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# PaiNEd app. Assessing central sensitization in survivors of breast cancer: A reliability study

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## Abstract

**Introduction:** Pain is a common adverse event in survivors of breast cancer (sBCs). As there is no gold standard to assess pain experience predominantly related to central sensitization (CS) symptoms, we designed the *PaiNEd app*, which includes an algorithm to report whether patients are under predominant CS pain mechanisms.

**Objective:** We aimed to assess the reliability of the *PaiNEd app* to estimate whether sBC pain experience is predominantly related to CS symptoms.

**Methods:** An observational, descriptive reliability design was employed to assess the inter- and intrarater reliability of the *PaiNEd app*. This app includes an algorithm that considers the number of painful body parts and some questionnaires related to pain, such as the Numeric Pain-Rating Scale, the Brief Pain Inventory, the Tampa Scale for Kinesiophobia, the Pain Catastrophizing Scale, and the Central Sensitization Inventory (CSI).

**Results:** A total of 21 sBCs with persistent pain were recruited. We observe a general trend of close agreement between the paper-based and app-based formats (ICCs ranged between 0.802 and 0.972; Cronbach's alpha ranged between 0.797 and 0.971). Test–retest reliabilities were moderate to excellent (ICCs ranged between 0.510 and 0.941; Cronbach's alpha ranged between 0.499 and 0.938). The agreement between the categorization of the CS algorithm and the CSI (cut-off point $\geq 40$ for CS symptoms) was 95.24%.

**Conclusion:** The *PaiNEd app* emerges as a robust tool for evaluating pain experience predominantly related to CS and pain-related symptoms in sBCs. Its demonstrated reliability not only bolsters its utility but also signifies its potential as a valuable asset for healthcare professionals engaged in pain education programs.

## Keywords

Central sensitization, cancer pain, persistent pain, chronic pain, breast cancer, reliability, app, mHealth, mobile health

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## Introduction

The implications of persistent pain can be devastating in the breast cancer (BC) population as they are already dealing with a cancer diagnosis and treatment-related effects.[1] Currently, chemotherapy, radiotherapy, surgery, immunotherapy, and hormonal therapy are the principal treatment

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strategies against cancer. The prevalence of persistent pain is usually higher in women who received chemotherapy and/or radiotherapy than women who did not.[2–4] In a cohort study of BC patients with pain more than 1 year after BC surgery, 38% of patients reported signs of hypersensitivity of the central nervous system.[5] Concerning immunotherapy and its possibility to cause psychological and neurological side effects, it seems feasible that it can also increase pain perception.[6] Furthermore, despite the aromatase inhibitors can ameliorate survival rates, they can increase joint pain during the first 12 months, which can lead to aromatase inhibitor therapy discontinuation.[7]

To appropriately address the needs of survivors of breast cancer (sBCs), it seems crucial to differentiate between various pain phenotypes. A previously established clinical algorithm to classify pain in survivors of cancer[8] was published for the distinction of postcancer pain as predominantly neuropathic, nociceptive, or central sensitization (CS) pain. This classification could improve clinical decision-making to optimize workday routines.[9] Moreover, greater consideration of these pain-related symptoms could impact adherence to exercise in different pain syndromes.[10] Among the nonpharmacological management options, pain education combined with physiotherapy can be effective and safe in cancer pain treatment.[11,12] This has necessitated that pain education programs target the predominant pain mechanisms of patients, and the use of telerehabilitation can help to provide the above programs in a novel and useful way to a broader population.

Some previous mHealth apps have been successfully tested in the oncological context. An example of this would be the ATOPE + mHealth system,[13] which is a reliable and valid tool that monitors readiness in sBCs, allowing physiotherapists to prescribe safer and more optimal doses of exercise. Another example is BENECA mHealth, which is also a reliable and valid mHealth app[14] that changes the lifestyles of sBCs through monitoring energy balance (healthy eating and physical activity).[15] Utilizing a user-friendly mHealth app for pain experience screening may serve as a valuable tool, providing instant results and allowing healthcare professionals to recognize the predominant pain mechanisms underlying different chronic pain entities. Therefore, patients could gain knowledge about the possible reason behind their suffering and will be able to seek for more appropriate health assistance. Nevertheless, in this article, the *PaiNEd app (Pain Neuroscience Education app)* is presented. It has been designed to report whether patients' pain experience is predominantly related to CS pain mechanisms. We must highlight the rise of mHealth for the assessment of pain in cancer and noncancer patients in the scientific literature.[16–19] However, none of the above apps are based on algorithms to differentiate between patients with and without experiences related to CS. Some assessment methods have been developed to try to detect CS symptoms, such as quantitative sensory testing (pressure pain threshold at the painful area and/or areas remote from the painful area), measurements of cytokines and neurotrophins (nerve growth factor, tumor necrosis factor-α, and brain-derived neurotrophic factor) and functional magnetic resonance,[20] which might be expensive and difficult to access. Nonetheless, there is no valid clinical diagnosis of the neurophysiological phenomenon of CS in pain patients.

As there is no gold standard to assess CS symptoms, we designed the *PaiNEd app*, which includes an algorithm that considers (1) the number of painful body parts to assess whether patients present a local or widespread distribution of pain[21] outside of the segmental area of (presumed) primary nociception[22] and (2) some questionnaires related to pain, such as the Brief Pain Inventory (BPI), Tampa Scale for Kinesiophobia (TSK-11), Pain Catastrophizing Scale (PCS) and the Central Sensitization Inventory (CSI), which have already been tested in cancer and noncancer chronic pain populations.[23,24] However, as the CSI has a high rate of false-positive cases,[8] the use of algorithms for proper classification is important.

Therefore, the aim of this study was to assess the reliability of the *PaiNEd app* to estimate whether sBC pain experience is predominantly related to CS pain mechanisms. Thus, targeting the predominant pain mechanisms in physiotherapy pain education programs.

## Methods

The study has been developed following the recommendations of the STROBE checklist.[25] An observational, descriptive reliability design was employed to assess the inter- and intrarater reliability of a groundbreaking mHealth app called the *PaiNEd app*, developed specifically for the evaluation of pain in cancer. Before the study was commenced, it received approval from the regional Ethics Committee of the Junta de Andalucía (2205-N-20).[26]

### Participants

Recruitment was conducted by consecutively recruiting participants from the radiotherapy and oncology services of both the "*San Cecilio University Hospital*" and the "*Virgen de las Nieves University Hospital*" in Granada (Spain). This inclusion followed recommendations from their respective oncologists to participate in the study, which took place from May 2022 to September 2022. Assessments were conducted at the CUIDATE unit, a cancer rehabilitation research unit affiliated with the *Sport and Health University Research Institute* (iMUDS), at the University of Granada.

The inclusion criteria were as follows: (1) age 18 years or older, (2) having undergone surgery and/or completed adjuvant treatment (radiotherapy and/or chemotherapy) at least 6 months but no more than 3 years ago, (3) no active cancer, (4) pain rating of ≥4 (Numeric Pain-Rating

Scale, NPRS, 0–10) in regions related to the tumor area for more than 4 weeks, (5) skills to use mHealth apps or living with someone who has this ability, and (6) agreeing to participate by signing an informed consent form. The exclusion criteria were as follows: (1) physical or mental incapacity to complete the study tests (i.e. Alzheimer's disease, Parkinson's disease, multiple sclerosis, schizophrenia, bipolar disorder, etc.); and (2) a history of chronic pain in the cranial, cervical, brachial, and shoulder areas or trauma to these regions before cancer diagnosis. Potential participants were informed of the study details both orally and in writing by a member of the research team, and they signed informed consent forms. The project followed the Declaration of Helsinki guidelines and Law 14/2007 on biomedical research.

## *PaiNEd app*

The *PaiNEd app* is a free mHealth system developed by the CUIDATE research group (Figure 1). The registration code of the app is IPR-969—FIBAO202122—PAINED. It was designed for both patients and health care professionals and is used for pain assessment and categorization of patients into different subgroups, according to CS mechanisms. The app is available for both the Apple iOS and Google Android platforms and is supported by a commercial server with centralized data storage (Figure 2). Both applications are implemented in their corresponding code, Android with Java and iOS with Objective-C, but each one faces the same system composed of a MySQL database and a PHP, JavaScript, and CSS language development that allows all the functionality offered by the application. This system is located on Amazon servers that automatically scale according to the level of user requests and is based in Ireland to maintain European data protection in force for processing health information. Its web version is also offered for use in any internet browser (https://www.painedproject.com/login/index.php).

Based on the algorithm proposed by Nijs et al.[22] the *PaiNEd* system guided the patient through a set of questionnaires that needed to be completed to decide whether patients had been suffering a disproportionate pain experience (Figure 3). The system considered a disproportionate pain experience, and the patient was led to draw pain distribution and location on body maps when the patient answered ≥4 on one or more NPRS and reached the cut-off points of at least one of the following questionnaires: BPI, TSK-11 and/or PCS (Figure 3). In the case of considering a disproportionate pain experience, the patient had to complete body part maps. Once the patient chose ≥3 specific body parts on body maps, it was considered diffuse pain distribution and therefore a probable CS process. Therefore, the patient was classified within the CS group. However, if the patient marked ≤2 specific body parts, the system instructed the user to complete the CSI. Finally, if the answers to the questionnaire scored ≥40, a probable sensitization process may affect the patient´s experience. Additionally, all the participants completed the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) to add more specific information about pain processes and sensitization mechanisms, although it was not part of the algorithm decision.

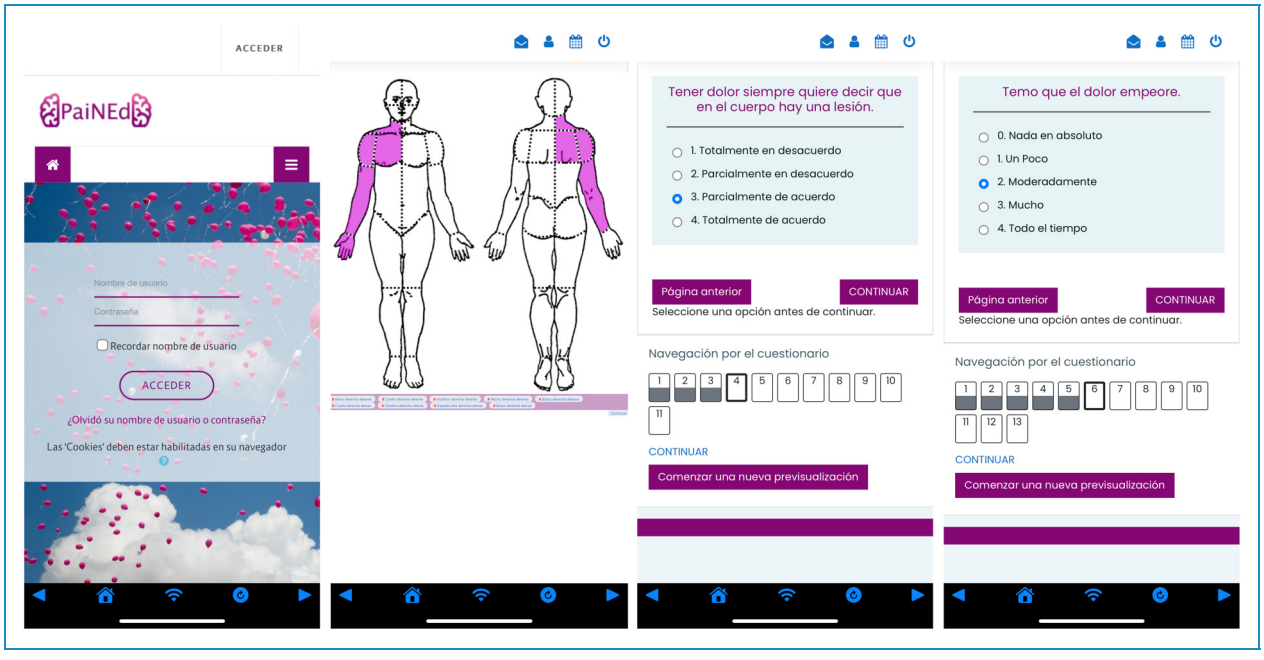


**Figure 1.** Screenshots of the *PaiNEd app* developed by the CUIDATE research group.

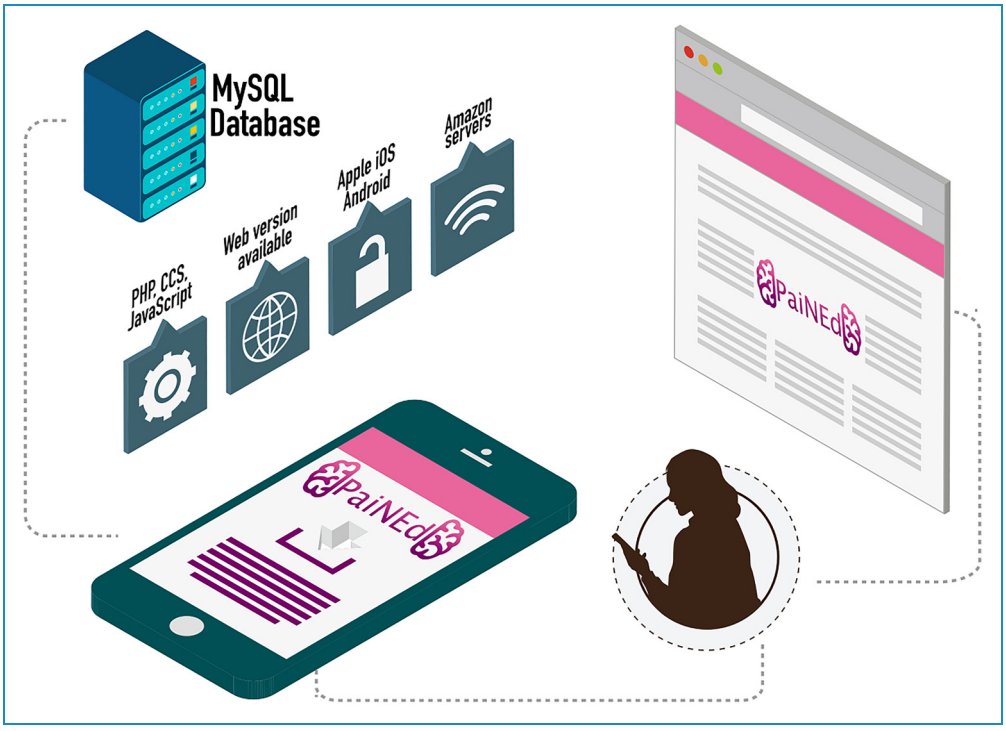


**Figure 2.** Technical characteristics of PaiNEd app.
*Note*: SQL: Structured Query Language; PHP: hypertext preprocessor; CSS: cascading style sheets.

## Data collection

Participants were instructed to use the *PaiNEd app* at least once in the presence of a member of the research team. These team members assisted participants in installing the *PaiNEd app* on their mobile phones and ensured the correct utilization of the system, addressing any questions or concerns.

Upon initial use of the app, users recorded their personal and anthropometric data, including weight, height, age, and BC subtype. Subsequently, participants were guided to complete a set of questionnaires essential for the classification algorithm. To assess the concordance of the *PaiNEd app*, participants were instructed to fill out these questionnaires both on paper and within the app in the first session. It is worth emphasizing that a deliberate 7- and 10-day interval was introduced between completing the on-site questionnaires (paper-based) and doing so through the app at home (app-based) for test–retest reliability. This deliberate delay was implemented to minimize the potential impact of recall bias. Moreover, the order in which participants completed the questionnaires through the app was randomized. This measure ensured that participants' responses were less likely to be influenced by their memory of the paper-based responses from the previous week. Additionally, throughout this process, if any participant encountered difficulties while using the *PaiNEd app*, a member of the CUIDATE group provided support through telephone calls or text messages to address their concerns and ensure a smooth experience.

## Comparison tools

*Clinical Outcomes*. A questionnaire based on sociodemographic issues was provided at the beginning of the assessment. Clinical data were retrieved from the electronic medical records by the participating health personnel.

*Numeric Pain-Rating Scale (NPRS)*. NPRS was utilized to measure current pain intensity in the cervical, temporomandibular joint (TMJ), and shoulder regions, in both affected and nonaffected sides. In this segmented numeric version of a visual analog scale (VAS), participants select a whole number (0–10 integers) that best reflects their intensity of pain. There are a total of 11 points ranging from 0 to 10, where a higher score indicates a more severe pain level. The common format is a horizontal bar or line, and NPRS is anchored by terms using pain and severity extremes. The NPRS exhibited good reliability with an intraclass correlation coefficient (ICC) of 0.88; [0.77 to 0.94].[27]

*Brief Pain Inventory (BPI)*. This questionnaire was used to measure the intensity of pain and its impact on activities of daily living. The BPI shares two core scales measuring pain severity and pain interference but uses different recall periods (24 hours vs. 1 week).

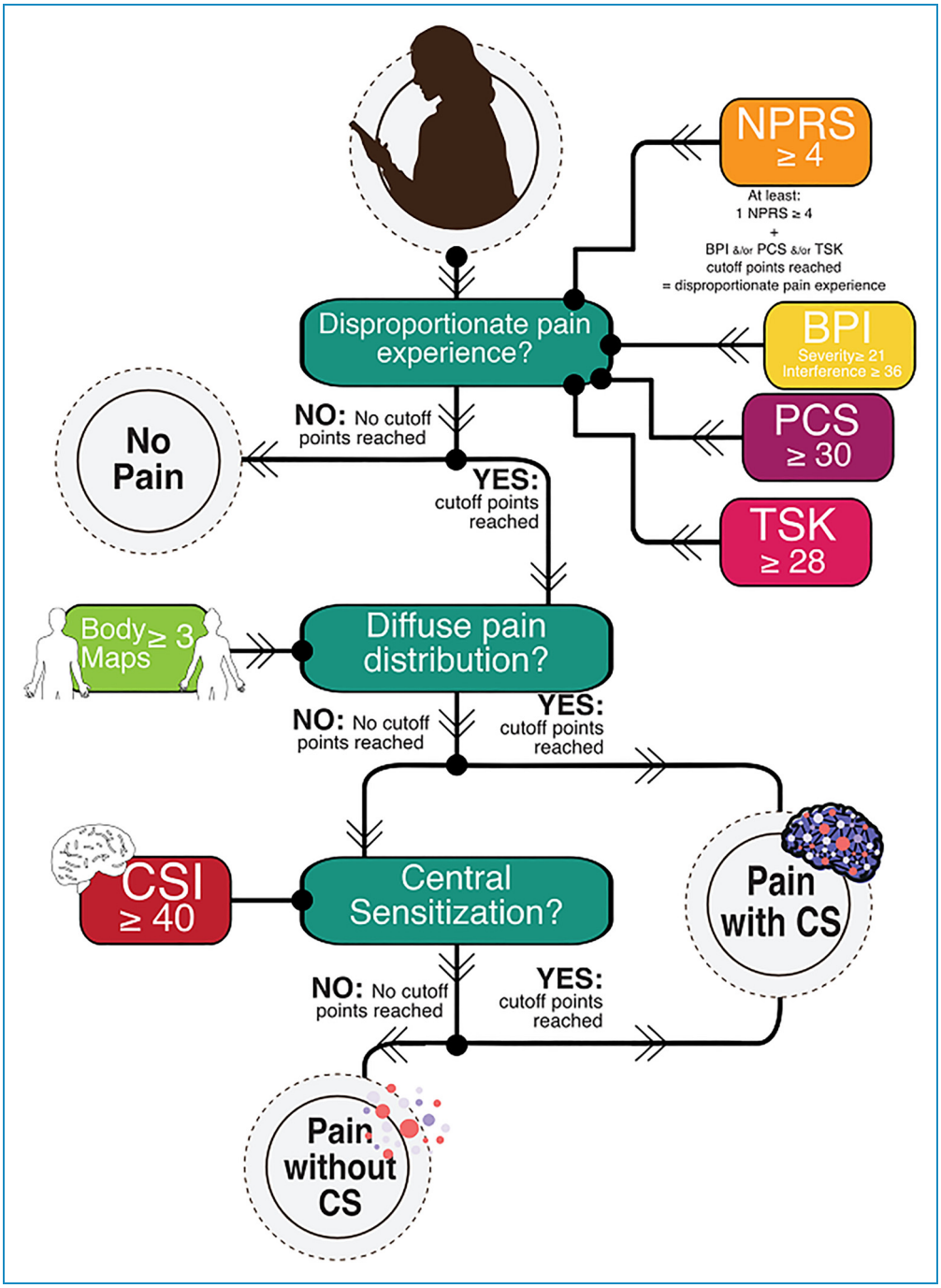


**Figure 3.** PaiNEd system algorithm to report whether patients are under predominant CS pain mechanisms.
*Note*: NPRS: Numeric Pain-Rating Scale; BPI: Brief Pain Inventory; PCS: Pain Catastrophizing Scale; TSK: Tampa Scale for Kinesiophobia; CSI: Central Sensitization Inventory; CS: central sensitization.

The Spanish version in the oncology population is considered a valid and reliable instrument to measure pain severity and interference.[28] It also obtained good overall internal consistency (Cronbach's alpha: 0.87) and excellent test–retest reliability for pain intensity and interference (ICC: 0.90 and 0.96, respectively), as well as interrater reliability for both dimensions (ICC: 0.77) in adults with chronic neuropathic and/or nociceptive and/or nociplastic pain.[29]

*Pain Catastrophizing Scale (PCS)*. This scale consists of a self-administered questionnaire of 13 items, based on a 5-point Likert scale from 0 (never) to 4 (always). Items are divided into three different subscales: rumination, magnification, and helplessness, with a general score indicating

the level of catastrophizing. Patients respond to the level of their pain experiences. The resultant score reflects the level of catastrophizing thoughts or feelings about the patient's pain experience, between 13 and 62, indicating high values and high catastrophizing.[30] The scale has proven to be reliable for daily use in chronic pain populations, with an ICC ranging between 0.62 and 0.75.[30]

*Tampa Scale for Kinesiophobia (TSK-11).* Kinesiophobia was assessed through an 11-item version of the Tampa Scale, consisting again of a Likert scale with four response options, "strongly disagree" that scores 1 point, and "strongly agree" that scores 4 points. The final scores reflect the level of fear of movement with a maximum of 44 points. was obtained using all 11 TSK items. The Spanish version showed good reliability and validity in a chronic pain sample with Cronbach's $\alpha = 0.79$.[31]

*Leeds Assessment of Neuropathic Symptoms and Signs (LANSS).* This tool is used to differentiate pain of predominantly neuropathic or nociceptive origin. It consists of two parts: a pain questionnaire with five items (testing thermal sensation, autonomic changes, dysesthesia, paroxysmal, and evoked pain) and a sensory testing component concerning allodynia and altered pin-prick threshold (two items). Patients can select a "yes/no" response, giving a total possible score of 24. When the score was $\geq 12$, the pain was classified as neuropathic; when the score was $<12$, the pain was classified as nociceptive.[32] The LANSS scale is considered a good predictor for pain type in a cancer population and is useful for classifying pain in cancer pain studies.[33] The Spanish version of the LANSS scale is reliable and valid for the differential diagnosis of neuropathic pain.[34] The scale had good construct validity with Cronbach's $\alpha = 0.76$.[33]

*Body maps (Number of painful body parts).* Pain drawing was used to obtain an illustration of pain locations and distribution. Participants were instructed to complete a pain drawing (with "X") of their perceived extent and location on a paper body chart (ventral and dorsal body views).[22] When patients marked $\leq 2$ specific body parts (shoulder pain, neck pain, back pain, knee pain, complex regional pain syndrome of one limb), it was considered a local distribution of pain and widespread pain if they chose $\geq 3$ specific body parts.[21] This method has been shown to be reliable for assessing body pain extent and location in adults with pain.[35]

*Central Sensitization Inventory (CSI).* The *PaiNEd app* includes this questionnaire scored with a 5-point Likert scale from 0 (never) to 4 (always), resulting in a total possible score of 100.[36] Higher scores indicate a worse self-perception of CS. If patients obtain a score greater than or equal to 40, they are considered to have sufficient psychometrics to be correlated with CS syndromes.[37] The CSI has been shown to be a valid and reliable measure for detecting CS symptoms in sBCs, with an ICC of 0.95 (95% confidence interval from 0.90 to 0.98).[23] The Spanish version of the CSI demonstrated high internal consistency ($\alpha = 0.872$) and test–retest reliability ($r = 0.91$).[38]

## Sample size

A sample size of 20 participants was calculated as the minimum requirement to achieve a statistical power of 85% in detecting a correlation coefficient of 0.9 between paper-based (on-site) and mHealth app assessment methods (specifically, the pain algorithm and *PaiNEd app*), while maintaining a type 1 error rate ($\alpha$) of 5%. This sample size was consistent with previous studies that investigated the agreement between on-site and telerehabilitation methods.[13,14] To account for potential participant attrition of 10% during the study, a total of 23 sBCs were recruited.

## Statistical analysis

The statistical package IBM SPSS version 24.0 (IBM Statistical Program for Social Sciences SPSS Statistic, Corp., Armonk, New York) was used for all analyses. A 95% confidence interval (CI) was established, and significance was set at $\alpha = 0.05$. A descriptive analysis encompassed summarizing the sociodemographic and clinical characteristics of the participants. Continuous variables were articulated as mean $\pm$ standard deviation (SD), and categorical variables were expressed in frequencies ($n$) and percentages (%). The normality of the distribution was ascertained using the Shapiro–Wilk test. All analyses were conducted by a researcher blinded to the participant groups. A 95% CI was established for all inferential statistics, with significance set at $\alpha = 0.05$.

## Concordance analysis

To assess the agreement between the paper-based and app-based questionnaire scores, we utilized a two-pronged approach. Firstly, we calculated Cronbach's alpha to estimate internal consistency. Secondly, we employed the ICC, using a two-way mixed-effects model with a consistency type. This model is particularly adept at determining the extent to which individual scores are consistent across different assessment methods. To complement these measures, Bland–Altman plots were generated, allowing us to visualize the limits of agreement and identify any potential biases between the two formats.

## Test–retest reliability analysis

The test–retest reliability of the *PaiNEd app* was evaluated over a deliberate 7- and 10-day interval to diminish the influence of recall bias. The reliability of the app-based assessment methods, specifically the pain algorithm and *PaiNEd app*, was quantified using Cronbach's alpha and ICC across the initial and final assessments. This approach

ascertained the consistency of the app over time, ensuring its reliability in capturing the chronic pain experience of sBCs.

## Results

A total of 23 sBCs with persistent pain were initially recruited for the study. Of these participants, 2 (2/23, 8.69%) could not be included in the final sample size due to personal reasons preventing them from completing all our assessments. Consequently, the study's final sample consisted of 21 participants.

The mean age of the participants was 51.43 (SD 5.98) years. Detailed demographic and clinical characteristics of the participants are presented (Tables 1 and 2). Out

**Table 1.** Demographic characteristics.

| Characteristic | Participants ($n = 21$) |
|---|---|
| Age (years), mean (SD) | 51.43 (5.98) |
| Social situation, *n* (%) | |
| Married | 11 (52.38) |
| Single | 4 (19.05) |
| Divorced | 4 (19.05) |
| Domestic partnership | 1 (4.76) |
| Widow | 1 (4.76) |
| Occupation, *n* (%) | |
| Currently working | 10 (47.62) |
| Her duties | 1 (4.76) |
| Current sick leave | 6 (28.57) |
| Unemployed | 3 (14.29) |
| Retired | 1 (4.76) |
| Education, *n* (%) | |
| No education | 0 (0) |
| Primary studies | 4 (19.05) |
| Secondary studies | 9 (42.85) |
| Higher education | 8 (38.10) |

**Table 2.** Clinical characteristics.

| Characteristic | Participants ($n = 21$) |
|---|---|
| Time since diagnosis in months, mean (SD) | 34.57 (22.25) |
| Time since surgery in months, mean (SD) | 29.33 (22.16) |
| Medical treatment, *n* (%) | |
| Surgery | 21 (100) |
| Radiotherapy | 19 (90.48) |
| Chemotherapy | 9 (42.85) |
| Type of surgery, *n* (%) | |
| Lumpectomy | 16 (76.19) |
| Mastectomy | 3 (14.29) |
| Bilateral mastectomy | 2 (9.52) |
| Chemotherapy sessions, *n* (%) | |
| 0 | 12 (57.14) |
| 4 | 1 (4.76) |
| 5 or more | 8 (38.10) |
| Affected side, *n* (%) | |
| Right | 11 (52.38) |
| Left | 6 (28.57) |
| Both | 4 (19.05) |
| Self-perceived health, *n* (%) | |
| Very good | 0 (0) |
| Good | 4 (19.05) |
| Fair | 6 (28.57) |
| Bad | 8 (38.10) |
| Very bad | 3 (14.29) |
| Frequent intake of painkillers, *n* (%) | |
| Yes | 14 (66.67) |
| No | 7 (33.33) |

of the participants, 10 (47.62%) were currently working, 21 (100%) had undergone surgery, and the most repeated surgical intervention was lumpectomy, 16 (76.19%). The means and deviations of paper-based and app-based measured variables are presented in Supplemental material 1.

### Compliance with methods

All the participants completed the paper-based versions of all scales as requested and completed the three *PaiNEd app* scale versions on the designated 3 days. Moreover, seven participants (33.33%) even exceeded the prescribed number of days for questionnaire completion. Participants demonstrated excellent compliance with the *PaiNEd app*, completing all sets of data without reporting any obstacles or difficulties during the process.

### Concordance analysis

Table 3 presents the concordance Cronbach's alpha reliability estimate and the mean difference (95% CI) between the paper-based version and the average scores obtained from the three app-based evaluations (Table 3). Additionally, intraclass correlation coefficients (rho) were calculated using a two-way mixed-effects model with consistency type. Standard error of measurement (SEM) and minimum detectable change (MDC) analyses between the paper-based version and the average scores obtained from the three app-based evaluations are presented in Supplemental material 2.

Furthermore, the agreement between the categorization of the CS algorithm and the CSI (cut-off point $\geq 40$ for central sensitization symptoms) was 95.24%.

We observe a general trend of close agreement between the two formats (Figures 4–7). The mean differences are mostly clustered around the bias line, suggesting no significant systematic difference between paper and mobile responses. The limits of agreement, indicated by the orange lines, show a reasonable range of variance for most measures, although some plots exhibit a wider spread, indicating more variability in those particular metrics. Notably, the scatter does not display any concerning patterns such as funneling or clear trends, which suggests that the agreement does not systematically change over the range of measurements. While there is some variability, as expected in clinical measurements, the absence of systematic trends across the range of scores supports the validity of the mobile app as an effective medium for questionnaire administration. Overall, these results support the interchangeability of the paper and mobile app questionnaire formats for the metrics analyzed.

### Test–retest reliability

The results for the test–retest Cronbach's alpha reliability estimate of the initial and final *PaiNEd app* assessments are presented (Table 4). SEM and MDC analyses between the first and last *PaiNEd app* assessments are presented in Supplemental material 3.

## Discussion

The results of our study highlight the potential utility of the *PaiNEd app* system in assessing pain experience predominantly related to CS pain mechanisms in sBCs. Our study's results have clearly demonstrated the reliability and consistency of the *PaiNEd app,* as evidenced by the data presented here. These findings hold significant implications for healthcare professionals who aim to delve into the root causes of pain within this patient demographic and to tailor treatments that better align with their specific needs.

The analysis presented in the results section highlighted a range of SEM and MDC values across different variables, both in the concordance study between paper-based and app-based questionnaires and in the test–retest reliability study of the mobile app itself. While most variables demonstrated satisfactory SEM and MDC values, suggesting reliable measurements, some variables such as the BPI severity subscale in both concordance and test–retest scenarios exhibited higher SEM and MDC, indicating significant measurement variability and less stability over time. These higher values could be attributed to the subjective nature of pain assessment, which may be more susceptible to interpretation and reporting variability, especially when transitioning between different mediums such as paper and digital formats.

While our research focused on the use of the *PaiNEd app* in sBCs, its potential extends beyond this specific population. The versatility of the *PaiNEd app* makes it applicable to various tumor locations, such as the head and neck, colon, and lung. This adaptability opens up exciting possibilities for broader applications and a wider range of patients who can benefit from its utility.

### Comparison with prior work

In 2014, a systematic review[39] identified 283 pain-related apps in the main stores (e.g. App Store and Google Play), and a much more recent study identified 508 apps focused only on pain management.[40] This exponential growth underscores the significant role these apps now play in multimodal treatment approaches,[26] potentially reinforcing behavioral changes among chronic pain patients.[41] Furthermore, they offer real-time valuable information to health care professionals,[42,43] enabling the identification of factors such as catastrophic or kinesiophobic thoughts through in-app questionnaires,[44] as well as

**Table 3.** Cronbach's alpha reliability estimate and concordance reliability.

| Variable | Mean difference between paper-based and app-based in units of measurement (95% CI)[a] | Cronbach's alpha reliability estimate | Concordance reliability ICC[b] | |
|---|---|---|---|---|
| | | | ICC[b] (Rho) | 95% CI[a] of ICC[b] |
| NPRS[c] affected cervical | −0.063 (−0.540/0.413) | 0.934 | 0.937 | 0.844–0.974 |
| NPRS[c] nonaffected cervical | −0.571 (−1.151/0.008) | 0.965 | 0.960 | 0.895–0.984 |
| NPRS[c] affected TMJ[d] | −1.444 (−2.301/−0.587) | 0.867 | 0.810 | 0.344–0.932 |
| NPRS[c] nonaffected TMJ[d] | −1.158 (−1.869/−0.447) | 0.900 | 0.857 | 0.485–0.950 |
| NPRS[c] affected shoulder | −0.508 (−1.131/0.115) | 0.941 | 0.936 | 0.841–0.974 |
| NPRS[c] nonaffected shoulder | −1.222 (−1.947/−0.497) | 0.938 | 0.908 | 0.618–0.969 |
| BPI[e] severity | −0.508 (−2.483/1.467) | 0.797 | 0.802 | 0.511–0.920 |
| BPI[e] interference | 0.825 (−1.552/3.203) | 0.965 | 0.966 | 0.916–0.986 |
| PCS[f] rumination | 0.222 (−0.652/1.097) | 0.953 | 0.954 | 0.888–0.981 |
| PCS[f] magnification | −0.555 (−1.448/0.337) | 0.888 | 0.885 | 0.722–0.953 |
| PCS[f] helplessness | 0.476 (−0.583/1.536) | 0.969 | 0.969 | 0.924–0.987 |
| PCS[f] catastrophizing | 0.143 (−1.915/2.201) | 0.971 | 0.972 | 0.931–0.989 |
| Kinesiophobia | 1.063 (−0.211/2.338) | 0.950 | 0.946 | 0.863–0.978 |
| LANSS[g] | 0.063 (−1.262/1.389) | 0.929 | 0.932 | 0.831–0.972 |
| Number of painful body parts | −0.746 (−2.318/0.826) | 0.956 | 0.956 | 0.893–0.982 |
| CSI[h] | 0.524 (−1.932/2.979) | 0.949 | 0.951 | 0.879–0.980 |

[a]CI: confidence interval.
[b]ICC: intraclass correlation coefficient.
[c]NPRS: Numeric Pain-Rating Scale.
[d]TMJ: temporomandibular joint.
[e]BPI: Brief Pain Inventory.
[f]PCS: Pain Catastrophizing Scale.
[g]LANSS: The Leeds Assessment of Neuropathic Symptoms and Signs.
[h]CSI: Central Sensitization Inventory.

tracking daily symptoms such as pain intensity and medication use.[45] Despite these advancements, the reliability of an app designed to assess whether sBCs exhibit symptoms of CS has not yet been investigated.

The *AvaliaDor mobile app*[44] demonstrated commendable test–retest reliability across several key pain-related metrics when assessed in a cohort of adults with musculoskeletal pain. Specifically, the BPI pain severity exhibited

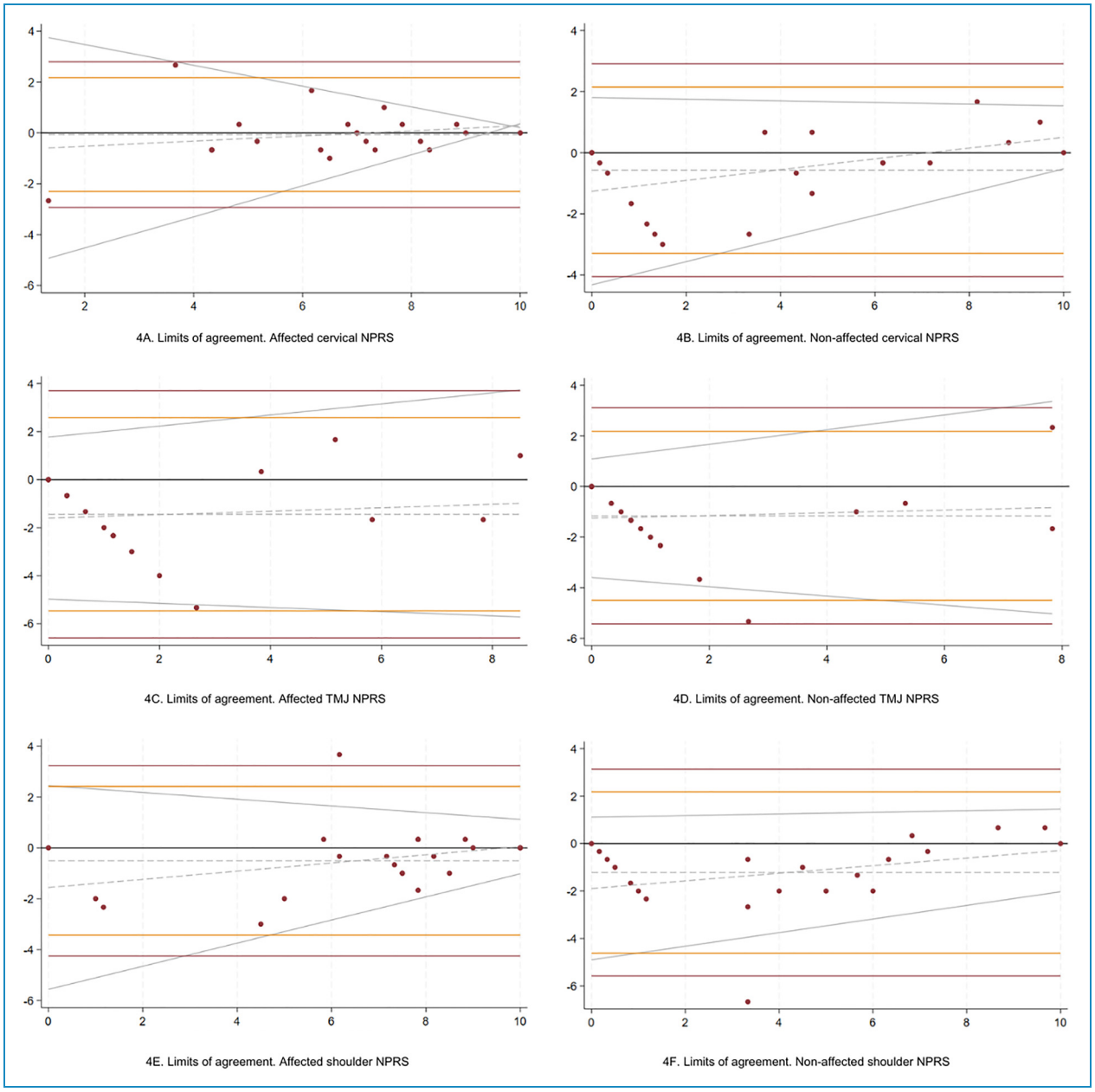


**Figure 4.** Bland–Altman plots for NPRS.

a high ICC of 0.86, indicating a high degree of consistency in measuring pain intensity over time. Similarly, the BPI pain interference score displayed a notable ICC value of 0.84, suggesting strong reliability in assessing the impact of pain on daily functioning and activities. Finally, this app yielded promising results for measuring pain catastrophizing, with an ICC of 0.76, indicating a good level of consistency in evaluating the cognitive and emotional aspects of pain perception. However, it is worth noting that the app exhibited slightly lower, albeit still moderate, reliability when assessing fear of movement, with an ICC of 0.65, signifying a reasonably stable measurement of this parameter within the musculoskeletal pain population. In contrast, the *PaiNEd app*, which was the focus of our study, surpassed these reliability metrics. It consistently achieved ICC values exceeding 0.90 for all these variables, highlighting an exceptional level of concordance reliability between the paper-based and app-based measures. This exceptional performance underscores the *PaiNEd app's* ability to assess pain severity consistently and accurately, pain interference, pain catastrophizing, fear of movement, and pain location.

It is important to note that only test–retest reliabilities (as measured by the ICC) for NPRS nonaffected cervical,

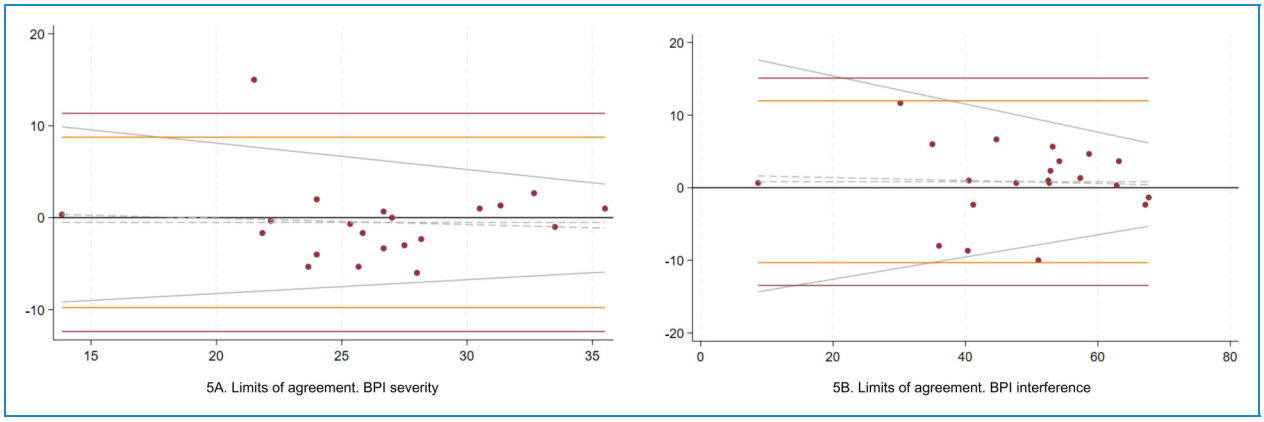


**Figure 5.** Bland–Altman plots for BPI.

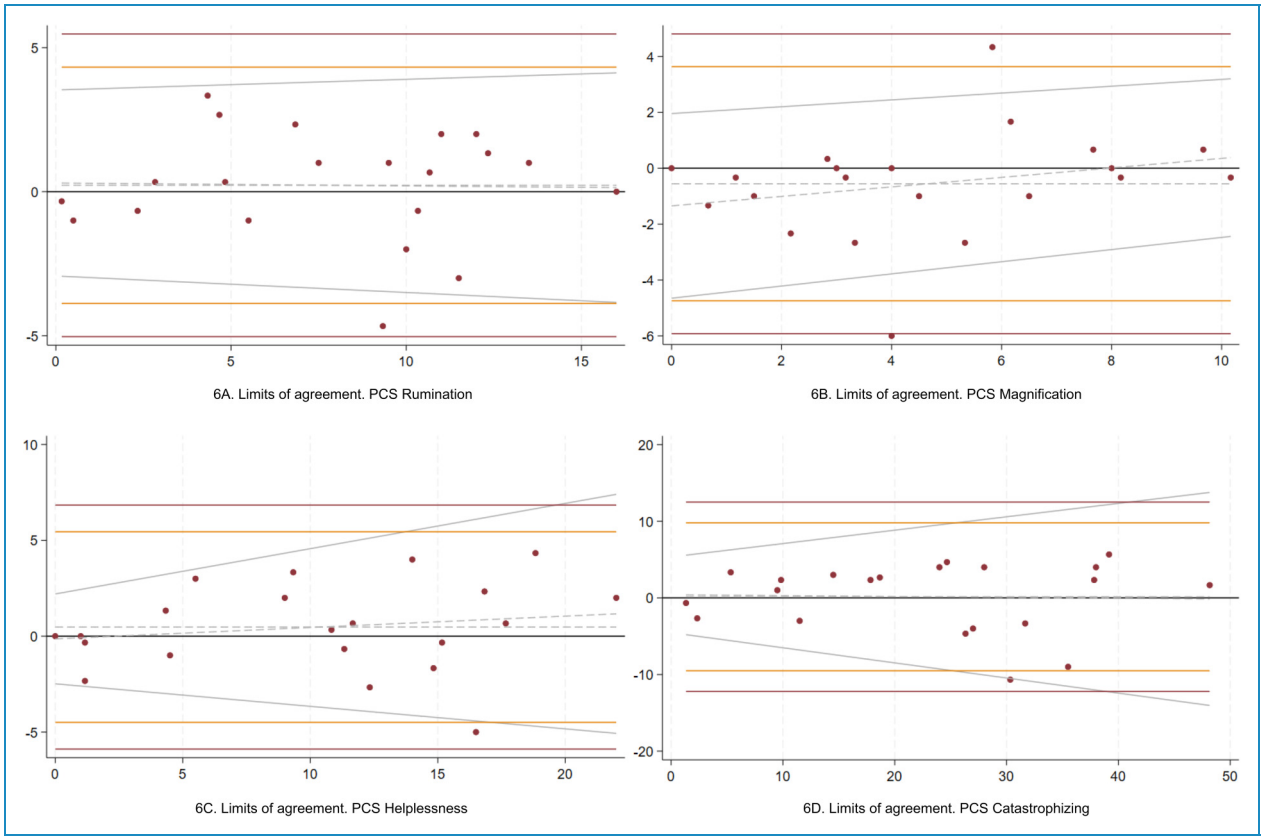


**Figure 6.** Bland–Altman plots for PCS.

NPRS affected TMJ, NPRS nonaffected TMJ, NPRS affected shoulder, NPRS nonaffected shoulder and PCS magnification were moderate (ICC 0.50–0.75). This observation may be attributed to the inherent complexity of chronic pain, where patients often grapple with pain that exhibits both constant and fluctuating intensity levels.[46] Specifically, it is worth highlighting that individuals, particularly cancer patients managing chronic pain with opioid medications, frequently encounter transient spikes in pain intensity, commonly referred to as "breakthrough" pain.[47] This variability in pain intensity over time can challenge the reliability of measurements taken within a specific timeframe. Additionally, it is essential to acknowledge that pain experienced by a patient at a specific moment may not necessarily reflect their overall pain experience.[46] These intricacies in chronic pain dynamics may have contributed

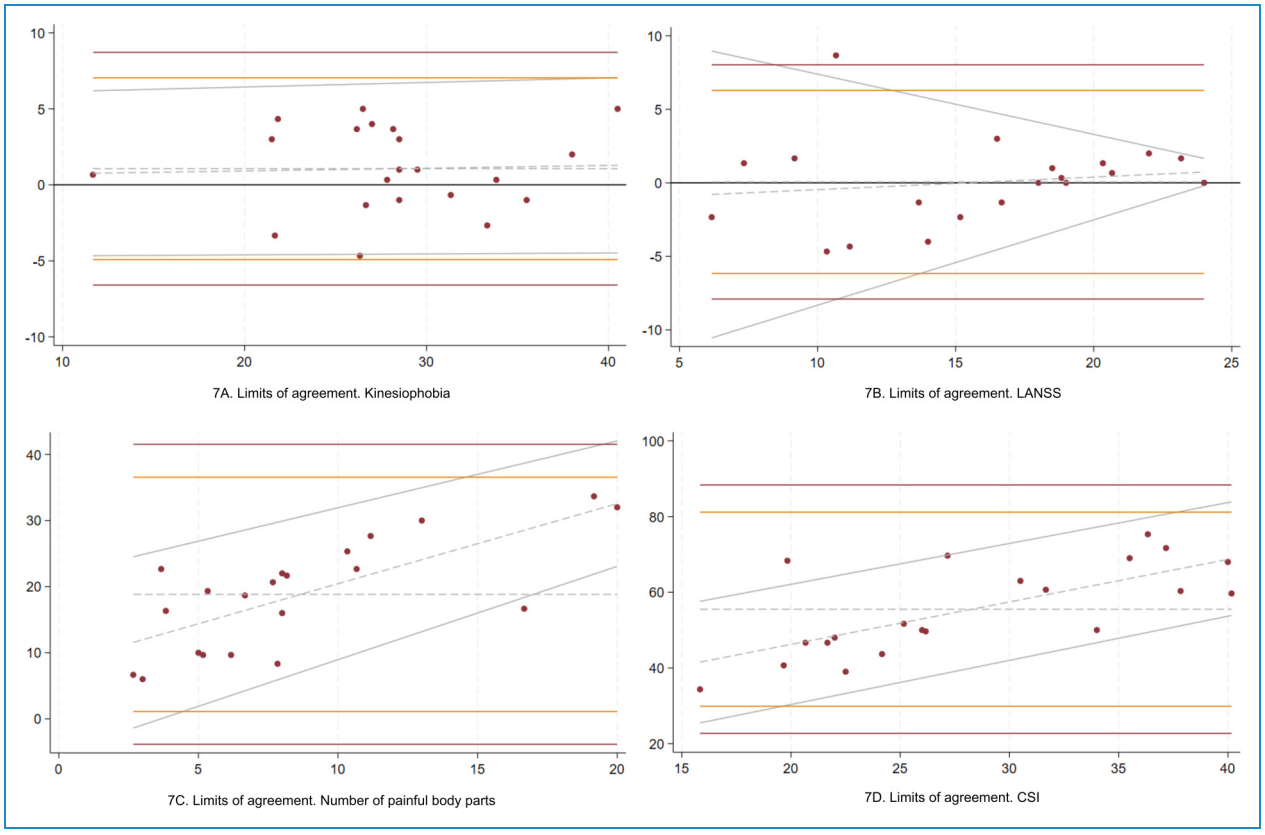


**Figure 7.** Bland–Altman plots for Kinesiophobia, LANSS, number of painful body parts, and CSI.

to the moderate ICC values observed in our assessment of NPRS measurements. In contrast, the *Pain Squad app*[42] demonstrated excellent internal consistency (Cronbach α of 0.96) when assessing pain intensity in children and adolescents with cancer. A key factor contributing to this enhanced consistency was the frequency of data collection. Participants in the Pain Squad study reported their pain levels twice daily over a span of 2 weeks using the app. This frequent data collection approach substantially increased the volume of measurements, thereby bolstering the reliability of the results.

Finally, our findings on method reliability are consistent with those reported for the *Pain Recorder app,*[48] in which significant correlations were found for pain intensity (Spearman's correlation coefficient $\geq 0.79$) and pain interference scoring (Spearman's correlation coefficient $\geq 0.40$) in adults with musculoskeletal pain. However, our concordance and test–retest reliability study included Cronbach's alpha and ICC for a more comprehensive analysis. Furthermore, the *Pain Monitor app*[49] also had moderate-to-strong correlations between app content and traditional measures for pain intensity and interference, pain catastrophizing, PCS (rumination), PCS (magnification), and PCS (helplessness) in adults with heterogeneous chronic pain. Furthermore, Muhammad Maarj et al.[50] pioneered the development of an electronic VAS through an mHealth app, which was deployed for children and adolescents diagnosed with hypermobility spectrum disorder/hypermobile Ehlers–Danlos syndrome. In a comparative analysis against the traditional paper-based VAS, their mHealth app approach demonstrated good reliability. This innovation showcases the potential for digital tools to reliably capture pain-related data even in younger populations, where traditional assessment methods may be less suitable or engaging. These collective findings emphasize the growing role of mHealth apps in providing reliable and effective means for pain assessment across various demographic groups and pain conditions.

## Study limitations and strengths

This study had several limitations. NPRS measures assessed current pain and not daily or weekly scores of pain intensity on average, which could affect our results bearing in mind the oscillatory nature of pain. Therefore, patients may not have given adequate relevance to their symptoms, and some data could be missed in the process. In addition, data were obtained from the same research center, which might affect the generalizability of our findings to the BC population. Other disadvantages include the fact that it is only available in Spanish and requires a stable Wi-Fi network or mobile data connection to use it.

**Table 4.** Cronbach's alpha reliability estimate and test-retest reliability.

| Variable | Mean difference between PaiNEd app measurements (95% CI)[a] | Cronbach's alpha reliability estimate | Test-retest reliability ICC[b] | |
|---|---|---|---|---|
| | | | ICC[b] (Rho) | 95% CI[a] of ICC[b] |
| NPRS[c] affected cervical | −0.190 (−1.434/1.053) | 0.499 | 0.510 | −0.246–0.804 |
| NPRS[c] nonaffected cervical | −1.238 (−2.265/−0.211) | 0.878 | 0.851 | 0.590–0.942 |
| NPRS[c] affected TMJ[d] | −2.619 (−4.090/−1.147) | 0.661 | 0.548 | −0.090–0.817 |
| NPRS[c] nonaffected TMJ[d] | −1.619 (−2.965/−0.273) | 0.649 | 0.596 | 0.061–0.832 |
| NPRS[c] affected shoulder | −0.857 (−1.793/0.079) | 0.864 | 0.849 | 0.625–0.939 |
| NPRS[c] nonaffected shoulder | −2.000 (−3.151/−0.848) | 0.830 | 0.756 | 0.210–0.912 |
| BPI[e] severity | −1.047 (−4.409/2.314) | 0.521 | 0.528 | −0.178–0.810 |
| BPI[e] interference | 0.095 (−3.899/4.089) | 0.897 | 0.901 | 0.754–0.960 |
| PCS[f] rumination | −0.047 (−1.439/1.344) | 0.875 | 0.880 | 0.701–0.951 |
| PCS[f] magnification | −0.857 (−2.055/0.341) | 0.788 | 0.779 | 0.469–0.909 |
| PCS[f] helplessness | 0.905 (−0.631/2.441) | 0.930 | 0.929 | 0.827–0.971 |
| PCS[f] catastrophizing | 0.000 (−2.964/2.964) | 0.938 | 0.941 | 0.853–0.976 |
| Kinesiophobia | 1.286 (−0.704/3.276) | 0.875 | 0.870 | 0.686–0.947 |
| LANSS[g] | −0.619 (−3.298/2.060) | 0.744 | 0.752 | 0.382–0.900 |
| Number of painful body parts | −1.714 (−4.640/1.211) | 0.839 | 0.836 | 0.604–0.933 |
| CSI[h] | 1.047 (−2.447/4.542) | 0.904 | 0.907 | 0.772–0.962 |

[a]CI: confidence interval.
[b]ICC: intraclass correlation coefficient.
[c]NPRS: Numeric Pain-Rating Scale.
[d]TMJ: temporomandibular joint.
[e]BPI: Brief Pain Inventory.
[f]PCS: Pain Catastrophizing Scale.
[g]LANSS: The Leeds Assessment of Neuropathic Symptoms and Signs.
[h]CSI: Central Sensitization Inventory.

Moreover, there is a digital divide in older patients, since in some cases they did not have the necessary knowledge to use the *PaiNEd app* properly. Fortunately, all sBCs who participated in this study had family support to complete all the questionnaires for the time requested. On the other hand, concerning the variables such as the BPI severity subscale that exhibited higher SEM and MDC, we are undertaking several approaches. First, enhancing the user interface and experience of the mobile app might reduce user-related variability. Clearer instructions and more intuitive navigation could help standardize the way participants respond, particularly in subjective assessments. Second, incorporating more rigorous training sessions for users before they start using the app can also minimize discrepancies in how questions are understood and answered. Lastly, increasing the sample size in future studies could provide

more robust statistical power and more reliable estimates of SEM and MDC, reducing the impact of outliers and variability in user responses. These strategic adjustments are not only aimed at improving measurement accuracy but also at ensuring that the transition to digital platforms maintains the integrity of the data collected, ultimately enhancing the utility and credibility of mobile health applications in clinical assessments.

This study also featured some strengths. It includes a comparison between the mHealth app and the paper-based assessment with a robust statistical analysis. The support of a multidisciplinary research team with physiotherapists, doctors, occupational therapists, nurses, and physical activity specialists involved in the process of developing, testing, and refining the *PaiNEd app*. The app interface is user-friendly, easy to install, with flexible setup tools, and compatible with both Android and IOS systems, so it can reach a larger number of smartphone and tablet users. Additionally, this app could be a great tool to facilitate the transmission of information between patients and health care professionals, as pain-related measures could be assessed remotely, thus saving time for healthcare services. Consequently, pain education programs could effectively target the predominant pain mechanisms of patients.

### *Future work*

In future updates, other languages could be included to make the app reach a larger population. Although this application has been tested in sBCs, it could be tested in other patients with persistent pain or even in different pain conditions. Therefore, the generalizability of our results should be widened to a more heterogeneous population.

### *Clinical implications*

The clinical implications stemming from our findings hold significant relevance in the realm of chronic pain assessment and management. Our results underscore the increasingly valuable role of, mHealth apps in measuring pain intensity and its interference with daily life, particularly among sBCs. This digital tool offers a more dynamic and frequent means of collecting pain-related data, potentially enhancing the accuracy of assessments and thereby enabling a more personalized approach to pain treatment. Furthermore, our conclusions emphasize the importance of considering pain intensity variability over time, especially in patients experiencing "breakthrough pain" within the context of opioid therapy. Ultimately, this knowledge can guide healthcare professionals in selecting appropriate assessment tools and tailoring pain management strategies to more effectively address the intricacies of the chronic pain experience.

## Conclusion

The *PaiNEd app* emerges as a robust and dependable tool for evaluating pain experience predominantly related to CS and pain-related symptoms in sBCs. Its demonstrated reliability not only bolsters its utility but also signifies its potential as a valuable asset for healthcare professionals engaged in pain education programs. By incorporating the *PaiNEd app* into their toolkit, these professionals can gain crucial insights into the predominant pain mechanisms at play in sBCs, enabling them to tailor interventions that address the specific needs of this patient group more effectively. Moreover, the app's capacity to facilitate remote, real-time communication between patients and healthcare services represents a pioneering approach in patient-centered care. This feature not only enhances the accessibility of care but also promotes a more responsive and personalized intervention strategy, ultimately fostering improved outcomes and a higher quality of life for sBCs dealing with chronic pain.

## Abbreviations

| | |
|---|---|
| BPI | Brief Pain Inventory |
| CI | confidence interval |
| CS | central sensitization |
| CSI | Central Sensitization Inventory |
| ICC | intraclass correlation coefficient |
| LANSS | The Leeds Assessment of Neuropathic Symptoms and Signs |
| MDC | minimum detectable change |
| NPRS | Numeric Pain-Rating Scale |
| PCS | Pain Catastrophizing Scale |
| sBCs | survivors of breast cancer |
| SD | standard deviation |
| SEM | standard error of measurement |
| TMJ | temporomandibular joint |
| TSK | Tampa Scale for Kinesiophobia |
| VAS | visual analog scale. |

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PAV helped supervise the project, wrote the manuscript, made substantial contributions to conception and design, and gave final approval of the version to be published.

NGC supervised the manuscript, made substantial contributions to conception and design, gave final approval of the version to be published, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

ITM supervised the manuscript, made substantial contributions to conception and design, gave final approval of the version to be published, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

LOC supervised the manuscript, made substantial contributions to conception and design, gave final approval of the version to be published, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

MLL wrote the manuscript, supervised the manuscript, made substantial contributions to conception and design, contributed to analysis and interpretation of data, gave final approval of the version to be published, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

CFL conceived and planned the idea, wrote the manuscript, made substantial contributions to conception and design, contributed to analysis and interpretation of data, gave final approval of the version to be published, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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