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Original Research Article

Psychometric Evaluation of the Electronic Pain Assessment Tool: An Innovative Instrument for Individuals with Moderate-to-Severe Dementia

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Keywords
Psychometric properties · Validity · Reliability · Electronic Pain Assessment Tool · Pain · Dementia · Automated facial recognition · Facial action units · Automated facial analysis · Observational pain scales · Application

Abstract
Background/Aims: Pain is common in aged care residents with dementia; yet it often goes undetected. A novel tool, the electronic Pain Assessment Tool (ePAT), was developed to address this challenging problem. We investigated the psychometric properties of the ePAT. ***Methods:*** In a 10-week prospective observational study, the ePAT was evaluated by comparison against the Abbey Pain Scale (APS). Pain assessments were blindly co-performed by the ePAT rater against the nursing staff of two residential aged care facilities. The residents were assessed twice by each rater: at rest and following movement. ***Results:*** The study involved 34 residents aged 85.5 ± 6.3 years, predominantly with severe dementia (Psychogeriatric Assessment Scale – Cognitive Impairment score = 19.7 ± 2.5). Four hundred paired assessments (n = 204 during rest; n = 196 following movement) were performed. Concurrent validity (r = 0.911) and all reliability measures (κ_w = 0.857; intraclass correlation coefficient = 0.904; α = 0.950) were excellent, while discriminant validity and predictive validity were good. ***Conclusion:*** The ePAT is a suitable tool for the assessment of pain in this vulnerable population.

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Introduction

A reduced self-reporting capacity in individuals with dementia is common due to disease-related progressive cognitive impairment [1]. In the absence of a valid and reliable self-report rating (i.e., gold standard), observational pain assessment tools are an appropriate replacement to evaluate pain for nonverbal populations such as those with advanced dementia [2, 3]. A study by Lukas et al. [4] concluded that the use of these tools improved pain recognition (by up to 25.4%) and rating (by up to 42.5%) in older adults with cognitive impairment.

Because ageing predisposes individuals to a number of comorbidities, pain is very common. In aged care facilities, up to 80% of residents experience pain at some stage during their stay [5, 6]. In this setting, dementia affects more than 50% of aged care residents in Australia and Germany [7, 8], and 69% in the UK [9, 10]. In the USA, over 61% of aged care residents have moderate-to-severe cognitive impairment [11]. Nursing staff have reported difficulty in detecting pain in these residents, and even with experience they remain poor at interpreting facial expressions indicative of pain [12, 13]. Moreover, there is evidence that even interdisciplinary evaluation of pain fails to assess pain correctly [14].

The importance of identifying pain in this population is critical to optimal pain management. Failure to do so may result in a denial of appropriate medication or therapeutic intervention, prescription of analgesics at inadequate dosages, or use of inappropriate medication (e.g., antipsychotics) [15–20]. These may lead to poor quality of life and premature death in these individuals [21–25]. Assessing pain requires a tool with sound psychometric properties and innovative characteristics so that timely access to appropriate pain management is assured.

Currently, there are more than 35 observational-behavioral pain assessment tools targeted at people with dementia [26]. Many of these tools have been criticized in a number of reviews for being inadequate due to the paucity of systematic evaluation of their psychometric properties [27–29]. Despite the abundance of tools for this population, they still suffer from lack of innovation [27]. Since the face is the richest source of behavioral expressions, a prudent approach is to integrate objective facial measures such as Ekman's Facial Action Coding System (FACS) into these tools [29, 30]. The FACS is an annotated catalogue of facial micro-expressions which describes each facial muscle action with a unique code called an action unit (AU) [31]. For instance, AU4 is brow lowering, while AU6 is a cheek raiser.

Current research supports this approach, which is why we have developed the electronic Pain Assessment Tool (ePAT), a novel instrument of great potential to transform the process of pain assessment in dementia [29, 32, 33]. The ePAT is a point-of-care tool that uses a hybrid model: automated facial recognition and analysis, digitization, and clinical observations [33]. The tool is built as a software application that is compatible with Android and iOS smart devices (see online suppl. File 1; see www.karger.com/doi/10.1159/000485377 for all online suppl. material,). Figure 1 illustrates the steps involved in pain assessment using the ePAT. Previous psychometric evaluation of the prototype version of the app (Android V3.0) demonstrated that ePAT had excellent concurrent validity and internal consistency when compared to the Abbey Pain Scale (APS), while possessing good discriminant validity and interrater reliability [33]. These data were evaluated using a mix of raters including nurses, health science students, and care workers [33].

In this study the Android V4.0 app was evaluated in the setting of aged care in comparison with APS assessments undertaken by nursing staff. The aim of the study was to evaluate the psychometric properties (concurrent validity, discriminant validity, predictive validity, internal consistency, and interrater reliability) of the ePAT (Android V4.0) in residents with moderate-to-severe dementia, and to compare these findings to those reported in our previous study.

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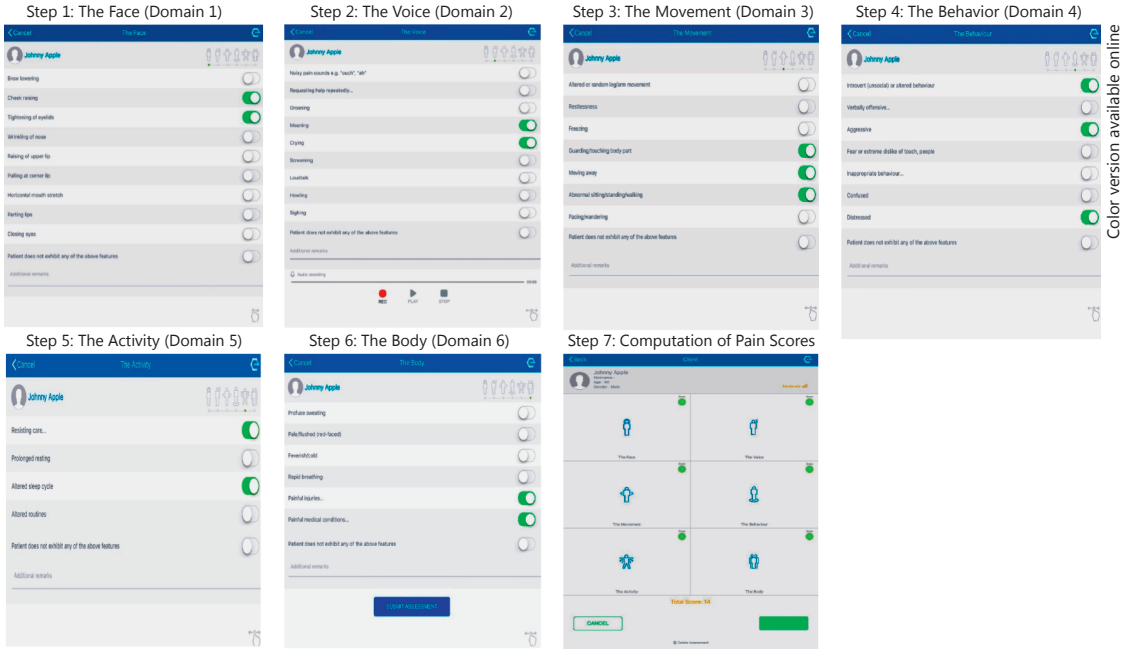

Fig. 1. Pain assessment process using the electronic Pain Assessment Tool (ePAT). Facial analysis is automated (step 1) in domain 1 (The Face), the app user then completes the checklists for the other 5 domains (steps 2–6), and the app then calculates a total pain score and pain severity score (step 7).

Methods

Study Design and Setting

This prospective observational study involved residents recruited from two accredited residential aged care facilities (RACFs), located in the Perth metropolitan area, Western Australia. Table 1 provides a summary of the characteristics of each RACF.

Procedure

The study was approved by the Human Research Ethics Committee of Curtin University, Western Australia (HREC: HR10/2014) and by Mercy Health Care (R15/50AC). This study also had Clinical Trial Notification (CTN) approval (CT-2016-CTN-04886-1 v1) from Therapeutic Goods Administration (TGA). Written invitations and information sheets were sent to authorized representatives to provide consent on behalf of residents as they were deemed incompetent of providing their own informed written consent. All assessments were completed in accord with the Declaration of Helsinki, as well as policy statements of the Alzheimer's Association and the World Health Organization on assistive technologies for people with dementia. All data were de-identified and protected to maintain confidentiality.

In this study, the ePAT (Android V4.0, Samsung Note 3-N9005) was evaluated in comparison with the APS in two RACFs. The study lasted for a period of 10 weeks, which was commenced in January and completed in April 2017. Weekly pain ratings of residents were made concurrently by two independent raters, one using the ePAT and the other using the APS. The ePAT rater was the primary investigator (M.A.), who is experienced with the use of the tool, while the APS was administered by a member of the nursing staff of the two RACFs.

The raters were required to complete a questionnaire to ascertain their familiarity (i.e., prior experience or exposure) with the APS. Before commencing the study, a test case was run and discussed between the ePAT rater and the APS raters to cement understanding of the protocol. Paired ratings were undertaken indoors during standard care in the afternoon hours of 1–4 p.m. The automated facial assessments with the ePAT were done under ambient lighting conditions and within 1 m of the resident's face. Each rater was blinded to the other rater's assessment/scoring and also to the drug and non-drug pain therapies received by the residents under assessment during that day. At each encounter, the residents were assessed twice by

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Table 1. Characteristics of the RACFs involved in the study

	RACF 1	RACF 2
Location of facility	Metropolitan	Metropolitan
State	Western Australia	Western Australia
Type of facility	Residential	Residential
Ownership of facility	Non-for-profit	Non-for-profit
Bed capacity	67	83
Clinical staff	4 registered nurses 1 enrolled nurse	1 clinical nurse 3 registered nurses 1 enrolled nurse
Re-accreditation due date	July 2018	July 2018

RACF, residential aged care facility.

each rater: at rest to replicate comfort conditions, followed by movement to instigate nociceptive experiences. The residents were clinically stable during these assessments, which were carried out under similar testing conditions (e.g., lighting). A similar methodology was used by the authors in a previous study [33].

Pain Assessments

The APS (see online suppl. File 2) was used as a point of reference in this study because it is widely used in Australia for patients with dementia who cannot verbalize, has been translated into various languages, and has sound psychometric properties [3, 27, 34–36]. The APS consists of 6 observational domains: vocalization, facial expressions, change in body language, behavioral change, physiological change, and physical change [37]. Scoring of the tool involves ordinal ratings that range from 0 to 3 to indicate the intensity in each domain, where 0 = not present, 1 = mild, 2 = moderate, and 3 = severe. Total pain intensity is calculated after adding all domain scores, which is then categorized based on the following cutoff points: 0–2 = no pain, 3–7 = mild pain, 8–13 = moderate pain, and ≥14 = severe pain [37].

The ePAT is the measure of interest in this study. Its psychometric data were investigated in comparison with those from the APS. The ePAT is a point-of-care app that utilizes automated facial recognition and analysis to detect pain-related facial AUs, which are then used in combination with other clinical indicators to calculate a pain intensity score [33]. The tool has a total of 42 descriptors, which were selected based on their association with pain according to the literature. Each descriptor is scored on a binary scale of yes = 1 and no = 0. These descriptors are contained within 6 domains: The Face, The Voice, The Movement, The Behavior, The Activity, and The Body (Fig. 1). A summation of the domain scores results in a total numerical score, which conforms to the following pain categories: no pain (0–6), mild pain (7–11), moderate pain (12–15), and severe pain (≥16) [33]. A full description of the tool's contents, scoring, and conceptual foundation has been published elsewhere [33].

Cognitive Assessments

Cognition of the residents was measured using the Psychogeriatric Assessment Scale – Cognitive Impairment Scale (PAS-Cog). The PAS-Cog is an informant-administered cognition scale which has been validated for various populations [38–40]. The scale is also endorsed by the Australian Government as a tool for cognitive assessment for the purposes of aged care funding [41]. The cognitive scores of the residents were extracted from their electronic profile data. Scores indicative of the stage of severity of cognitive impairment are as follows: 0–3 = minimal, 4–9 = mild, 10–15 = moderate, and 16–21 = severe [38].

Residents

Residents were selected for participation if they were older than 65 years; had been living in the facility for at least 3 months; had been diagnosed with dementia by a geriatrician; had been classified as having moderate-to-severe dementia based on a PAS-Cog score of >10; and had a medical history or presenting complaint(s) that involved painful conditions.

Residents were excluded from the study if they were deemed medically unfit to participate (as determined by the treating physician); had a facial deformity; or were unable to display facial expressions.

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APS Raters

APS raters were staff employed by the facility who were recruited into the study if they had been working in the facility for at least 3 months to ensure familiarity with the residents; were familiar with or cognizant of the use of the APS; were able to converse in English; were trained or registered nurses; were involved in providing direct care to residents; and were willing to participate (conferred by providing a written consent).

Staff were excluded from participation if their duties did not include pain assessment and management or if they were likely to be absent during the course of the study.

Statistical Analyses

Descriptive statistics were used in this study to provide a summary of variables for the residents, raters, and assessments. Psychometric measures of validity and reliability were calculated using appropriate statistical tests.

Concurrent validity was evaluated using Pearson's (r) correlation coefficient between the two instruments (ePAT vs. APS) for each of the following instances: at rest, with movement, and overall (i.e., at rest or with movement). The strength of correlation is denoted by the following increment values: none to weak, 0.00–0.25; weak to moderate, 0.26–0.50; moderate to strong, 0.51–0.75; and strong to extremely strong, 0.76–0.99 [42].

Discriminant validity was examined through conducting a comparative analysis between ePAT scores and APS scores for all residents under conditions of rest as opposed to movement. Regression analysis was selected to show the difference in pain scores using a mixed model. The dependent variable was the difference in pain scores, while the independent variable was timing (rest or with movement). The p value associated with the timing of an activity – e.g., sitting (representative of rest) versus exercise (representative of movement) – demonstrated whether the correlation of a difference in scores was activity dependent.

Predictive validity was assessed using t statistics of the mean pain scores. Other central tendency measures (median and mode) for pain scores at rest compared to those following movement activities were also reported.

Reliability measures explored in this study included internal consistency, interrater reliability, and the intraclass correlation coefficient (ICC). Internal consistency determined whether the two instruments were measuring the same construct, i.e., pain. Cronbach's α was used to assess the internal consistency, with values of ≥0.7 considered illustrative of good agreement between the two tools [43]. Interrater reliability was assessed by measuring agreement using Cohen's κ on the categorical pain scores: no pain, mild pain, moderate pain, and severe pain. Weighted κ (κ_w) was used to determine the overall agreement on ordinal scores. Interpretation of the κ values ranged from poor (0.0) to perfect (1.0), with moderate agreement in the range of 0.41–0.60 [44]. ICC values were calculated for continuous pain scores. Interpretation of the ICC values followed the same guidelines as the correlation coefficients above [42].

Statistical significance was expressed as p values (<0.05) or 95% confidence intervals (CI). All analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 22 (SPSS, Inc., Apache Software Foundation, Chicago, IL, USA).

Results

Resident Sample

Thirty-seven residents with differing dementias, pain conditions, and genders were consented (through their proxies) to participate in the study. Three residents dropped out before the study commenced; of these, 1 resident died and the other 2 were discharged to other facilities/home, leaving a final sample of 34 residents. All the residents were over 68 years of age, with the majority being female (58.8%). A total of 27 residents (79.4%) were classified as having severe dementia according to PAS-Cog scores (mean: 19.7 ± 2.5; median: 21; range: 11–21). Table 2 provides the clinical and demographic data on the residents.

APS Raters

The APS raters were nursing staff employed in one or the other of the two facilities with a mean age of 29.4 ± 6.8 years. Four of the 5 raters were female. The raters were nurses with

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Table 2. Clinical and demographic characteristics of the resident sample at baseline (*n* = 34) from the two aged care facilities

Mean age (SD), years	85.5 (6.3)
Median age (range), years	83.8 (68–93.2)
Gender, *n* (%)	
Female	20 (58.8)
Male	14 (41.2)
Ethnicity, *n* (%)	
Caucasian	33 (97.1)
Other	1 (2.9)
Country of birth, *n* (%)	
Australia	24 (70.8)
UK	5 (14.7)
Italy	1 (2.9)
The Netherlands	1 (2.9)
Poland	1 (2.9)
South Africa	1 (2.9)
USA	1 (2.9)
Primary language, *n* (%)	
English	33 (97.1)
Italian	1 (2.9)
Secondary language, *n* (%)	
Afrikaans	1 (2.9)
Dutch	1 (2.9)
Polish	1 (2.9)
Ukrainian	1 (2.9)
None	30 (88.4)
Mobility, *n* (%)	
Fully ambulant	1 (2.9)
Ambulant with assistance	19 (55.9)
Non-ambulant	14 (41.2)
Mean dementia severity (PAS-Cog) score (SD)	19.7 (2.5)
Median PAS-Cog score (range)	21 (11–21)
Diagnosis of dementia, *n* (%)	
Alzheimer disease	12 (35.3)
Unspecified dementia	15 (44.1)
Frontotemporal dementia	1 (2.9)
Lewy body dementia	2 (5.9)
Parkinson dementia	2 (5.9)
Vascular dementia	2 (5.9)

PAS-Cog, Psychogeriatric Assessment Scale – Cognitive Impairment Scale

varying roles (1 clinical nurse and 4 registered nurses) and years of experience (2.8 ± 0.8). All 4 registered nurses were employed in the same facility (RACF 1), while the clinical nurse was working in the other facility (RACF 2). All nurses had received pain education in the past and were familiar with the use of the APS. Table 3 describes the demographic characteristics of the APS raters.

Clinical Pain Assessments

The residents had a total of 400 paired pain assessments conducted over the period of the study. Of those, 204 assessments were performed during rest, whereas 196 assessments were done following movement. All assessments were undertaken during activities of daily living such as sitting, walking, and repositioning.

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Table 3. Demographic characteristics of the APS raters (n = 5)

	n (%)	Mean (SD)	Median (range)
Age, years		29.4 (6.8)	28 (24–41)
Gender (female)	4 (80)		
Ethnicity			
Caucasian	1 (20)		
Asian	4 (80)		
Primary language (English)	5 (100)		
Employment status, h		35.4 (3.2)	36 (30–38)
Part time (<38 h)	3 (60)		
Full time (≥38 h)	2 (40)		
Years of experience			
Nursing		2.8 (0.8)	3 (2–4)
Aged care		2.4 (0.5)	2 (2–3)
Cognitive impairment/dementia care		2.4 (0.5)	2 (2–3)
Employment in facility		1.6 (0.9)	1 (1–3)
Role in facility			
Clinical nurse	1 (20)		
Registered nurse	4 (80)		
Past pain education			
Yes	5 (100)		
No	0 (0)		
Last received pain education			
<3 months	2 (40)		
<12 months	1 (20)		
>12 months	2 (40)		
Familiarity with the APS			
Yes	5 (100)		
No	0 (0)		

APS, Abbey Pain Scale.

Validity

Concurrent Validity

All correlation coefficients had high positive values, indicating excellent concurrent validity of the ePAT when compared with the APS (Table 4). The association between ePAT and APS total scores is also shown in Figure 2. The graph demonstrates the strong positive correlation between the two instruments.

Discriminant Validity

The statistical difference (expressed by the p value) was computed to demonstrate whether the timing of activity (rest vs. movement) had any effect on the correlation between the ePAT and the APS. It was found that the correlation between the two instruments was not situation dependent (p = 0.243).

Predictive Validity

Both tools showed increased pain scores as a consequence of movement. On the ePAT, the pain scores were significantly higher (p < 0.0001) with movement (mean: 11.44 ± 3.54; median: 11; mode: 13) than at rest (mean: 8.33 ± 3.34; median: 9; mode: 10). Similarly, the APS had significantly higher pain scores (p < 0.0001) following movement (mean: 6.96 ± 3.85; median: 7; mode: 8) than at rest (mean: 4.34 ± 3.14; median: 4; mode: 1).

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Table 4. Correlation values between the ePAT and the APS under various conditions

	Number of paired pain assessments, *n* (%)	Pearson's correlation, *r*
Rest	204 (51)	0.896
Movement	196 (49)	0.904
Overall	400 (100)	0.911

ePAT, electronic Pain Assessment Tool; APS, Abbey Pain Scale. All correlation values are significant at the 0.01 level (2-tailed).

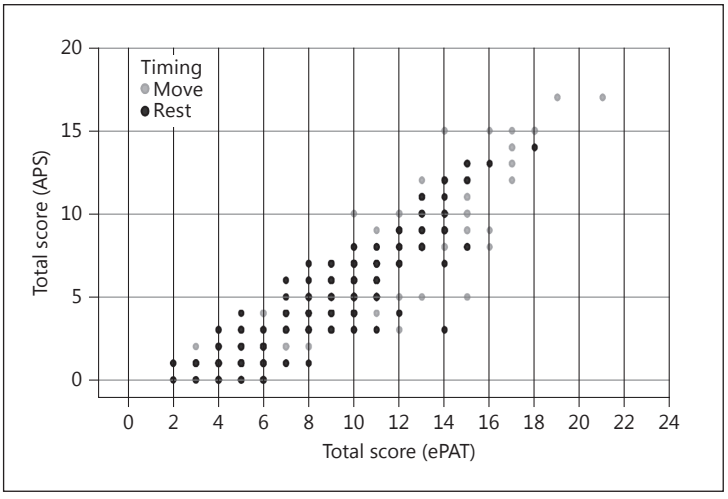

Fig. 2. Association between electronic Pain Assessment Tool (ePAT) and Abbey Pain Scale (APS) total scores. Dark-colored dots: rest; light-colored dots: movement. One dot may represent more than one rating score.

Reliability

Interrater Reliability (Interrater Agreement)

Overall agreement on the categorical pain scores was excellent (κ_w = 0.857; 95% CI: 0.819–0.895). Greater agreement among raters was found during rest (κ = 0.840; p = 0.000) compared to movement (κ = 0.772; p = 0.000).

Intraclass Correlation Coefficient

As a single measure, the ICC value of the ePAT was excellent (0.904; 95% CI: 0.885–0.921). During rest, the ICC value was 0.902 (95% CI: 0.872–0.925), while following movement the ICC was 0.879 (95% CI: 0.843–0.908). Both of these values fall within the "excellent" range.

Internal Consistency

Overall internal consistency (Cronbach's α) of the ePAT when compared to the APS was 0.950, which is classified as excellent. The α values were greater for movement (α = 0.797) than for the rest condition (α = 0.766).

Discussion

The findings of this validation study provide further evidence of the psychometric properties of the ePAT which make it a suitable instrument for the assessment of pain in people with moderate-to-severe dementia who cannot verbalize pain. The significance of the current research was to demonstrate the robustness of a previous study and to ensure the repeat-

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ability of the initial psychometric findings. These are essential criteria for adopting a tool into clinical practice.

Unsurprisingly, there was a strong positive correlation of the ePAT with standard assessment of pain (i.e., by the APS) in the RACFs involved in the study. This is because both scales have a similar construct and conceptual foundation and both measure similar aspects of pain-related behaviors. Based on the current findings, it seems that the psychometric characteristics of the ePAT have improved, as they have slightly higher correlation values when compared to previous findings [33]. This is perhaps due to variation in the APS rater samples between the two studies. In the current study, all APS raters were nurses (with a greater experience in pain assessment), whereas they were a mix of nurses, health science students, and care workers in the previous study [33].

The "state-of-the-art" systematic review by Herr et al. [45] set correlation values of 0.4–0.6 as an adequate range for new pain assessment scales for nonverbal populations. The ePAT had shown excellent concurrent validity under various testing conditions (rest: r = 0.896; movement: r = 0.904). These results are much higher than the recommended range suggested by Herr et al. [45] and in line with our previous findings [33]. Other pain assessment tools with good-to-excellent concurrent validity are the Rotterdam Elderly Pain Observation Scale (REPOS) (0.61–0.75) when compared to the Pain Assessment in Advanced Dementia (PAINAD) [46], and the Rating Pain in Dementia (RaPID) scale (0.8–0.86) when compared to the McGill Pain Questionnaire [47]. In our study, the strength of correlation between the ePAT and the APS was slightly better during movement than at rest. A number of studies on observational tools (the Checklist of Nonverbal Pain Indicators [CNPI], FACS, Mobilization-Observation-Behaviors-Intensity Dementia Pain Scale [MOBID], and Pain Behavior Measurement [PBM]) have shown parallel findings in this regard [48–50].

All pain scores recorded by the ePAT following movement were higher than those under rest conditions. Similarly, the APS had greater scores observed for each resident under the same conditions. This is consistent with our previous work [33], which supports that the ePAT has discriminative properties, i.e., discriminant validity. Out of 28 tools, Lichtner et al. [27] listed only 8 (the Certified Nurse Assistant Pain Tool [CPAT], CNPI, Discomfort Scale – Dementia of the Alzheimer's Type [DS-DAT], Pain Assessment Checklist for Seniors with Limited Ability to Communicate [PACSLAC], MOBID, APS, Assessment Discomfort in Dementia [ADD] Protocol, and Behavior checklist) which showed evidence of discriminant validity.

There were also significant differences in mean ePAT and APS scores at rest (treated as preintervention) and following movement (treated as postintervention), providing support for the predictive validity. Abbey et al. [37] reported the predictive validity of the APS as a significant change in mean pain scores before and after interventions.

The properties of reliability were excellent, as demonstrated by the overall values of α, κ, and ICC. Except for internal consistency (α values), all reliability measurement values were higher for rest than for movement. This is probably because when a resident is at rest, he/she has fewer behaviors recorded by raters; hence the raters have a lower chance of disagreement. Internal consistency is a reliability measure of the correlation of the subscales of an instrument (i.e., the ePAT) to assess the construct of interest (i.e., pain behaviors). Raters may have various interpretations as to whether certain behaviors are related to pain or part of neuropsychiatric symptoms of dementia. There is an overlap between pain and these symptoms, and there is evidence to suggest that pain is linked to depressive symptoms in residents with dementia [51, 52]. Other observational tools with excellent interrater reliability κ values include the Pain Assessment in Noncommunicative Elderly Persons (PAINE) (0.711–0.999), RaPID (0.97), DS-DAT (0.61–0.98), and PAINAD (0.72–0.97) [27].

Strengths of this study include the use of blinded rating and blinded knowledge of the pain management given to reduce learning bias. Prior to the first (paired) rating, a test case

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was used to ensure the steps of the study protocol were followed correctly. The vast majority of assessments were matched under various conditions indicative of rest and movement. The study was conducted in a real-world clinical environment and without interrupting the work flow. The statistical analyses of the psychometric data were comprehensive. Important implications of using this app include (1) automated facial analysis, which has the potential to improve the process of pain assessment through objective measures, and (2) digital documentation, which provides a pragmatic approach for use in clinical settings.

This study has similar limitations to those documented in our previous study, such as sampling bias and reporting bias [33]. Further, cognitive evaluations were based on informant ratings, which have their own limitations regarding subjectivity. These evaluations were conducted at various time points prior to commencement of the study. In our sample, the majority (79.4%) of the residents had severe cognitive impairment, as indicated by their PAS-Cog scores. Given the fact that the course of dementia has a progressive nature, it is likely that the cognitive status of all residents (including the remaining 20.6%) may have worsened since it was last assessed. In addition, the clinical pain assessments were limited to certain time periods, i.e., the afternoon, and findings may be different if they are performed during other times.

In conclusion, this study adds further to the body of evidence regarding the psychometric merits of the ePAT as a valid and reliable tool for the assessment of pain in residents with moderate-to-severe dementia. Further research on technology and refinements in using the presence and intensity of facial expressions as a means of fully automating pain assessment are warranted.

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Disclosure Statement

All authors are shareholders in EPAT Technologies Ltd, which is marketing the ePAT instrument (also known as PainChek™). They also have a patent application titled "A pain assessment method and system" (PCT/AU2015/000501), which is currently under national phase examination since February 2, 2017. M.A. is a Research Scientist for EPAT Technologies Ltd while serving as a Research Fellow and PhD Candidate with the School of Pharmacy, Curtin University. K.H. is employed as a consultant by EPAT Technologies Ltd while serving as an Assistant Professor at University of Pristina, and an Adjunct Senior Lecturer at the School of Pharmacy, Curtin University. J.D.H. is employed as Chief Scientific Officer of EPAT Technologies Ltd while serving as a Professor at the School of Pharmacy, Curtin University.

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Author Contributions

All authors conceived the idea and designed the study. M.A. conducted the literature search and drafted the manuscript. All authors reviewed the manuscript. M.A. recruited the patients and collected the data. M.A. and J.D.H. conducted some statistical analyses and interpreted all results. All authors contributed to and approved the final version of the manuscript.

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