyloarthropathy.
- ▶ Previous lumbar spine surgery.
- ▶ Previous lower extremity surgery.
- ▶ Currently receiving ongoing care from or have been in consultation with a secondary care doctor or physiotherapist for the same problem in the last 3 months.
- ▶ Serious comorbidity preventing them from attending the research clinic and/or undergoing assessment and interventions.
- ▶ Severe enduring mental health condition.
- ▶ Pregnancy.
- ▶ Current participation in any other research study because of symptoms of back and leg pain or sciatica.

- ▶ Scoliosis of the spine >10 degrees (Cobb's angle), as measured on an X-ray.

Candidate predictors

All participants will be assessed at baseline by the main researcher to ensure reliability of the procedure. Patients' basic characteristics including age, gender, weight, height will be recorded. In addition, a range of (1) patient-reported outcome measures (PROMs) and (2) performance-based measures (PBOs) to assess sciatica will be collected. PROMs used in this study have been translated and cultural adapted into Greek and have been investigated for their reliability and validity.^{26–33} The summary of the candidate predictor factors is shown in [table 1](#). These factors have potential predictive ability identified from a recent systematic review (manuscript under review) investigating the diagnostic value of PROMs and PBOs used to assess patients presenting with sciatica and previous predictive studies.³⁴ Finally, expert's opinion informed the final list of candidate predictors.

Outcome

GPESs are broadly used in clinical practice to assess patient outcome following intervention. They are used for several musculoskeletal conditions and in many languages. In this study the GPES-7 GR will be used to assess outcome at 3 weeks postbaseline and after the completion of their standard physiotherapy. The 3-week follow-up was chosen to be immediately after the completion of the standard physiotherapy treatment provided by public health insurance in Greece. The GPES-7 GR was translated and assessed for reliability in a previous study (manuscript under review) in patients with sciatica in Greece and showed excellent test–retest reliability. In the analysis of the test–retest reliability, the GPES-7 showed excellent agreement with $k=0.919$ (95% CI 83.3 to 92). The following question of the GPES-7 GR will be asked: To what extent are your complaints changed when compared with the situation just before you started treatment? The possible answers, to the question, are 7: '(1) completely recovered, (2) much improved, (3) slightly improved, (4) no change, (5) slightly worsened, (6) much worsened and (7) worse than ever.' Results will be dichotomised such that 'completely recovered' and 'much improved' will be categorised as 'improved'.³⁵

Sample size

In predictive modelling a larger sample size enables lower bias and variance, and permits the prospective prediction of new observations.³⁶ The minimum required sample was calculated, equal to 420 patients because for a predictive study there is a minimum framework for 10 participants per predictor. In order to cover a possible loss of 10% of patients, the inclusion of a total sample of participants was set to $n=467$.³⁷

Methodological quality in the prediction model

Limited research has identified criteria for quality in a prediction model, but authors have identified potential



Table 1 Summary of candidate predictors to be collected at baseline

Candidate predictor	Measure/data item and how recorded
General patient characteristics	
Age ³⁴	In years
Gender ³⁴	Female/male/other
BMI ³⁴	Calculated from height and weight measurements
Pain duration ³⁴	>3 weeks>6 weeks>3 months
Pain below knee ³⁴	Yes/no
Pain after coughing / sneezing ³⁴	Yes/no
MRI ³⁴	Clear/possible nerve root compression/disc prolapse/stenosis/other
PROMs	
Disability	Oswestry Disability Index ²⁶
Overall impact of sciatica symptoms	Sciatica Bothersomeness Index ²⁷
Fear of movement or fear of injury or re-injury during movement	Tampa scale of kinesiophobia ²⁸
Anxiety and depression	Depression Anxiety and Stress Scale-21 ²⁹
Neuropathic pain	Leeds Assessment of Neuropathic Symptoms and Signs ³⁰
Central sensitisation/central sensitivity syndromes	Central Sensitisation Inventory ³¹
Pain intensity	Short-form McGill Pain Questionnaire ³²
Quality of life	Short Form-12 ³³
PBOs	
Straight Leg Raise	Sciatica symptoms
Muscle strength	Neurological examination
Reflexes	Neurological examination (quadricep tendon/Achilles' tendon)
Heat pain threshold	Evaluation of pain threshold using a heat stimulus
Cold pain threshold	Evaluation of pain threshold using a cold stimulus
Vibration pain threshold	Evaluation of pain threshold using a tuning fork
Pin prick response	Evaluation of pinch sensation using a pin prick
Light touch sensation	Evaluation of light touch sensation using a cotton
Two-point discrimination sensation	Evaluation of two-point discrimination sensation using a discrimination two-point tool

BMI, body mass index; PBOs, performance-based measures; PROMs, patient-reported outcome measures.

quality issues to ensure methodological rigour.³⁸ All issues have been addressed/planned for in this study (table 2).

Data collection

This study is coproduced by patients with sciatica, the specialist musculoskeletal physiotherapist which is the main researcher of the study and healthcare professionals over Greece that are participating as clinical sites.

Patients will be examined only by the specialist musculoskeletal physiotherapist that is the main researcher of this study. The researcher will collect and record all data. The baseline assessment will consist of PROMs, neurological examination and Straight Leg Raise (SLR) to ensure all candidate predictors are recorded. Self-reported questionnaires will be completed in the presence of the specialist musculoskeletal physiotherapist to avoid any queries. The specialist musculoskeletal physiotherapist will perform the neurological examination and quantitative sensory tests with the tool kit to draw conclusions about the neurological dysfunction of each patient. Muscle strength of the lower quadrant and reflexes of quadricep's tendon and Achilles' tendon will be evaluated. The tool kit will include a coin for the hot/ cold sensatio,³⁹ a tuning fork for vibration, a pin prick for pinch sensation, a soft tissue for light touch and a discrimination point tool. The SLR will be considered as positive when the symptoms of the patient will be reproduced from the test. If the SLR is positive the specialist musculoskeletal physiotherapist will then measure the angle of hip flexion at which the symptoms occurred. The angle will be measured with a goniometer pro app (G-PRO) for IOS and android.⁴⁰ All patients will undergo standard physiotherapy provided by their public insurance with 3 weeks duration. This physiotherapy consists of electrotherapy, massage therapy and exercises. Outcome will be assessed at 3 weeks post-baseline on completion of the standard physiotherapy by answering the following question of the GPES-7GR: To what extent are your complaints changed when compared with the situation just before you started treatment? The possible answers, to the question, are 7: - (1) completely recovered, (2) much improved, (3) slightly improved, (4) no change, (5) slightly worsened, (6) much worsened and (7) worse than ever.' The specialist musculoskeletal physiotherapist that is the main researcher of this study will contact by telephone each patient and will be recording their answer.

Statistical methods and management of missing data

Potentially eligible patients, numbers examined for eligibility, confirmed eligible, recruited into the study, completing follow-up and analysed will be reported in a flow diagram. The diagram will illustrate the flow of participants through the study, including the number of participants with and without the outcome, and capturing all time points. The correlation between candidate predictive factors will be calculated at baseline. Reasons for non-participation, exclusion, drop-outs and withdrawal will be reported at each stage. For the descriptive statistical analysis, the continuous candidate predictors will be expressed in the form of 'mean' and 'SD'. The characteristics of the participants (demographics, clinical features, predictors) will be reported, with clarity of the number of participants with missing data for either outcome or predictors. For each variable of interest, the number of participants with missing data will be reported.

Table 2 Methodological decisions to improve quality in prediction models

Criteria ¹⁷	Methodological decisions to improve quality
Study design	
Inception cohort	<ul style="list-style-type: none"> ▶ Clear description of population. ▶ Clear description of the participants at baseline.
Source population	<ul style="list-style-type: none"> ▶ Clear description of population. ▶ Clear description of sampling frame and recruitment (method and timing).
Inclusion and exclusion criteria	<ul style="list-style-type: none"> ▶ Clarity of eligibility criteria.
Prospective design	<ul style="list-style-type: none"> ▶ Clarity of study design
Study attrition	
No of drop-outs	<ul style="list-style-type: none"> ▶ Adequate participation rate. ▶ Clear description of attempts to collect information on participants who dropped out.
Information provided on method of management of missing data	<ul style="list-style-type: none"> ▶ Appropriate methods of imputation of missing data.
Predictive factors	
All predictive factors described used to develop the model	<ul style="list-style-type: none"> ▶ Clear definition of predictive factors. ▶ An adequate proportion of participants has completed data for the predictive factor.
Standardised or valid measurements	<ul style="list-style-type: none"> ▶ The measurement of the predictive factor is reliable and valid. ▶ The measurement of the predictive factor is the same for all participants.
Linearity assumption studied	<ul style="list-style-type: none"> ▶ Linearity of data will be reported.
No dichotomisation of predictive variables	<ul style="list-style-type: none"> ▶ Continuous variables will be reported.
Data presentation all predictive factors	<ul style="list-style-type: none"> ▶ Complete data will be presented.
Outcome measures	
Description of outcome measures	<ul style="list-style-type: none"> ▶ The outcome is clearly defined.
Standardised or valid measurements	<ul style="list-style-type: none"> ▶ The measurement of the outcome is reliable and valid. ▶ The measurement of the outcome is the same for all participants.
Data presentation of most important outcome measures	<ul style="list-style-type: none"> ▶ Complete data will be presented.
Analysis	
Presentation of univariate crude estimates	<ul style="list-style-type: none"> ▶ An appropriate strategy for model building is described. ▶ An adequate statistical model described.
Sufficient numbers of subjects per variable	<ul style="list-style-type: none"> ▶ Adequate data will be presented.
Selection method of variables explained	<ul style="list-style-type: none"> ▶ Sufficient data will be presented to enable assessment of the adequacy of the analytic strategy. ▶ All results will be reported.
Presentation of multivariate estimates	<ul style="list-style-type: none"> ▶ An appropriate strategy for model building is described. ▶ An adequate statistical model described.
Clinical performance/validity	
Clinical performance	<ul style="list-style-type: none"> ▶ Clinical performance of the model will be reported.
Internal validation	<ul style="list-style-type: none"> ▶ Internal validation will be reported
External validation	Not a focus of this study

Statistical modelling for prediction has been planned a priori. To explore the influence of each predictive factor, in terms of the level of improvement or worsening of the symptoms, a logistic multivariable regression model will be fitted to the dichotomised outcome scores to calculate

outcome. ORs for each candidate predictive factor will be reported, adjusted for other factors and account for clustering. Multivariable analysis will initially include all candidate predictive factors, and full results reported. If necessary, multiple imputation.⁴¹ will be used to deal



with missing data. Reduced multivariable analyses will be considered if necessary (eg, removing one of two candidate predictive factors that are highly correlated at baseline), to examine the robustness of the conclusions. Selection of items for the model will include those factors which are statistically significantly ($p < 0.05$) associated with poor outcome according to the full multivariable regression analysis using backward stepwise selection,²³ and those deemed clinically important to retain (regardless of statistical significance) to improve face validity for clinicians. The regression model with included predictive factors will be fitted to the cohort data to obtain a final set of parameter estimates (ie, alpha and beta terms) which will be used to form the model. Cross-validation will be used for internal validation of the model. Cross-validation can be seen as an extension of the split-sample approach. In a 10-fold cross-validation, the model is developed on 90% of the population and tested in the remaining 10%. This is repeated 10 times, each time using another 10% of the population for testing so that all patients have been included in the test group once. Internal validation will provide estimates of the ability of the model to discriminate between patients with different outcomes as well as the agreement between the observed and predicted risks (calibration). External validation of the derived model is not a focus of this study, because this clinical prediction model targets to patients with sciatica treating with physiotherapy in the Greek health system. External validation would be very useful if this model was targeted in other patient samples; other physiotherapy settings; wider range of therapists; other rehabilitations techniques and other populations. Also, a new bigger sample is needed for this analysis. Due to COVID-19 restrictions unfortunately, this sample cannot be gathered. A further research in the future with larger sample will address the external validity. All data will be analysed using IBM SPSS V.25 Statistics.

Patients and public involvement

Patients and the general public were not involved in the development of the research questions, the design, recruitment and implementation of this study. However, the study participants will be informed for the results of this study through a peer-reviewed journal, national and international conferences and through social media.

ETHICAL CONSIDERATIONS

All patients before the procedure will be informed by the specialist musculoskeletal physiotherapist about the purpose of this study by an information sheet and about the assessment that they will experience. After that and before the beginning of the assessment, they will have the chance to ask questions about the procedure, they will sign a consent form and they will be given with a separate form for any complaints that may have. Confidentiality due to sensitive personal data will be secured during the study, but also after publication of the results. Finally, they

will consent for publication of the results and they will be informed that they allowed to withdraw from the study at any time they wish without any implication.

Ethical approval

The study is approved from the Ethics and Deontology Committee of the University of West Attica, Athens, Greece, protocol number: 38313-09/06/2020, 10226-10/02/2021.

Privacy of information

All data collected will be kept confidentially, and only the main researcher will have access to it. Raw data initially collected by patients will be stored in excel format on the main researcher's personal computer where only the one with security codes will have access. An excel-type backup file will be created on an external disk, accessible only by the main researcher with security codes. No other member of the research team will have access to data. The original raw files will then be destroyed.

DISCUSSION

Many treatments have been investigated to treat people with sciatica, but none have proven statistically or clinically significant.⁴² An explanation for this unsuccessful treatment may be related to the inability to differentiate the problem clinically, which in turn contributes to the lack of classification of these patients into subgroups according to their clinical characteristics. Individual remarkable efforts highlight the necessity of this issue and offer the first relevant information limited to a specific health system and population.³⁴ The categorisation of Stynes *et al*³⁴ was limited to the English public health system and in particular to the primary healthcare setting. This study will be the first in Greece, and aims to categorise patients with sciatica in terms of early clinical outcome based on their initial clinical characteristics in the Greek health system. Data analysis and expert opinion from the field will be taken into consideration for potential classification of patients as low/high or low/medium/high-risk probability to have a successful outcome with physiotherapy. As a limitation of this study is that the outcome will be dichotomised and that maybe will lead to loss of information and risk of misclassification. Data will be collected from multiple physiotherapy clinics across Greece. The main researcher of this study will be responsible for data collection in all sites and to gain reliability of all the PBOs maybe there is a bias in performing them. For that reason, this is a limitation of this study. Another limitation is that due to COVID-19 restrictions during the planned period of the study, this may create difficulties for gathering a larger sample. Despite these accepted limitations, this study will enable important insights into this important subject. Procedures are already in place to enable data collection through physiotherapy clinics.

Clinical implication

This study will enable predictions to be made regarding the outcome of the physiotherapy treatment of patients

with sciatica based on their clinical characteristics. That will happen through classification of these patients based on their clinical characteristics and will enable initial decision making in primary care of the Greek health system. The predictive model that will be developed will be fully adapted to the Greek reality and will lead to the selection of the most useful predictors for improving the clinical effectiveness of daily specialised physiotherapeutic practice in patients with sciatica. Future implementation of the prediction model will enable patients' classification based on their clinical characteristics that may predict the outcome of the patients after physiotherapy treatment. The clinical application of the prediction model will be easy to use, fast and will provide a sufficient way of assessing this population. It will also promote communication between health professionals (especially doctors and physiotherapists) managing populations with sciatica.

DISSEMINATION PLAN

The study's findings will be published in a peer-reviewed journal and disseminated at national and international conferences and through social media.

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Contributors NK led the design of the study as a doctoral research supervised by GG. ABR drafted the manuscript and provided feedback on the manuscript. EB and GP will contribute to data interpretation, conclusions and dissemination. All authors approved the final version.

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