

Clinical Pain Research

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Short- and long-term test-retest reliability of the English version of the 7-item DN4 questionnaire – a screening tool for neuropathic pain

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Abstract

Objectives: The original French version of the “Douleur Neuropathique en 4 Questions (DN4) questionnaire” is a valid screening tool for the identification of neuropathic pain (NeP). The DN4 has been translated into English, but the reliability of the English version has not yet been investigated. The aim of this study was to investigate the 7-item DN4 questionnaire in regards to short-term reliability before (T0) and immediately after (T1) the clinical examination and long-term reliability one week later (T2).

Svenja Hardt and Selina-Antonette Bergau contributed equally to the study.

Previous presentations: The results of this study were presented as a poster titled “Kurz- und Langzeitreliabilität der englischen Version des DN4-Fragebogens – ein Screening Tool für neuropathische Schmerzen” at the Forschungssymposium Physiotherapie, Hildesheim/Germany 22 to 23-11-2019; and as a poster titled “Reliabilität der englischen Version des DN4-Fragebogens” (<https://doi.org/10.1007/s00482-021-00580-3>) at the Deutscher Schmerzkongress, Mannheim/Germany, 20 to 23-10-2021.

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Methods: A total of 222 participants (age 56.33 ± 16 years, 56 % female) were recruited from a Pain Management Department and Neurosurgery Spinal Clinic. For T2 measurements, the 7-item DN4 was sent by post with the “Patient Global Impression of Change Scale”. The scale detects possible changes of symptoms, scoring from “very much improved” (1) to “very much worse” (7). Only participants whose symptoms had not changed much (scores 3–5) were included in the T0-T2 analysis. Weighted Kappa was used to analyse the reliability of the DN4 total scores and unweighted Kappa for the DN4 classifications.

Results: Considering missing data and exclusions, data of 215 participants could be used for the T0-T1 and data of 103 participants for T0-T2 analysis. There was almost perfect agreement for the 7-item DN4 total score between T0-T1 (weighted k : 0.891, CI: 0.758–1.024) and T0-T2 (weighted k : 0.850, CI: 0.657–1.043). Classifications between neuropathic pain and no neuropathic pain showed almost perfect agreement (k : 0.835, CI: 0.755–0.915) for T0-T1 and substantial agreement (k : 0.733, CI: 0.598–0.868) for T0-T2.

Conclusions: The English 7-item DN4 is a reliable screening tool for neuropathic pain.

Ethical committee number: #RGS0000001759.

Keywords: DN4; neuropathic pain; reliability; screening tool.

Introduction

The substantial burden of neuropathic pain (NeP), defined as “pain caused by a lesion or disease of the somatosensory system” [1], on patients’ health related quality of life, function and psychological wellness as well as on health care costs has been well documented [2, 3]. Early identification of NeP is crucial for timely and targeted evidence-based treatment. Numerous screening tools have been developed to assist clinicians in the identification of NeP, including the “Douleur Neuropathique en 4 Questions (DN4) questionnaire” [4].

The DN4 was originally developed in a French patient cohort with nociceptive and neuropathic pain. The questionnaire exists in two versions: The 10-item DN4 contains

both sensory descriptors and signs related to a bedside sensory examination, the 7-item DN4 contains just sensory descriptors [4] and has been used as a self-reported screening tool [5]. The 7-item DN4 demonstrated a sensitivity of 78 % and specificity of 81.2 % in the identification of NeP [4] which was lower compared to the sensitivity (82.9 %) and specificity (89.9 %) of the 10-item DN4 (4). The original study did not assess the 7-item DN4's test–retest reliability.

The DN4 questionnaire has been translated into numerous languages and validated: Thai [6], Spanish [7], Dutch [8–10], Portuguese [11], Turkish [12], Arabic [13, 14], Swedish [15], Italian [16], Persian [17], Greek [18], Korean [19], Hindi [20], Japanese [21] and Taiwanese [22]. For the 7-item DN4, sensitivity ranged from 70 to 97 % and specificity from 67 to 84 % [9, 10, 13, 14, 16, 20, 23], the reliability ranged from 0.79 to 0.97 (ICC) [10, 13, 20]. An English version of the 7-item DN4 exists, however its reliability and validity have never been explored.

The aim of this study was to investigate the reliability of the English version of the 7-item DN4 pre- and post-clinical consultation and at one week follow up. The reliability of the total DN4 score and the DN4 classifications (NeP, no NeP) as well as the reliability of each single item were examined, consistent with previous methodologies [4, 24].

Materials and methods

The study involved repeated measures to assess the short- and long-term reliability of the 7-item DN4 questionnaire at three time points. For the short-term reliability the questionnaire was filled out before (T0) and immediately after the clinical consultation (T1) and one week later (T2) for the long-term reliability.

Study population

Data collection took place from March to May 2019 at Sir Charles Gairdner Hospital in Perth, Australia. Patients presenting to the Pain Management Department and Neurosurgery Spinal Clinic were recruited. The inclusion criteria were the presence of pain and age ≥ 18 years. Patients were excluded if they were unable to read, write or speak English, had impaired vision, mental health illness like dementia and if they received pain interventional procedures such as injections on the day of recruitment. All participants were informed about the study protocol prior to giving written consent. The study was approved by the institutional ethics committee (#RGS0000001759) and adhered to the Declaration of Helsinki.

Sample size

A minimum of $n=101$ subjects has 80 % power to detect $\kappa=0.9$ from a null value of 0.7, assuming $p=0.5$ positive ratings [25]. We anticipated to recruit around 200 patients considering a dropout rate of at least 30 % [24].

Measurement tools

Douleur Neuropathique en 4 Questions: The 7-item DN4 questionnaire consists of two questions. The first question asks if the pain has one or more of the following characteristics: the quality of burning, painful cold and electric shocks. The second question asks if the pain is associated with one or more of the following symptoms in the same area: the sensations of tingling, pins and needles, numbness and itching. Patients are asked to tick one answer, “yes” or “no” for each item in the two questions.

The final score of the DN4 is calculated with scoring 1 point for each positive (“yes”) answer. Results range between a minimum of 0 and a maximum of 7 points. As the English version of the 7-item DN4 had not yet been validated, we used the cut-off score of 3 from the original French study [4]. A total score of 3 or above is classified as having NeP and scores <3 are classified as having no NeP.

Patient Global Impression of Change Scale: The Patient Global Impression of Change (PGIC) Scale was used for the detection of changes in the participants' pain condition between T0 and T2 [24, 26]. The PGIC is commonly used in clinical research for measuring a person's own impression of change occurring over time [24, 26]. Patients rated any change on the numeric 7-point scale between “very much improved” (1) and “very much worse” (7). No change is stated with “4”. Participants scoring <3 or >5 were excluded from our T0-T2 statistical analysis as this indicated a change in symptoms.

Study protocol

Participants completed the DN4 before seeing the clinician (T0) and immediately after their consultation (T1) as well as one week afterwards (T2). Based on our observation that patients reported multiple pain areas, we asked them to answer the questionnaire in regards to their main pain area. Participants were reminded that a copy of the DN4 as well as the PGIC, together with a pre-paid postage envelope would be sent via registered post. Participants were instructed to complete the DN4 and PGIC seven days after their consultation and to return them via post. Documents were dispatched and at time point T2 participants were contacted by phone to remind them to complete the questionnaires. A maximum of two phone calls was conducted.

Missing data

Participants who failed to complete the DN4 at T0 were excluded from the study. If they failed only at time point T1 they were still included for the statistical analysis of long-term reliability (T0-T2), as long as they were not excluded due to changes indicated in the PGIC (<3 or >5). If they failed to complete the DN4 only at time point T2, they were still included for statistical analysis of the short-term reliability (T0-T1). Failures at filling out the questionnaire could have been not ticking a box or ticking two boxes (*yes* and *no*).

Statistical analysis

Data analysis was performed using SPSS vs. 26. Means with standard deviations were calculated for the DN4 total scores. Paired t-tests were

performed to detect statistically significant differences between the means of total scores between the different time points.

Weighted kappa was used to analyze agreement of the total scores between T0-T1 and T0-T2. Unweighted kappa was calculated for the agreement in classifying patients into having NeP or no NeP and for the agreement of the seven single items which were binary variables (yes or no). Kappa values between 0.41 and 0.60 indicate moderate agreement, values between 0.61 and 0.80 indicate a substantial agreement and values between 0.81 and 1.00 indicate an almost perfect agreement [27]. For all kappa values, 95 % confidence intervals (CIs) were calculated. Bland-Altman plots were used to graphically investigate the agreement of measures taken on the same individual at two different time points and to assess the presence of possible systematic bias.

Results

Characteristics of study population

Two hundred and twenty-three participants were enrolled in the study. One participant could not be included because he failed to fill out the questionnaire correctly at time point T0. Accordingly, information on 222 participants (age range 18–90 years; 56 % female) was available, i.e. 222 participants had questionnaires included in at least one reliability analysis. The demographic and clinical characteristics for the cohort are shown in Table 1.

The mean symptom duration was 10.5 (± 10.8) years, ranging from six weeks to 61 years. The participants' main pain areas and clinical diagnoses are documented in Table 1. One hundred and eighty-one (82 %) participants reported the presence of multiple pain areas. The intake of pain medication was recorded, however for the purpose of the study, the specific name and dosage of medication were not documented.

T0-T1 reliability

Two hundred and twenty-two participants completed the DN4 at T0, of whom 215 (94.8 %) also completed the questionnaire correctly at T1. Hence, 215 were included in the T0-T1 analysis. There was a statistically significant difference between the mean total DN4 score at T0 (3.7 ± 1.9) and T1 (3.4 ± 2.0) ($p < 0.001$) (Table 2). The weighted kappa of the DN4 total scores between T0 and T1 was 0.891 (95 % CI: 0.758–1.024). Figure 1 displays a Bland-Altman plot for the total DN4 score at T0 and T1. As the limits of agreement (-1.540 and 1.987) contain zero, there is no obvious discrepancy in agreement of the two measures and no evidence of systematic bias. Three outliers were apparent, showing a reduction in the DN4 score from T0-T1. One patient demonstrated a reduction

Table 1: Clinical and demographic characteristics of the study population.

Age in years, mean, SD	56.3 (15.8)
Gender, n female/n male, %	124 (55.9 %)/98 (44.1 %)
Pain duration in years (n=210), mean (SD)	10.48 (10.8)
Main pain area, n, %	
Head	6 (2.7)
Neck	27 (12.2)
Back	104 (46.8)
Upper limb	29 (13.1)
Lower limb	41 (18.5)
Other	15 (6.8)
Clinical diagnosis, n, % ^a	
Stenosis (spinal canal, foraminal)	64 (28.8)
Other changes of the spine	24 (10.8)
Disc prolapse/protrusion	24 (10.8)
Chronic back pain	28 (12.6)
Inflammatory joint diseases	33 (14.9)
Fibromyalgia	7 (3.2)
Fractures	7 (3.2)
Complex regional pain syndrome	4 (1.8)
Post op	6 (2.7)
Trauma	7 (3.2)
Oncological diseases	5 (2.3)
Other ^b	34 (15.3)
Unknown	5 (2.3)
Pain medication, n, %	181 (81.5)
Daily	147 (66.2)
As required	34 (15.3)

SD, standard deviation; op, operation. ^aTotal numbers are greater than the total number of participants as some participants have more than one diagnosis. ^bOther includes: Crohn's disease, diabetes mellitus, rare syndromes, neuropathic pain, central sensitization.

from 6 to 0 points, and the two other outliers a reduction of 4 points (4–0 and 5–1).

Based on the cut-off score of 3, the DN4 classified 152 patients as having NeP and 63 patients as not having NeP at T0 (Table 2). At T1, 147 patients were identified as having NeP

Table 2: 7-Item DN4 scores (mean/SD) and classifications at each time-point for patients included in the baseline (T0) to immediately post-consultation (T1) comparison, and baseline (T0) to one-week follow up (T2) comparison.

	T0-T1 (n=215)		p-Value	T0-T2 (n=103)		p-Value
	T0	T1		T0	T2	
DN4 total score	3.7 (1.9)	3.4 (2.0)	<0.001	3.4 (2.1)	3.3 (2.2)	0.350
DN4 classification, n, %						
Neuropathic pain	152 (71)	147 (68)	0.600	65 (63)	62 (60)	0.185
No neuropathic pain	63 (29)	68 (32)		38 (37)	41 (40)	

DN4, Douleur Neuropathique en 4 Questions; SD, standard deviation.

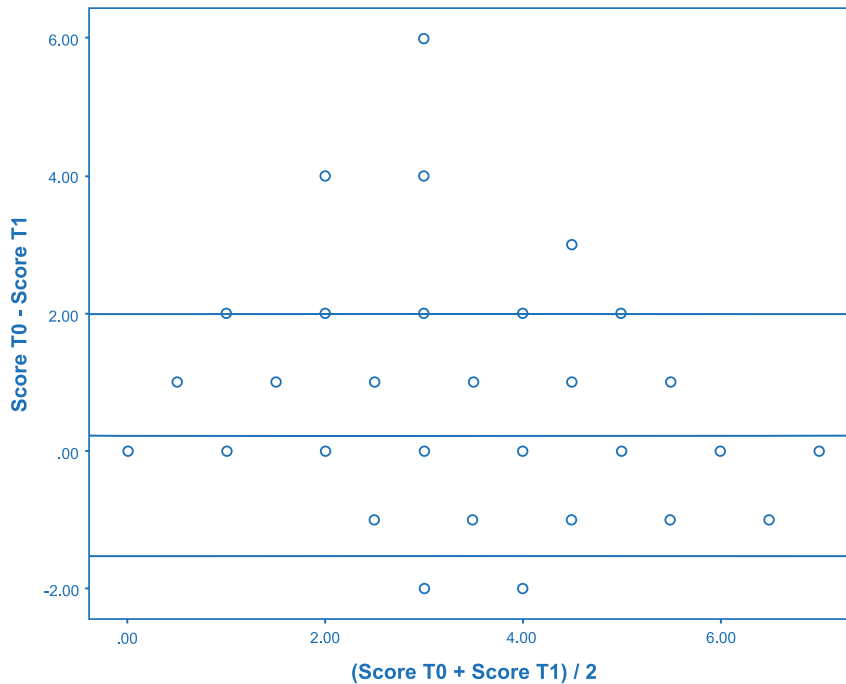


Figure 1: Bland-Altman plot for total DN4 scores at T0-T1.

Table 3: Agreement estimates (kappa, weighted kappa) and 95 % confidence intervals (CIs) for DN4 total scores, classifications and individual items at time-point comparisons of T0-T1 and T0-T2.

	T0-T1 (n=215) Kappa (95 % CI)	T0-T2 (n=103) Kappa (95 % CI)
DN4 total score ^a	0.891 (0.758–1.024)	0.850 (0.657–1.043)
DN4 classifications ^b	0.835 (0.755–0.915)	0.733 (0.598–0.868)
Burning ^b	0.835 (0.759–0.911)	0.714 (0.575–0.853)
Painful cold ^b	0.767 (0.677–0.867)	0.651 (0.490–0.812)
Electric shocks ^b	0.795 (0.715–0.876)	0.784 (0.664–0.904)
Tingling ^b	0.798 (0.714–0.882)	0.657 (0.508–0.806)
Pins and needles ^b	0.809 (0.731–0.887)	0.582 (0.423–0.741)
Numbness ^b	0.811 (0.731–0.891)	0.722 (0.587–0.857)
Itching ^b	0.807 (0.717–0.897)	0.706 (0.543–0.869)

^aWeighted kappa. ^bUnweighted kappa.

and 68 as not having NeP. The DN4 classifications from T0 and T1 demonstrated a weighted kappa score of 0.835 (95 % CI: 0.755–0.915) (Table 3). For individual DN4 items, weighted kappa values ranged between 0.767 (95 % CI: 0.667–0.867) and 0.835 (95 % CI: 0.759–0.911) (Table 3).

T0-T2 reliability

One hundred and thirty-two participants completed the DN4 at T2. After excluding 29 participants due to missing data or a PGIC score of <3 or >5, a total of 103 participants were included in the T0-T2 analysis. There was no statistically

significant difference between the mean total DN4 score at T0 (3.4 ± 2.1) and T2 (3.3 ± 2.2) ($p=0.350$) (Table 2). The weighted kappa of the DN4 total scores between T0 and T2 was 0.850 (95 % CI: 0.657–1.043) (Table 3). Figure 2 displays a Bland-Altman plot for the total DN4 score at T0 and T2. As the limits of agreement (–2.155 and 2.369) contain zero, there is no obvious discrepancy in agreement of the two measures and no evidence of systematic bias. There were four outliers evident. Two patients showed a reduction in the DN4 score (4–0 and 7–4) between T0 and T2 and two showed a score increase (2–5 and 4–7).

Based on the cut-off score of 3, the DN4 classified 65 patients as having NeP and 38 patients as not having NeP at T0 (Table 2). At T2, 62 patients were identified as having NeP and 41 patients as not having NeP. The classifications at these two time points demonstrated a weighted kappa score of 0.733 (95 % CI: 0.598–0.868) (Table 3). Kappa scores for the individual items varied between 0.582 (95 % CI: 0.423–0.741) and 0.850 (95 % CI: 0.657–1.043) (Table 3).

Discussion

This is the first study to investigate the reliability of the English language version of the 7-item DN4 in a large cohort of patients with chronic pain. The results showed almost perfect agreement for the 7-item DN4 total score and DN4 pain classification at pre- and post-clinical consultation (T0-T1) and almost perfect agreement for the 7-item DN4

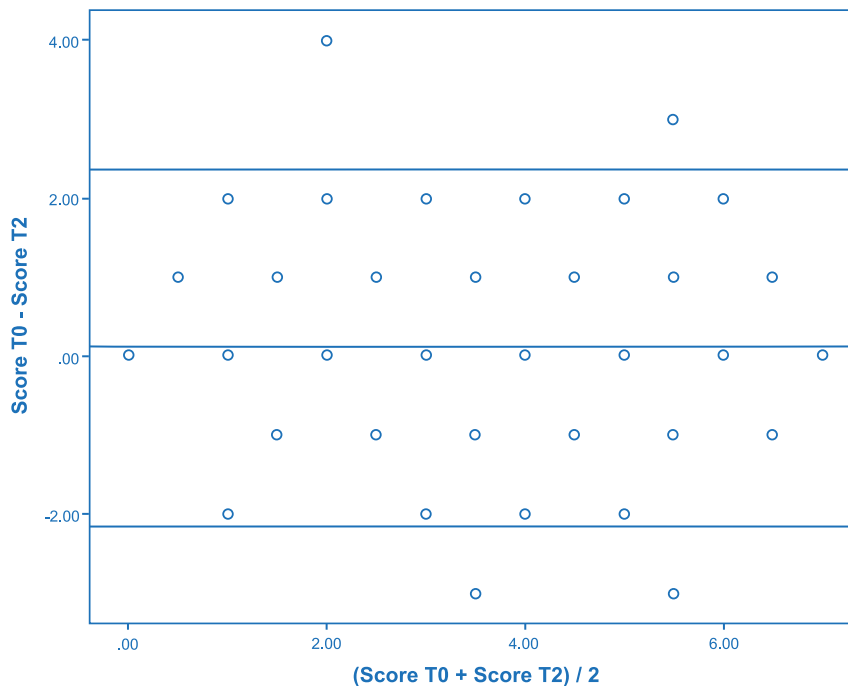


Figure 2: Bland-Altman plot for total DN4 scores at T0-T2.

total score and substantial agreement for DN4 pain classifications at one week follow-up (T0-T2).

A representative sample with a broad age range and balanced gender distribution was achieved. We did not exclude specific diseases or pain presentations compared to other studies which did not include diseases associated with diffuse pain, such as fibromyalgia [4, 9–11, 14, 17, 19, 21]. In addition, we did not define minimal pain intensity whereas many studies included only participants with moderate to severe pain intensity [4, 9, 11, 15, 17–19]. Our study population would reflect the type of pain presentations seen in everyday clinical practice and, in combination with a much larger sample size compared to others [4, 7, 10–21], allows for greater generalizability to a wider range of people suffering from persistent pain. We also did not define a minimum pain duration. However, it is evident from our results that most patients were chronic pain patients comparable with cohorts in the original study [4] and other studies [7, 9–11, 13–15, 17–21].

Out of three studies investigating the reliability of the 7-item DN4 questionnaire [10, 13, 20], one study used the questionnaire in interview format [13] and only two studies are comparable with our methodology, applying the DN4 as a self-reported tool [10, 20]. The Hindi version was assessed using only one follow-up period of three days [20]. The results were comparable to ours with an almost perfect agreement for the overall score (ICC of 0.92) and substantial to almost perfect agreement for the individual items (ICC between 0.71 and 0.96). Their follow-up sample consisted of

only 82 subjects. By contrast, the Dutch version also used two follow-up periods, longer than ours, lasting two weeks and three months [10]. T0 starting not before but directly after the clinical consultation. Their results were slightly worse than ours, demonstrating almost perfect (ICC 0.85) and substantial agreement (ICC 0.79) respectively which may relate to the longer time frame between measurements.

In our cohort, the difference between the DN4 total score between T0 and T1 was statistically significant, however this was not clinically significant, as the mean still fell into the same NeP classification and the agreement of DN4 classifications was almost perfect between the two time points. DN4 classifications between T0-T2 showed substantial agreement. Unfortunately our results cannot be compared to other studies using the 7-item DN4 questionnaire as they did not report on this comparison [10, 20]. With respect to the classifications of the English painDETECT [24], better to equal results were observed. While the measurement period T0-T2 showed equally substantial agreement (weighted Kappa of 0.691), the results for T0-T1 in our study were better in contrast to the substantial agreement of the painDETECT (weighted kappa of 0.771).

We observed outliers in the time interval T0-T1 as well as T0-T2. A 65-year-old woman with chronic low back pain had a total score of 6 at T0, whereas a score of 0 was obtained at T1. While she reported all symptoms except “burning” as present at T0, no symptoms seemed to be present at T1. Two other outliers, a 19-year-old woman and a 55-year-old woman with degenerative joint disease, also had reductions

(both minus 4 points) in the total score. We assume that the visit to the health professional somehow had an effect on the symptoms of the subjects mentioned. For the interval T0-T2, two outliers related to a reduction in the DN4 score and two showed a score increase. Since all subjects included in the long-term analysis stated on the PGIC that their complaints had not changed or had changed only slightly, these results remain difficult to explain.

The individual DN4 symptom descriptors showed substantial to almost perfect agreement in the short-term interval and substantial agreement for the long-term interval except for the symptom “pins and needles” (moderate agreement). It remains unclear why this item was less stable as other studies did not report the same observation [13, 20].

The majority of our patients had multiple pain areas. In order to guarantee the validity of the questionnaire, patients were asked to indicate their main pain area and to answer the DN4 questions in regards to their main pain area. They were also told that the following DN4 questionnaires should also be completed for the same pain area. Similar observations of the presence of multiple pain areas were made in the English painDETECT study [24], but not reported in any studies using the DN4. One DN4 study used a body chart to verify the location of pain [11]; another study defined that the questionnaire should be completed in regards to the pain which is the reason for current physician consultation [7]. However, subjects in our study had difficulty identifying a main area of pain due to multiple areas of pain with varying intensity. Hence, it cannot be conclusively ruled out that the repeated questionnaires were completed for a different pain area. While in our study the presence of multiple pain areas seemed not to affect the reliability, it has to be considered that the discriminative ability of NeP screening tools is reliable only when applied to one pain area [28].

We encountered some difficulties in our study. Some participants did not understand the meaning of used terminologies in the DN4, such as “painful cold”. The investigators were not supposed to assist the participants, as the 7-item DN4 was used as a self-reported tool. At most, they suggested that the character of pain might not have been experienced if it was unknown to the participant. Although there is an instruction on the DN4 that each question has to be answered with either “yes” or “no”, some participants had to be explicitly instructed to tick one of the options. In the Dutch study [10], help was provided to complete the survey, however, questions were rarely asked. In the Arabic version [14], subjects were asked at the end of the questionnaire whether they had understood the questions.

The time frame between T0 and T2 varied amongst individuals, as delays in mail delivery were not uncommon and participants could not always complete the questionnaire on

time after one week. A solution could be to digitise the questionnaire and this would also minimise the risk of missing data.

Conclusions

The English version of the 7-item DN4 has been shown to be a reliable tool for measurements of short-term (same day) and long-term reliability (one week). The validity of the questionnaire has yet to be investigated.

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Informed consent: Informed consent has been obtained from all individuals included in this study.

Ethical approval: Research involving human subjects complied with all relevant national regulations, institutional policies and is in accordance with the tenets of the Helsinki Declaration (as amended in 2013), and has been approved by the authors’ Institutional Review Board (IRB #RGS0000001759).

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