

## Criteria Useful in Measurement of Pain and Monitoring Treatment Outcomes

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### Abstract

**Objective:** Persistent pain has profound effects on the health and quality of life. A reliable, comprehensive yet simple, measurement tool is essential for research, optimising clinical practice and treatment outcomes for persistent pain patients. We seek to devise a tool to aid physicians in assessing persistent pain.

**Design:** A scoring tool was developed to measure the direct and indirect markers of persistent pain across the following domains: Score of pain(S), Physical activity (P), Additional medication (A), Additional GP/ED visit (A), Sleep quality (S), Mood (M) and Side-effects of pain medication (S). These characteristics were rated and scored monthly in persistent pain patients for 9 months. SPAASMS score was inversely proportional to improved pain management.

**Results:** The test-retest analysis for SPAASMS score (n=20) showed a concordance correlation coefficient of 0.94; 95%-confidence interval=0.86, 0.97 and Cronbach's alpha for Reading 1 and 2 were 0.66 (p=0.001) and 0.67 (p<0.001), respectively. Comparison of the score with the Numerical Rating Scale (NRS), Physical Disability Index (PDI), Depression, Anxiety, Stress Scale (DASS21) and a combined score of NRS, PDI and DASS21 showed improved sensitivity except for DASS21. The score declined when patients responded well but remained high in patients not responding to treatment or increased with precipitating events like further trauma. With optimum relief, scores remained static.

**Conclusion:** SPAASMS is a simple, rapid and comprehensive tool which quantifiably indicated the progress of the patient under treatment. It can also be used to determine symptoms which have not responded to it.

**Keywords:** Persistent pain; Assessment tool; NRS; PDI; DASS21

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### Introduction

Persistent pain has been described as continuous or recurrent pain of sufficient duration and intensity to adversely affect a patient's well-being, mood, level of functioning and quality of life. A reliable measurement tool is essential for research, optimising clinical practice and treatment outcomes for patients with persistent pain [1,2]. According to Gatchel [3], physical and psychogenic pain hurt equally.

Persistent pain has profound changes on a patient's activity, mobility, sleep, social life, leisure activities, mental health and quality of life [4]. Single dimensional scales like the Numerical Rating Scale (NRS), the Visual Analogue Scale (VAS), the Verbal Rating Scale (VRS) or multi-dimensional scales like Wisconsin

Brief Pain Inventory, McGill Pain questionnaire etc are used for measurement of pain. Other scales, e.g. Depression, Anxiety, Stress Scale (DASS21) and PDI (Pain Disability Index) may be used to measure some components of persistent pain, like psychological and physical factors, respectively. The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommendations are very useful for measurement of clinical trial outcomes for medicines used for persistent pain [5]. The Norwegian Pain Society has also recommended a four-page, 31 item screening questionnaires for treatment outcomes [6]. These scales and recommendations are comprehensive and precise. However, these tools may prove lengthy and tedious for patients experiencing intense pain. For persistent pain clinicians it is important to have a concise, time efficient tool

and to evaluate progress of treatment. Successive reduction of SPAASMS (the new measurement tool) scores should indicate clinical improvement of the seven components of persistent pain.

## Method

Pain is a multidimensional subjective experience [7]. The effects of persistent pain may include poor sleep, restricted mobility, decreased activity, poor mood, greater use of medications and more health practitioner visits. Therefore, SPAASMS score includes the majority of these components.

### Score of pain

Turk and Melzack have stressed on intensity as the most salient feature of pain [8]. As intensity of pain is a subjective experience and there is no equipment at present to measure pain, we rely on the patient's self-report for monitoring intensity. Common measures used in this context are VRS, VAS and NRS. The NRS can be presented graphically or delivered verbally. As the monthly assessments would be done by telephone and NRS was easily understood by patients, it was convenient for our purpose. It has been shown that NRS has greater power to detect pain intensity than VRS and it is superior to VAS in terms of comprehension by patients [2]. Also, from review by Williamson and Hoggart [9], it appears that VAS is the least sensitive, though easy to use. VAS has the highest failure rate. Repeated scores using VAS can vary by as much as 20%. Therefore, NRS was chosen above others. Reduced scores of pain intensity indicate successful treatment.

### Physical activity

Physical activity levels are considered as an important factor in pain assessment which could indicate functional outcomes such as improved activities of daily living (ADL) like household chores, walking, working or travel [10-12]. In 1985, Linton [13] found that activity and pain levels were related, only when based on overall physical functioning. This relationship gradually disappears when the activity becomes more specific and objective as would happen, when measures like the Assessment of Motor and Process Skills (AMPS) or similar other measures are applied. A more recent study found that more than two-thirds (68%) of the persistent pain patients considered improvement in daily activities as necessary for a successful outcome [14]. Thus, any measure indicating successful treatment needs to show increased activity levels.

### Mood

Mood defined as a state of mind or emotion. A World Health Organization (WHO) study showed that 22% of primary care patients are suffering from constant debilitating pain and are four folds more likely to have a depression or anxiety mood disorder than the patients without persistent pain [15]. Similarly, Patten et al. [16] in a large-scale study in Canada, showed that long-term pain increases the risk of major depression. Several studies found increased depression rates with a persistent pain condition [17]. Increased number of painful sites or more diffuse pain increases the risk of depressive illness [18]. Gambassi [19] discussed in a review that pain and depression share genetic factors,

biological pathways and neurotransmitters. The IMMPACT study (2003) has recommended emotional functioning as one of six outcome domains to be considered in assessing persistent pain [5]. Therefore, we have included mood as one of the major components for clinical assessment in our SPAASMS scale.

### Sleep

Studies have demonstrated the inverse relationship between sleep quality and pain [20,21]. Insomnia increases severity of pain [22]. A study has found that in comparison to healthy controls, subjects with fatigue and pain experience poor sleep. These patients also experience higher incidence of depression and functional disability [23]. In their study, McCracken and Iverson [24] found that patients with insomnia reported greater pain intensity. For improvement in persistent pain to be inferred, problems with sleep need to be measured and reduced. Whether it is a cause or consequence of the pain condition, sleep disorders must be treated in the same way as pain [25]. Further, several studies have used assessment of insomnia based on the patient's self-description as poor sleepers and good sleepers or satisfactory and unsatisfactory sleep groups [26-28]. Therefore, quality of sleep has been used in SPAASMS as one of the multidimensional constructs. It was self-rated from very good to poor and scored accordingly.

### Side effects

NSAIDs and opioids have been used widely for non-malignant pain for several years [29]. Opioids have a range of adverse, unpleasant side effects of which nausea; constipation, vomiting, drowsiness and cognitive impairment of varying degrees have been reported by patients [30]. Lately, the use of other synthetic and semi-synthetic opioids like transdermal Fentanyl and Buprenorphine for treatment of persistent pain has added to the list of unwanted side-effects of local irritation, rashes and skin eruptions [31,32]. These adverse reactions may compromise drug compliance.

Therefore, the severity of reaction to the medication and patients' compliance with it are important factors to consider in the management plan. Therefore, the side effects of medication have been accounted for in SPAASMS assessment and are self-rated by patients as nil, mild, moderate or severe side effects.

### Additional medication

Medical management of persistent pain often involves a combination of analgesic, psychiatric and/or neuropathic medications [29]. The results of a Finnish study indicate that daily or continuous pain of high intensity resulted in increased frequency of analgesic medication use [33]. Historically, successful pain management has been indicated by decreased frequency of medication use [34]. For moderate to severe persistent pain, long acting opioids, either in the form of oral or trans-dermal medications, are used. They may be used with acetaminophen and non-steroidal anti-inflammatory drugs (NSAIDs) for treatment of mild intermittent pain flares. Short acting opioids are often used for moderate to severe break-through pain [29]. Therefore, the frequency of medication used, is an important

factor to be considered in persistent pain assessment. We postulate that decreased frequency of medication, especially short acting opioids, would follow decreased pain intensity and frequency of pain flares, because of better pain management.

### Additional GP/ED visit

One Australian study has found that patients with back pain visit GP 2.4 times more than patients without it [35]. Another study in UK concluded that medically unexplained abdominal pain, chest pain, headache, and back pain accounted for a significant proportion of consultations in secondary health care facility [36]. Researchers have also reported that depressive symptoms were the major predictor for frequent GP visit [37] and persistent pain frequently co-exists with depressive illness [15]. Therefore, we considered patients' frequency of Doctor visits for pain relief should also be one of the factors to be determined in assessing persistent pain.

The SPAASMS score was designed to measure the direct and indirect markers of persistent pain, across the above seven domains. For simplicity and ease of administration each component except pain, was self-rated by patients from 0 to 3\* on a scale based on severity of symptoms. For pain measurement NRS was used on a scale of 0 to 10\*. SPAASMS was recorded and scored to a maximum of 25 at the initial assessment before starting the treatment, excluding side effects of medication. The subsequent score was a maximum of 28 including the side effects (Table 1).

### Procedure

A study was conducted to test if the SPAASMS scale would indicate treatment efficacy for persistent pain patients. DASS21 is an internationally validated tool to assess Depression, Anxiety and Stress symptoms whereas; PDI is a measure for Disability. Concurrent validity was assessed via the correlation between SPAASMS, DASS21 and PDI at the end of the study, over 9 months. The study was conducted according to ethical guidelines approved by Townsville Hospital Ethics committee.

### Patients

Patients' details are outlined in Table 2. In brief, 25 adult patients (mean age ( $\pm$  SD) 47.96 years ( $\pm$  13.27); 16 male and 9 females) being treated for persistent pain (mean duration ( $\pm$  SD) 13.52

years ( $\pm$  12.87)) were recruited at the Townsville Hospital Pain Management Clinic. Their progress on treatment was studied using the SPAASMS scale. For uniformity, opioid naïve patients having persistent pain for more than one year, for the greater part of the day or night and deemed appropriate for treatment with transdermal patches were recruited. After history taking, clinical examination, appropriate investigations, and evaluation, treatment was initiated by the senior clinician conducting this trial. The patients were titrated to optimal doses of medications and followed up every three months by for consultation by the same clinician. During treatment, the patients were asked to keep a record of any additional medicines or doctor visits that they made for break through pain and record any increase in daily activities. Patients who had unsatisfactory relief, developed unacceptable or severe adverse reaction/s during their treatment, were given alternative treatment and discontinued from follow-up. The rest were monitored monthly for 9 months. Monthly SPAASMS scoring was done by an interviewer telephonically using a predetermined, structured questionnaire. The senior clinician evaluated the patients' progress independently over nine months. Details of any aggravation or improvement of symptoms observed during the three monthly clinical assessments were recorded. Additional support was provided when deemed necessary. Patients completed the DASS21 and PDI questionnaires every three months for comparison with SPAASMS. The final scores of SPAASMS were recorded and the results were collated. A graph was charted following the patients' progress (Figures 2A and 2B).

### Statistical analysis

Overall assessment of reliability was conducted using the test-retest data. A scatter plot was used for graphical assessment of reliability. A concordance correlation coefficient (CCC) was calculated [38]. Cronbach's alpha was calculated to assess internal consistency of SPAASMS using SPSS (SPSS Inc., PASW version 18, Chicago, Illinois). All other statistical analyses were performed using GraphPad software (Version 5, GraphPad Software, Inc., and La Jolla, CA, USA). Clinical measures concerning pain intensity (NRS), DASS21, PDI, etc., were based on mean, SE and range. Two-way repeated measurement ANOVA was used for comparison between SPAASMS and NRS, DASS21, PDI or NPD, followed by Bonferroni post-tests. Pearson's correlation coefficient (r-square) was computed to examine the correlation

Table 1 SPAASMS score card.

Pain on Numerical Rating Scale	1	2	3	4	5	6	7	8	9	10
	No pain	→								Most pain
	0	1	2	3						
Activity and mobility	Very good	Good	Fair	Nil						
Additional pain medication	Nil	<4 times/month	<8 times/week	>8 times/week or daily						
Additional GP/ED visits	Nil	Once a month	Once a week	>5/month						
Sleep Quality	Very good	Good	Fair	Poor						
Side Effects	Nil	Mild	Moderate	Severe						
Mood	Very Good	Good	Fair	Low						
Total Score=25 (Initial)										
Total Score=28 (Monthly)										

**Table 2** Participant demographics.

Serial No.	Age	Gender	Diagnosis	Duration Illness (years)
1	68	M	CLBP	20
2	45	F	CRPS	3
3	58	F	Osteoarthritis, CLBP	20
4	46	F	Shoulder Pain	3
5	59	F	CLBP	12
6	34	M	CLBP, Psoriatic arthritis	12
7	41	F	CLBP	5
8	24	F	Fibromyalgia, Seronegative Arthritis	1
9	49	F	CLBP, Sciatica	20
10	40	M	Compression Fracture - spine	12
11	22	F	CLBP, Cervical pain	5
12	53	M	Osteoarthritis, carpal tunnel syndrome	34
13	43	M	CLBP, Cervical pain	3
14	56	F	CLBP, Cervical pain	20
15	39	M	CLBP	18
16	65	F	CLBP, knee pain	6
17	59	F	CLBP, Failed back syndrome	15
18	67	F	CLBP	6
19	43	M	CLBP	25
20	72	F	CLBP, Cervical pain	50
21	39	M	Coccygeal Fracture	1
22	32	F	CLBP, Cervical pain	1
23	38	F	CRPS-arm, CRPS - leg	4
24	62	M	CLBP	41
25	45	F	Cervical pain	1

CLBP: Chronic Low Back Pain; CRPS: Complex Regional Pain Syndrome

between SPAASMS, NRS, PDI or DASS21 scores. The relationship between SPAASMS and NRS or NPD was not checked as NRS was one component of the SPAASMS score card. P values of less than 0.05 were considered as statistically significant.

## Results

Twenty patients were interviewed by phone twice (readings 1 and 2), 2 to 4 days apart telephonically. Then a scatter plot was made and CCC was calculated as 0.94 with 95%-confidence interval=0.86, 0.97 (**Figure 1**) showing high reliability of SPAASMS scoring. Cronbach's alpha for readings 1 and 2 were 0.66 (P=0.001) and 0.67 (P<0.001), respectively.

We compared SPAASMS with the most vital factor in pain assessment, NRS (**Figure 2A**). SPAASMS scores showed a similar trend to NRS. Initial scores for SPAASMS and NRS were almost identical. However, with initiation of treatment SPAASMS scores were persistently lower, with scores at 6 months being statistically significant from NRS (P<0.05). No significant differences between SPAASMS and PDI scores were detected throughout the study (**Figure 2B**). R square for the correlation between SPAASMS and PDI was 0.84 (P=0.085). In contrast, DASS21 scores were always lower in comparison to SPAASMS scores (**Figure 2C**). The difference between the two scales was significant only at 0 month (P=0.001). R square for the correlation between SPAASMS and DASS21 was 0.89 (P=0.056).

In clinical practice, we consider pain intensity, depression and physical ability as the most important factors to assess persistent pain. Therefore, we compared SPAASMS with combined NRS, PDI and DASS21 scores (NPD) (**Figure 3**). There was no significant difference between NPD and SPAASMS (P>0.05; respectively).

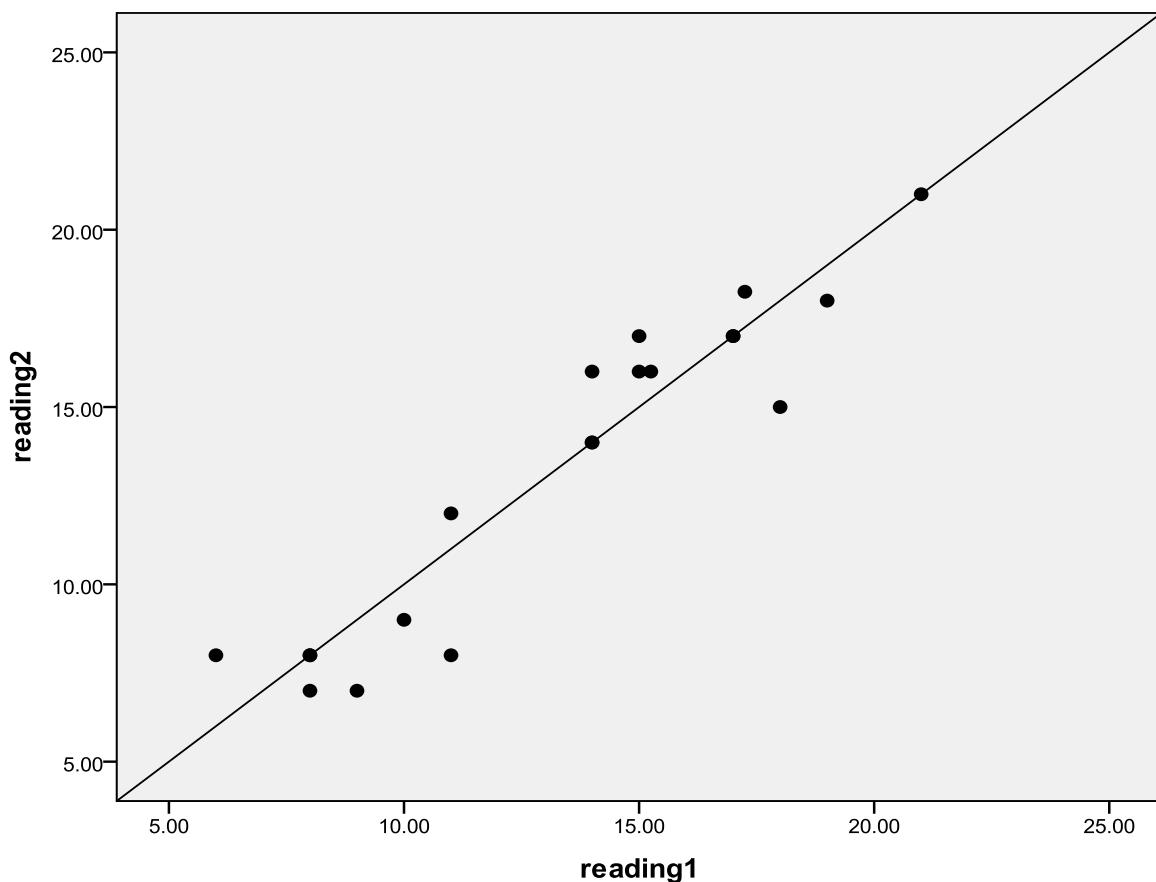
## Discussion

In the present study we have designed the SPAASMS scale to aid clinicians, assessing the progress of a patient on a treatment plan, in a practical and time efficient manner. SPAASMS has taken into consideration Turk et al.'s [39] recommendations that a new measure is required with comparable psychometric properties to existing measures but less onerous for patients to complete. The SPAASMS scale has also endeavoured to incorporate the IMMPACT recommendations to assess pain levels, physical activity, and mood as they would have the most impact on a patient and determine the severity of a patient's distress [5]. A review determined that quality of sleep, greater usage of medications and of health resources would be the other indirect important markers of the persistent pain condition. Self-report was used for the assessment of the patient's condition as advocated by Katz and Melzack [40]. NRS represented more than 35% of SPAASMS score as it measures the most vital component of persistent pain. The remaining six components of assessment were rated equally.

The Reliability Test for SPAASMS score was excellent (**Figure 1**). Lower NRS indicated patients' improvement in intensity of pain after treatment (**Figure 2A**). However, SPAASMS score was even lower than NRS throughout the study. We assume that SPAASMS reflected a greater response to treatment as it included other components of persistent pain assessment. In **Figure 2B**, PDI and SPAASMS scores both showed a decrease. However, SPAASMS score was lower than PDI that may suggest a better reflection of the treatment response. Again, physical disability as reflected by the multidimensional PDI may not be directly related to persistent pain intensity, however global physical activity levels as reflected by improved ADL are related to pain intensity [13]. Functional improvement in disability may not immediately follow an improvement to nociception because of other factors like de-conditioning, wasting of muscles or depression [41]. In addition, the decreased pain intensity could improve other factors like sleep or mood relatively rapidly. Therefore, PDI score may not improve as quickly as SPAASMS. This might have been reflected in the relatively higher PDI scoring. The SPAASMS scale indicated a general tendency in improvement which was maximal at the end of third month as compared to DASS21 (**Figure 2C**). However, DASS21 seemed to be a more sensitive indicator as it

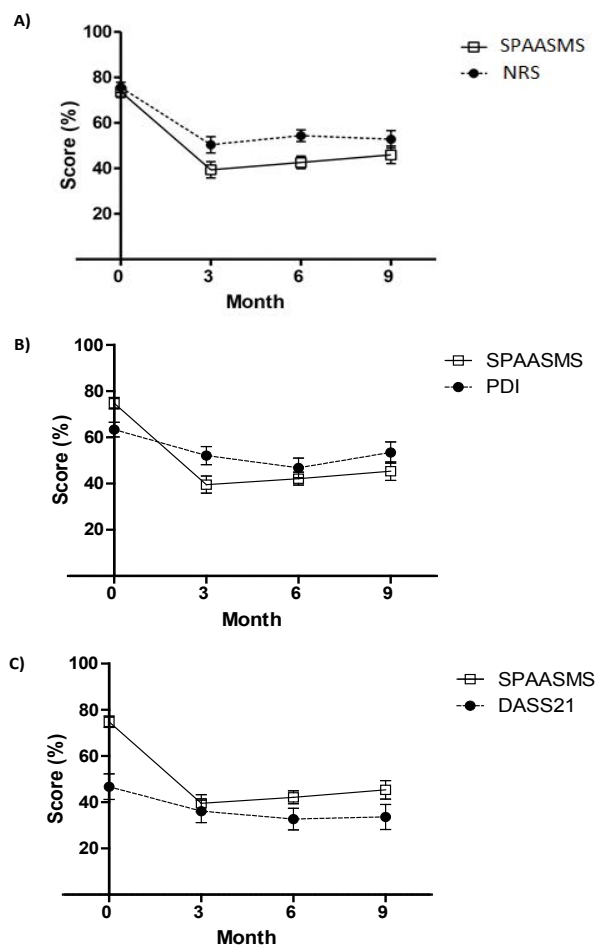
has components to measure different aspects of psychological distress that is, Depression including Anxiety and Stress. No significant difference between SPAASMS and NPD scores was found (**Figure 3**). During the initial 3 months, SPAASMS and NPD scores declined progressively signifying a successful response to treatment. Individual patient's scores remained high when they did not respond to treatment or, increased briefly with some precipitating event like unusual increased activity or further trauma. From the 6th month, the trend reversed in both scoring. At the same time, it was clinically observed that several patients developed tolerance or side effects to opioids leading to additional doctor visits and medications. All these changes were more marked in SPAASMS score than NPD. Thus, the initial assessment at the beginning of the study and the progress of the patients' condition after starting treatment was reflected more strongly on the SPAASMS score. This was likely due to additional indicators of persistent pain being included in this score.

Thus, the SPAASMS score card had the advantage of being a simple, time efficient bed-side clinical assessment tool, and easy for patients. Possibly the most important advantage of the tool was that it indicated specific symptoms of persistent pain, to



**Figure 1** Test-retest result for n=20 participants.  
Graphical display of results: Scatter plot with line of equality



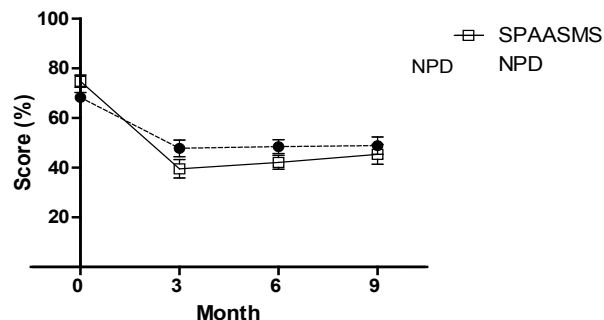


**Figure 2** SPAASMS Score was compared to VAS. **A)** SPAASMS score ( $\square$ ) was compared with NRS (A) (n=25), **B)** with PDI (B) (n=24) or, **C)** with DASS21 (C) (n=24) score ( $\bullet$ ). In the same subjects SPAASMS was scored out of 28, NRS was out of 10, PDI was scored out of 70 and DASS21 was out of 126. Then all scores were expressed in % for comparison purpose. All data were represented as mean score  $\pm$  SE for same sample size as mentioned above.

which the patient had not responded. Further assistance could then be provided, addressing the need according to sub-scale score indications. The scale could also be delivered by phone or by consultation. Furthermore, the patient could be shown objective progress regarding their treatment. However, in this study patients' satisfaction or rating of improvement/worsening

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**Figure 3** SPAASMS score ( $\square$ ) was compared with combined score NPD ( $\bullet$ ) (n=24) of NRS (N), PDI (P), DASS21 (D). To make resemblance with SPAASMS, NPD was summed out of 16 maximum as 10 for NRS, 3 each for PDI and DASS21 in %. All data were represented as mean score  $\pm$  SE.

of the pain condition and their dispositions data were not included [42].

The Reliability Test for SPAASMS score was excellent (**Figure 1**). Hence, we believe that there would be very little room for error. But it would have to be confirmed by larger studies. We do not know what influence, larger number of patients or those on placebo would have on the total scores and rating; future research could be directed to address this variation. This scoring was used only on adults with no intellectual disability, we do not know if this could be used on children or elderly with failing memory. The SPAASMS scoring could be tried on a larger number of patients to test the accuracy of the scoring.

## Conclusion

We thus propose the SPAASMS score card as a reliable clinical tool for a rapid measurement of persistent pain. Further refinement of structure and component of SPAASMS, tested on larger number of patients may be regarded in the future.

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