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Translation into Greek, cross-cultural adaptation and test-retest reliability of the Global Perceived Effect Scale for use with patients with sciatica
A quick clinical tool for evaluating progress after treatment

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Δοκιμή αξιοπιστίας, μετάφραση και διαπολιτισμική προσαρμογή της παγκόσμιας κλίμακας αντίληψης στα Ελληνικά σε ασθενείς με ισχιαλγία. Ένα γρήγορο κλινικό εργαλείο αξιολόγησης της προόδου των ασθενών μετά τη θεραπεία

Περίληψη στο τέλος του άρθρου

OBJECTIVE **Translation into Greek, cross-cultural adaptation and reliability testing of the 7-point Global Perceived Effect Scale (GPES-7) for use with patients with sciatica.** METHOD **This study was conducted in three stages: The first stage was the translation into Greek, the second stage was cultural adaptation of the GPES-7 for patients with sciatica and the third stage was determination of the test-retest reliability of the GPES-7. Translation was carried out according to published guidelines. A combination of a forward-backward-translation and dual-panel-approach was used. For the cultural adaptation procedure, 15 patients with sciatica took part and for the test-retest reliability procedure, 70 patients. To estimate the test-retest reliability, GPES-7 was administered at baseline and again, three days later, and the Cohen's kappa coefficient analysis was used.** RESULTS **The translation process was performed without any major difficulties. Taking into account the participants' choices, the final version of the Greek translation of the GPES-7 was agreed upon by the expert panel and an independent physiotherapist. The test-retest reliability of the Greek version of GPES-7 was shown to be excellent (k=0.919; 95% CI: 83.3–92.0).** CONCLUSIONS **The GPES-7 was successfully translated and culturally adapted into a Greek version, and tested for reliability. The Greek version of GPES-7 (GPES-7 GR) is suggested for use as a reliable quick clinical tool to evaluate the progress of patients with sciatica after treatment.**

Key words

Cultural adaptation
Global Perceived Effect Scale (GPES)
Greek
Reliability
Sciatica
Translation

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Patient-reported outcome measures are very important in modern heath care and rehabilitation.[1] Their significance is acknowledged by professional bodies and administrative organizations.[2,3] They are broadly used both in clinical practice, during the assessment of patients, and in research. Global rating of change scales (GRCS) or global perceived effect scales (GPES) are a conventional kind of patients' statement, usually used to sum up the patients' global view of progress during or after treatment.[4] Several formats of GPES are available, but in all of them, the patient must indicate in a single response whether his(her) condition has improved or worsened in comparison to a previous time point, usually after treatment.[5] The question may reflect the change in specific domains, such as pain or disability, or the combination of multiple changes considered relevant by the patients, which is why they are referred to as global.[6,7] Although such scales do not supplant the utilization of normalized measures for assessment in specific areas, the estimation of the extra data given from the patient's point of view is broadly perceived as positive.[8] Hence, GRCS were first prescribed as a standard to test the responsiveness and interpretability of patient-reported outcome measures.[9]

GPES is often used to measure patient satisfaction with treatment,[10] but there are two major concerns regarding the use of the global rating scales, namely (a) the reliability and validity of global ratings are unknown, and (b) global ratings are typically correlated with the patient's present status, and are not an unbiased measure of change.[11] Studies have suggested that global rating of change scales answer is influenced by post-intervention status rather than memory

of health status prior to intervention, particularly for longer recall periods.[5,12] Therefore, the influence of baseline status in changing the response after an intervention should be examined, in order to gather evidence to support its use.

In general, very little information is available regarding the reliability and validity of GPES.[11] A study that assessed the construct validity concluded that the scale could be used to separate "stable" patients from "improved" patients regarding their physical impairment.[13] As the global rating scale used ranges from -7 ("a very great deal worse") through 0 ("about the same") to +7 ("a very great deal better") it was difficult to compare with the 7-point scale. A recent study successfully made the cross-cultural adaption of the 11-point scale, GPES-11, into a European Portuguese (PT) version and assessed its reliability and validity.[14] Although there is no gold standard to compare with the GPES-11, the authors reported that the GPES-11 PT is a simple and comprehensible measure that demonstrated adequate reliability, validity, and responsiveness. They concluded, therefore, that this instrument can be used to measure global perception of change in patients with chronic low back pain, and that clinicians can be confident that a 2.5-point change on the GPES-11 PT in patients with chronic low back pain represents a clinically meaningful change.

Other authors regard GPES as being clinically relevant, and the outcome measures and as being valid and responsive measures of the perceived benefit of the patients.[15–17] Most therapists, however, would be reluctant to consider a patient's condition as improved or deteriorated based on the patient's personal assessment. In the field of low back pain, the use of a global rating of change is common. Based on a systematic review, the expert panel recommends the use of a 7-point GPES (GPES-7).[10] One study explored the effectiveness of rehabilitation programs following lumbar disc surgery using the GPES-7 as an outcome measure.[18] The researchers used GPES-7 to evaluate progress in 105 patients 6 and 12 months post-surgery, and suggested the following question: "To what extent are your complaints changed when compared with the situation just before you started treatment?: 1=Completely recovered, 2=much improved, 3=slightly improved, 4=no change, 5=slightly worsened, 6=much worsened, 7=worse than ever". Questions similar to the GPES-7 have been used in other musculoskeletal conditions, including whiplash,[19] back pain,[20,21] ankle pain,[22] low back pain,[23] and shoulder pain,[24] and it is considered an easy and quick clinical tool in everyday practice. Although there are reports of using the GPES in many musculoskeletal conditions there are no reports of using it for patients with sciatica. To date, there has been no translation into the Greek language of the GPES-7, although it is often used in Greek clinical practice without any evidence-based translation and cultural adaptation.

MATERIAL AND METHOD

Stages of the study

This study was conducted in three stages: The first stage was the translation into Greek and back translation by professionals, the second stage was the cultural adaptation of the GPES-7 for patients with sciatica, and the third stage was determination of the test-retest reliability of the Greek version of the scale, GPES-7 GR. The study was approved by the Ethics Committee of the University of West Attica, Athens, Greece (protocol number: 10226/10.2.2021). In the first stage ten recommended[25] translation steps were defined: (a) Authorization, (b) translation of a sample, (c) physiotherapy expert panel review, (d) backward translation, (e) approval by copyright holders, (f) translation of the remaining section, (g) review of the entire translation by expert panel, (h) review by a user panel, (i) conclude final draft, (j) publication and dissemination. In the second stage, 15 patients referred with sciatica pain participated for cognitive debriefing and clarification of the anchor question of the GPES-7 GR. Several adjustments were needed until the final Greek version was compiled. In the third stage 70 patients took part in the test-retest reliability exercise. The Cohen kappa coefficient analysis and the agreement percentage were calculated as estimators of discriminative reliability and error, respectively.

Translation procedure

The translation procedure was conducted from 4th January 2021 to 12th February 2021 and the aim was to translate the English version of GPES-7[18] into the Greek version, GPES-7 GR. To ensure cultural and conceptual compliance with the source instrument,[18] GPES-7 was translated and cross-culturally adapted according to published guidelines,[26,27] following the ten steps described. Two bi-lingual translators (native Greek speakers – one physiotherapist with a master's degree in the United Kingdom (UK) and one professional English translator) produced independent translations from the original version of GPES-7 into Greek. A single version was produced after discussion and consensus between the two translators and the research team. Totally blind to the original question of the GPES-7, two other translators back-translated the synthesized version of the GPES-7 into the English language. Both back translators were native English-speakers (one physiotherapist with a master's degree in the UK and one professional English translator) and were blinded to the purpose of the translation. An expert panel composed of one professor of physiotherapy and two physiotherapists (all with a PhD degree) was formed, whose role was to reach consensus, consolidate all versions of the GPES-7 and propose a pre-final version for field testing. The expert panel assessed all the material independently, looking for inadequate expressions/concepts of the translation and any discrepancies

between the English and the Greek versions of the GPES-7. The panel also checked for clear language, spelling, grammar, writing style, consistency, understanding and correct use of terminology. Discrepancies were discussed as many times as needed, and solved by the professor of the panel. Finally, the GPES-7 GR was reviewed by an independent physiotherapist with a master's degree in the UK and experience in clinical practice, who assessed understanding, irregularities and ease of use of each part of the scale.

Cross-cultural adaptation

The pre-final version of the GPES-7 GR was cognitively debriefed with a convenience sample of 15 native Greek patients with sciatica pain. The patients were recruited from a specialist musculoskeletal physiotherapist, to whom they had been referred for standard physiotherapy treatment for sciatica by an orthopedic surgeon. All the patients provided their written informed consent after receiving information about the study. The patients were interviewed by one researcher to assess the comprehensibility and acceptancy of the GPES-7 GR pre-final version. The completion time and comments about the GPES-7 GR were recorded. The participants had the opportunity to choose between three options of the anchor question: (a) "Compared to when this episode first started, how would you describe your pain at this moment?"; (b) "to what extent are your complaints changed when compared with the situation just before you started treatment?"; (c) compared to the beginning of treatment, how would you describe your pain at this moment?". They were given three questions, to investigate which was the most understandable in relation to their problem. Two of them were different from the original question.[18] The terms "episode" and "pain" were the most debated words amongst the patients. The decision on the final version was based on the number of participants who selected each option. Following field tests and revisions, the final version of the Greek version of the GPES-7 was then agreed upon by the expert panel and the independent physiotherapist.

Test-retest reliability procedure

The test-retest reliability procedure was conducted from 15th to 28th February 2021. Patients referred for physiotherapy from an orthopedic or spine surgeon with diagnosed sciatica took part in the test-retest reliability procedure. The inclusion criteria were: Age 18–75 years, males and females with the ability to read and communicate in Greek and willingness to participate in the study. Patients with suspected serious spinal pathology or clinical red-flags such as cauda equina syndrome, suspicion of spinal tumor, infection, fractures, and inflammatory spondyloarthropathy, previous lumbar spine surgery, previous lower extremity surgery and those currently receiving ongoing care from or having been in consultation with a secondary care doctor or physiotherapist for the same problem in the last three months, were excluded from the study. All patients provided their written informed consent after receiving information about the study. Patients completed the GPES-7 GR at two time points, once at baseline (immediately after the completion of the physiotherapy treatment program) and then 3 days later. Sample size calculation was performed using a specific formula.[28] The determination of a minimum sample size requirement is based on the pre-specified values of power, type I error (alpha) and effect size. Using power 80%, type I error (alpha) 0.05 and effect size 0.2 (K1=0, K2=0.2), the 7-category will yield a minimum sample size of 46. To ensure the minimum required sample, expecting a response rate of at least 70% at the second completion of the questionnaire, the final sample was set at 70 participants. Descriptive statistics, including mean and standard deviation (SD) for continuous variables were used to describe the participants. To estimate the test-retest reliability of the GPES-7 GR given at baseline and three days later, the Cohen's kappa coefficient analysis was used. Data entry and analysis was performed using the Statistical Package for Social Sciences (SPSS), version 25.0. The significance level was set at $p<0.05$.

RESULTS

Translation and cross-cultural adaptation

The translation process was performed without any major difficulties. Of the 15 patients in the field test, 9 (60%) were women and 6 (40%) were men. Their mean age was 54.9±7.58 years, range 39–70 years. Eleven patients (73.3%) had basic/primary education and 4 (26.7%) had university education. In general, the majority of the patients interviewed considered the question clear and easily understandable, but the term "episode" was considered confusing by four of them. For example, one patient reported that "seems to refer to the first time I had sciatica pain" while another suggested change to "comparing with the last sciatica pain flare up...". Because of the long duration of pain in patients with sciatica, the expert committee anticipated this eventuality. Another point that was unclear to six patients was the term "pain". As "pain", they described that felt in their lower back, but also that in their lower leg. 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,[29] but in many cases sciatica pain is accompanied by other symptoms such as numbness, weakness and pins and needles in the affected side.[29] For this reason, 9 of the 15 patients preferred the question with the term "complaints" and not those with the term "pain". Taking into account the patients' choices (13 of the 15 participants selected the same option), the original question ("to what extent are your complaints changed when compared with the situation just before you started treatment?") was the version that was selected as the final translation. The final version of the GPES-7 GR is provided in table 1.

Table 1. 7-point Global Perceived Effect Scale (GPES-7). English (left) and Greek (right) version.

To what extent are your complaints changed when compared with the situation just before you started treatment?	*Σε ποιο βαθμό έχουν αλλάξει οι ενοχλήσεις-τα συμπτώματά σας, όταν τα συγκρίνετε με την κατάσταση που ήσασταν ακριβώς πριν από τη θεραπεία;*
Completely recovered	Αποκαταστάθηκαν πλήρως
Much improved	Βελτιώθηκαν αρκετά
Slightly improved	Βελτιώθηκαν λίγο
No change	Δεν άλλαξαν
Slightly worsened	Επιδεινώθηκαν λίγο
Much worsened	Επιδεινώθηκαν αρκετά
Worse than ever	Είμαι χειρότερα από ποτέ

Reliability

To achieve as wide a range as possible for the test-retest reliability procedure, the 70 patients were recruited according to different ages and sex. The mean age of the participants was 52.4±11.3 years, range 28 to 74 years. A few more women than men were included, which corresponds to the sex distribution in the population of patients who are referred for physiotherapy in the Greek health system; 42 patients were female (60%) and 28 were male (40%), 15 patients (21.4%) had basic/primary education and 55 (78.6%) had university education. Of the original 70 patients, 59 responded to the second measurement (response rate 84.3%). The chance of correlated agreement reliability at two time points was calculated using Cohen's kappa statistic. The strength of agreement of Cohen's kappa statistics between 0.81–1.00 is classified as almost perfect, 0.61–0.80 as substantial, 0.41–0.60 as moderate, 0.21–0.40 as fair, 0.00–0.20 as slight, and <0.00 as poor.[30] In the analysis of the test-retest reliability, the GPES-7 showed excellent agreement with k=0.919 (95% CI: 83.3–92).

DISCUSSION

The GPES-7 is a key tool in physiotherapy, because it is very important for the physiotherapist to know the perceived progression of their patients after the chosen treatment, but its use in countries where the official language is not English has been limited. Translation and cross-cultural adaptation and test-retest reliability, need to be applied in other countries, cultures and languages. The aim of the present study was translation and the culturally adaptation of the GPES-7 into Greek and examination of the test-retest reliability. Based on other published studies, 10 steps were followed for the completion of the translation. These steps are needed to facilitate the validity and appropriateness of future translations. This procedure ensures that the Greek version of the GPES-7 is consistent and reliable for use in every day clinical practice. Defining these recommended steps it is based on three primary reasons. First, the GPES-7 is becoming a key tool in clinical practice, because it is quick and easy to understand, and is a tool that will provide practical help in assessment, to ensure high-quality and specialized physiotherapy rehabilitation to patients with musculoskeletal pain. It is expected to help physiotherapists to evaluate each stage of treatment and its results. Second, to assist further international application and distribution of the GPES-7, the recommended steps are critical to the standardization of procedures, and will guide other non-English speaking health care professionals who decide to translate this or similar scales. Health care professionals have only recently begun to identify best practices for the translation and evaluation of translations of assessment tools into other languages.[31] Not many researchers have reported their methods of translation, following current standards for translation procedures.[27,32,33] Third, valid translations will facilitate the comparison of results of the international implementation process ongoing in different countries and cultures, and will help in further studies to investigate the reliability of the GPES-7. This is important because the use of GPES-7 in every day clinical practice will help health care professionals all over the world to understand their patients' perceptions of progress or not after the chosen treatment.

The process of translation was conducted without major difficulties and a new formulation of the anchor question was adopted according to the choice of the participants. The 7-point format allows a neutral response and an equal number of options for improvement and worsening. This characteristic represents important advantages. First, it ensures that the patient provides information about the health condition of interest to the clinician or researcher; in addition, the patient is not induced to rate his(her) improvement as positive in the absence of response options for worsening. Although there were no major issues in the translation of the GPES-7, this is likely to vary by country. The Greek experience showed that it is both feasible and useful to incorporate contextual and cultural considerations, and that it is possible to follow a rigorous methodological translation and adaptation process that is achievable with a minimal time frame of three weeks. A major role in the process was played by the expert panel who were native speakers of the target language, proficient in the writing and reading of the source language and experienced in the relevant clinical practice within their health services.

Using an expert panel that consisted of physiotherapists with PhD and, in particular, one who was a professor of physiotherapy, was the best way to ensure quality and strictness in following the guidelines.

Even though the GPES-7 GR consists of one question only, and is relatively easy to understand, this study estimated the reliability of the scale with the test-retest method. The GPES-7 GR was given at baseline (immediately after completion of the physiotherapy treatment), and three days later, to determine the test-retest reliability of the scale. Although not all of the patients responded the second time of completion of the GPES-7 GR, the sample size was large enough, and the results of the statistical analysis showed excellent test-retest reliability (k=0.919). This value is similar with those observed in previous studies, which ranged from 0.90 to 0.99.[12,20] This similar value in the Intraclass Correlation Coefficient might partly due to the easy and simple question of the GPES. The short test-retest time interval (30 min to 24 hours) used in these studies[12,20] appears to have no effect on the Intraclass Correlation Coefficient value. The longer interval time used in our study (3 days) reduces the chance of a recall bias, but may increase the possibility of a change in the measured construct, but not in this case, because the statistical analysis showed excellent test-retest reliability with k=0.919 in our study. On the other hand, the GPES is a complex and unstable construct that can be influenced by multiple contextual and health-related aspects of patients.[34,35] This issue needs to be addressed in future studies in order to clarify the influence of time interval and health condition in the test-retest reliability of the GPES.

Strengths and limitations

The main strengths of this study are the consideration of the perspective of the patients in the definition of the final version of GPES-7 GR, and the perceived improvement of the symptoms after physiotherapy treatment in a specific sample. This is the first study to evaluate GPES in a specific sample consisting of Greek patients diagnosed with sciatica. Considering its simplicity and excellent test-retest reliability results, GPES-7 GR could become an important and cost-effective tool in clinical practice and research with patients with sciatica. This is the only study that has translated the GPES into the Greek language. The involvement of the expert panel into the translation procedure is another strength of this study.

Although, this study has many implications for clinical practice, the translation procedure carried out following published guidelines and test-retest reliability procedure was evidenced based, a limitation that should be addressed regarding the construct validity of the GPES-7 GR. This study did not investigate the construct validity of the GPES-7 GR, mainly for two reasons: First, there is no corresponding questionnaire in the Greek language to be used as a gold standard for evaluating the overall progress of patients' symptoms after treatment; Second, construct validity could not be evaluated because the GPES consists of only one question that includes all the patients' symptoms, and for this reason is difficult to separate and evaluate each symptom. Previous studies[12,36] that have questioned the construct validity reported low variance values (0–3%) because they observed only the pain intensity. The researchers suggested that higher pain scores at baseline and lower pain scores after intervention predict higher GPES scores, but this is not the case because GPES was not for pain measurement only. Future studies need to address these issues, using questionnaires similar to the GPES, if there are any in the same language, that evaluate the patients' overall progress and not only one symptom.

In conclusion, the English version of GPES-7 was successfully translated into a Greek version, according to the published guidelines. The additional adjustments that were required for the Greek version justify the need for the detailed and multifaceted translation process that was outlined in this manuscript. The results of this study showed excellent test-retest reliability for the Greek translation of the GPES-7. Based on these findings, the GPES-7 GR can be recommended as a quick and reliable clinical tool that evaluates the progress of patients with sciatica.

ΠΕΡΙΛΗΨΗ

Δοκιμή αξιοπιστίας, μετάφραση και διαπολιτισμική προσαρμογή της παγκόσμιας κλίμακας αντίληψης στα Ελληνικά σε ασθενείς με ισχιαλγία. Ένα γρήγορο κλινικό εργαλείο αξιολόγησης της προόδου των ασθενών μετά τη θεραπεία

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ΣΚΟΠΟΣ Μετάφραση, διαπολιτισμική προσαρμογή και έλεγχος της αξιοπιστίας του GPES στα Ελληνικά σε ασθενείς με ισχιαλγία. **ΥΛΙΚΟ-ΜΕΘΟΔΟΣ** Η μελέτη διεξήχθη σε τρία στάδια: το πρώτο στάδιο περιλάμβανε τη μετάφραση στα Ελληνικά, το δεύτερο στάδιο ήταν η πολιτιστική προσαρμογή του GPES-7 από ασθενείς με ισχιαλγία και το τρίτο στάδιο ήταν ο καθορισμός της αξιοπιστίας δοκιμής του GPES-7 GR. Η μετάφραση πραγματοποιήθηκε σύμφωνα με δημοσιευμένες οδηγίες. Χρησιμοποιήθηκε ένας συνδυασμός της προσέγγισης «εμπρός-πίσω» μετάφρασης και της προσέγγισης διπλού πίνακα. Δεκαπέντε ασθενείς με ισχιαλγία συμμετείχαν στη διαδικασία πολιτιστικής προσαρμογής και 70 ασθενείς στη διαδικασία αξιοπιστίας. Για την εκτίμηση της αξιοπιστίας δοκιμής, η GPES δόθηκε στην αρχή της θεραπείας και 3 ημέρες αργότερα, και χρησιμοποιήθηκε ο συντελεστής κάππα του Cohen. **ΑΠΟΤΕΛΕΣΜΑΤΑ** Η διαδικασία μετάφρασης πραγματοποιήθηκε χωρίς σημαντικές δυσκολίες. Λαμβάνοντας υπ' όψιν τις επιλογές των συμμετεχόντων, η τελική έκδοση της ελληνικής έκδοσης της GPES συμφωνήθηκε από την ειδική ομάδα και τον ανεξάρτητο φυσικοθεραπευτή. Η αξιοπιστία δοκιμής της GPES αποδείχθηκε εξαιρετική (k=0,919, 95% CI: 83,3-92). **ΣΥΜΠΕΡΑΣΜΑΤΑ** Η GPES δοκιμάστηκε με επιτυχία για αξιοπιστία, μεταφράστηκε και προσαρμόστηκε πολιτιστικά σε ελληνική έκδοση και προτάθηκε ως ένα αξιόπιστο γρήγορο κλινικό εργαλείο που αξιολογεί την εξέλιξη των ασθενών με ισχιαλγία μετά τη θεραπεία.

Λέξεις ευρετηρίου: Αξιοπιστία, Διαπολιτισμική προσαρμογή, Ελληνικά, Ισχιαλγία, Μετάφραση, Παγκόσμια κλίμακα αντίληψης

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