SUPPLEMENTARY MATERIAL

*Table S1. Description of selected studies.*

| Author | Year of publication | Data collection | Country | Intervention (n) | Controls | Sex | | | | Average Age | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Male | | Female | | | |
| | | | | | | n | (%) | n | (%) | Mean | SD |
| de Vries, et al.[69] | 2023 | 2014-2018 | Netherlands | 60 | | 32 | 57% | 28 | 43% | 79.3 | 8 |
| Haghi M, et al.[70] | 2020 | 2017 | Iran | 138 | | 64 | 46,37% | 74 | 53,62% | 74,5 | 8,9 |
| Morrison, R. A, et. al. [71] | 2020 | 2010-16 | USA | 1,036,806 | | 411612 | 39,80% | 625194 | 60,20% | N/A | N/A |
| Fox MA et al. [1] | 2019 | 2014-15 | USA | 48 | | 13 | 27% | 35 | 73% | 29,2 | 13 |
| Muñoz-Narbona, L, et. al.[72] | 2019 | 2017 | Spain | 325 | | 189 | 58,20% | 136 | 41,80% | 71,1 | 13,4 |
| Soares CD. et. al., [57] | 2018 | | USA | 36 | | 19 | 52,70% | 17 | 47,30% | 61 | N/A |
| Atee M et. al. [59] | 2018 | 2016 | Australia | 10 | | 5 | 50% | 5 | 50% | 74,4 | 5,9 |
| Lautenbacher S et. al. [39] | 2018 | | Germany | 42 | | 22 | 52,40% | 20 | 47,60% | 76,7 | 7,3 |
| López-López C et. al. [40] | 2018 | 2014-15 | Spain | 124 | | 96 | 77,40% | 28 | 22,60% | 45,9 | 16,4 |
| Riquelme I et. al.[73] | 2018 | | Spain | 96 | | 63 | 65,60% | 33 | 34,40% | 18,9 | 12,7 |
| Pickering G et. al.[74] | 2018 | | Spain, Portugal, Italy, Australia, Turkey | 176 | | 60 | 34,10% | 116 | 65,90% | 83,4 | 7,9 |
| Moon Y et. al. [75] | 2017 | | S.Korea | 98 | | 38 | 31,8 | 60 | 68,20% | 77,3 | 6,3 |
| Atee M. et. al. [51] | 2017 | 2015-16 | Australia | 40 | | 11 | 30% | 29 | 70% | 79,7 | 9,1 |
| Benromano T. et. al. [24] | 2017 | | Israel | 16 | 25 | 8 | 50% | 8 | 50% | 36,4 | 7,3 |
| Benromano T et. al.[25] | 2017 | | Israel | 13 | 20 | 6 | 46,20% | 7 | 54,80% | 34,5 | 4,9 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Al Darwish ZQ, et. al.[26] | 2016 | 2014 | Saudi Arabia | 47 | | 27 | 57% | 20 | 43% | 55,5 | 20,2 |
| Gregersen, M et al. [76] | 2016 | | Denmark | 50 | | 20 | 40% | 30 | 60% | 85,4 | 7,9 |
| Latorre-Marco, I., et. al [55] | 2016 | | Spain | 190 | | 135 | 71% | 55 | 29% | 61 | N/A |
| Thé, K.B, et. al [49] | 2016 | | Brazil | 50 | | 11 | 22% | 39 | 78% | 87,8 | 6,5 |
| Poulsen, I., et. al., [50] | 2016 | | Denmark | 26 | | 16 | 61,50% | 10 | 48,50% | 56,5 | N/A |
| Rahu MA, et. al. [52] | 2015 | | USA | 150 | | 78 | 52% | 72 | 48% | 53 | 15,5 |
| Ford B, et. al. [77] | 2015 | | USA | 78 | | N/A | N/A | N/A | N/A | N/A | N/A |
| Roulin MJ, et. al. [53] | 2015 | | Switzerland | 116 | | 66 | 56,90% | 50 | 43,10% | 56,2 | 1,6 |
| Arbour, C., et. al. [48] | 2015 | | Canada | 25 | | 17 | 68% | 8 | 32% | 56,5 | N/A |
| Apinis C, et. al. [78] | 2014 | | Canada | 59 | | 30 | 50,84% | 29 | 49,16% | 82 | 11,7 |
| Chan S, et. al. [79] | 2014 | | Canada | 124 | | 88 | 71% | 36 | 29% | 83,94 | 7,95 |
| Shinde SK,et. al., [54] | 2014 | | USA | 44 | | 23 | 52% | 21 | 48% | 46 | 9,87 |
| Neville, C, et. al. [80] | 2014 | | Australia | 126 | | 22 | 17% | 104 | 83% | 85,2 | 6,6 |
| Chanques, G, et. al. [56] | 2014 | 2012 | USA | 30 | | 11 | 36,70% | 19 | 63,30% | 67 | N/A |
| Le Q, et. al. [81] | 2013 | | Canada | 9 | | 9 | 100% | 0 | 0% | 25.5 | 58 |
| Linde SM, et. al. [42] | 2013 | | USA | 30 | | 23 | 77% | 7 | 23% | 70,43 | 9,63 |
| Rahu MA, et. al. [41] | 2013 | | USA | 50 | | 26 | 52% | 24 | 48% | 52,5 | 17,2 |
| Takai Y, et. al [82] | 2013 | 2012 | Japan | 117 | | 30 | 25,60% | 87 | 74,40% | 82,3 | 9,5 |
| Pickering, et. al [83] | 2013 | | France | 33 | | 19 | 57,57% | 14 | 42,42% | 38 | 3 |
| Chatelle C,et. al [44] | 2012 | | Belgium | 64 | | 40 | 62,50% | 24 | 37,50% | N/A | N/A |
| Meir L, et. al [45] | 2012 | | Isrrael | 228 | | 137 | 60% | 91 | 40% | 38,7 | N/A |
| Jeitziner MM, et. al. [46] | 2012 | | Switzerland | 21 | | 9 | 42,80% | 12 | 57,20% | 70 | N/A |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Paulson-Conger M, et. al. [84] | 2011 | | USA | 100 | | 60 | 60% | 40 | 40% | 55,52 | 17,5 |
| Vázquez M, et. al., [47] | 2011 | 2007-8 | Spain | 96 | | 55 | 57,30% | 41 | 42,70% | 62,11 | 14,38 |
| Sheu E, et. al. [85] | 2011 | | Canada | 60 | | 11 | 18,30% | 49 | 81,40% | 84 | N/A |
| Gélinas, C., et. al. [86] | 2011 | | Canada | 90 | | 57 | 63,30% | 33 | 36,70% | 59,8 | 18,94 |

*N/A: not available; SD: standard deviation*

*Table S2. Population, pain observational scales and painful procedure of the included studies.*

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| Population | Author | Year of publication | Scale | Painful procedure | n | Control |
|---|---|---|---|---|---|---|
| Elderly with dementia | Haghi M, et al. | 2020 | *PACSALC-II* | Routine activities | 138 | |
| | Morrison, R. A, et. al. | 2020 | *MDS 3.0* | Routine assessment | 1,036,806 | |
| | Lautenbacher S et. al. | 2018 | *PAIC-FACE-SCALE* | Painful pressure | 42 | |
| | Moon Y et. al. | 2017 | *FLACC* | Routine assessment | 98 | |
| | Thé, K.B, et. al | 2016 | *PACSALC-II* | Exposure to painful circumstances | 50 | |
| | Ford B, et. al. | 2015 | *NOPPAIN* | Routine activities | 78 | |
| | Chan S, et. al. | 2014 | *PACSLAC*<br>*PACSLAC-II*<br>*Doloplus-2* | Injection, mobilization | 124 | |
| | Neville, C, et. al. | 2014 | *APS*<br>*CNPI* | Routine assessment | 126 | |
| | Takai Y, et. al | 2013 | *PACSLAC* | Mobilization, Walking | 117 | |
| | Sheu E, et. al. | 2011 | *PACSLAC*<br>*NOPPAIN*<br>*PAINAD*<br>*Doloplus-2*<br>*Mahoney Pain Scale* | Routine activities, walking | 60 | |
| | Apinis C, et. al. | 2014 | *APS*<br>*PACSLAC*<br>*PAINAD* | Mobilization | 59 | |
| Elderly with Communication Disorders | Apinis C, et. al. | 2014 | *PACSLAC*<br>*PAINAD* | Mobilization | 59 | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | Pickering G. et. al. | 2018 | *Algoplus* | Routine activities | 176 | |
| | Gregersen, M et al. | 2016 | *APS* | Movement | 50 | |
| Mechanically ventilated patients | López-López C et. al. | 2018 | *ESCID*<br>*BPS* | Suctioning/mobilization | 124 | |
| | Al Darwish ZQ, et. al. | 2016 | *CPOT*<br>*NVPS* | Suctioning/ mobilization | 47 | |
| | Latorre-Marco, I., et. al | 2016 | *ESCID*<br>*BPS* | Suctioning/ mobilization | 190 | |
| | Rahu MA, et. al. | 2015 | *FLACC*<br>*BPS*<br>*ANVPS*<br>*COMFORT*<br>*PABS* | Suctioning/ mobilization | 150 | |
| | Linde SM, et. al. | 2013 | *CPOT*<br>*FLACC* | Mobilization | 30 | |
| | Rahu MA, et. al. | 2013 | *BPS*<br>*ANVPS*<br>*COMFORT*<br>*PABS* | Suctioning | 50 | |
| | Jeitziner MM, et. al. | 2012 | *FACS*<br>*RASS*<br>*GCS* | Suctioning | 21 | |
| | Vázquez M, et. al | 2011 | *CPOT* | Suctioning | 96 | |
| Cerebral palsy | Fox MA et al. | 2019 | *FLACC* | Routine assessment | 48 | |
| | Riquelme I et. al. | 2018 | *NCCPC* | N/A | 96 | |
| | Benromano T et. al. b) | 2017 | *Pyramid Pain scale*<br>*FACS* | Painful pressure | 13 | 20 |
| Brain injury | Poulsen, I., et. al | 2016 | *"PAS Preliminar"* | Mobilization | 26 | |
| | Roulin MAcute pain, et. al. | 2015 | *BPS*<br>*CPOT* | Mobilization | 116 | |
| | Le Q, et. al. | 2013 | *PBAT*<br>*CPOT* | Mobilization | 9 | |
| | Muñoz-Narbona, L, et. al. | 2019 | *PAINAD* | Movement | 325 | |
| Intellectual disability | Shinde SK,et. al | 2014 | *PADS*<br>*FACS* | Prick with neuropen | 44 | |
| | Meir L, et. al | 2012 | *NCAPC* | Injection | 228 | |

| | | | | | |
|---|---|---|---|---|---|
| Critical patients | Chanques, G, et. al. | 2014 | *BPS*<br>*CPOT*<br>*NVPS* | Routine activities, Suctioning/mobilization | 30 |
| | Paulson-Conger M, et. al. | 2011 | *PAINAD*<br>*CPOT* | Routine assessment | 100 |
| | Gélinas, C., et. al. | 2011 | *CPOT* | Routine assessment | 90 |
| Acute pain | Pickering, et. al | 2013 | *Algoplus* | Routine assessment | 33 |
| Vegetative/minimum consciousness | Chatelle C,et. al | 2012 | *NCS* | Painful pressure | 64 |
| Cancer patients | Muñoz-Narbona, L, et. al. | 2019 | *PAINAD* | Movement | 325 |
| Post stroke aphasia | Soares CD. et. al | 2018 | *PACSALC-II* | Painful pressure | 36 |

*Abbreviations:*
*PACSALC: Pain Assessment Checklist for Seniors with Limited Ability to Communicate*
*PACSALC-II: Pain Assessment Checklist for Seniors with Limited Ability to Communicate Version II*
*FLACC: Face, Legs, Activity, Cry, Consolability*
*ESCID: Escala de Conductas Indicadoras de Dolor*
*NCCPC: Non-Communicating Children Pain Checklist*
*BPS: Behavioral Pain Scale*
*NRS: Numeric Rating Scale*
*ANVPS: Adult Non-Verbal Pain Scale*
*PABS: Pain Behavior Scale*
*NOPPAIN: Non-Communicative Patient's Pain Assessment Instrument*
*PBAT: Pain Behavior Assessment Tool*
*PADS: Pain and Distress Scale*
*FACS: Facial Action Coding System*
*NCS: The Nociception Coma Scale*
*PAINAD: Pain Assessment in Advanced Dementia*
*APS: The Abbey Pain Scale*
*MDS 3.0: Minimum Data Set 3.0*
*CNPI: Checklist of Nonverbal Pain Indicators*
*"PAS Preliminar": Pain Assessment Scale "Preliminar"*
*PAIC-FACE-SCALE: Pain and Impaired Cognition-Face-Scale*
*CPOT: Critical Care Pain Observation Tool*
*NVPS: The Nonverbal Pain Scale*
*NCAPC: Non-Communicating Adults Pain Checklist*
*RASS: Richmond Agitation Sedation Scale*
*GCS: Glasgow Coma Scale*

*Table S3. Facial recognition measures, population and painful procedure of the included studies.*

| Author | Year of publication | Electronic pain assessment | Population | Painful procedure | n | Control |
|---|---|---|---|---|---|---|
| Atee M et. al. | 2018 | ePAT (electronic pain assessment tool) | A | Routine assessment | 10 | 0 |
| Atee M. et. al. | 2017 | ePAT (electronic pain assessment tool) | A | Routine activities | 40 | 0 |

*A: elderly with dementia.*

*Table S4. Physiological measures, population and painful procedure of the included studies.*

| Author | Year of publication | Physiological measure | Population | Painful procedure | n | Control |
|---|---|---|---|---|---|---|
| Benromano T. et. al. a) | 2017 | Brain activity (contact heat–evoked potentials) | H | Thermal stimulus | 16 | 25 |
| Benromano T et. al. b) | 2017 | HR, HRV, PA, GSR | C | Painful pressure | 13 | 20 |
| Arbour, C., et. al. | 2015 | Brain activity (Bispectral Index System) | D | Mobilization | 25 | |
| Jeitziner MM, et. al. | 2012 | BP, HR, SpO2, RR, TV, sweating, pupil size, body movement, muscle tone | F | Suctioning | 21 | |
| Vázquez M, et. al | 2011 | BP, HR, RR, SpO2, sweating | F | Suctioning | 96 | |

*HR: Heart rate; HRV: Heart rate variability; PA: Pulse amplitude; GSR: Galvanic skin response; BP: Blood pressure; SpO2: Arterial blood oxygen saturation; RR: Respiratory rate; TV: Tidal volume.*
*C: Cerebral Palsy; D: Brain injury; H: Intellectual disability; F: Mechanically ventilated patients*

*Table S5. Reliability findings of pain observational scales included in the systematic review*

| Scale | Research Study | Population | Reliability findings |
|---|---|---|---|
| **PACSLAC** | | | |
| | Takai Y, et. al | A | Interrater reliability: 0.917 (ICC 2,1)<br>Test-retest reliability: 0.600 (ICC 1, k) |
| | Sheu E, et. al. | A | Interrater reliability: r=0.25-0.53 (Pearson product-moment correlation coefficient) |
| | de Vries, et al. | B | Internal consistency: 0.71 Cronbach α<br>Test-retest reliability: 0.88-0.95(ICC- type not reported) |
| **PACSLAC II** | | | |
| | Haghi M, et al. | A | Interrater agreement: 0.76 Cronbach α |
| | Chan S, et. al. | A | Interrater reliability: k = 0.63 |
| | Soares CD. et. al | B | Interrater reliability: 0.87-0.94 Cronbach α<br>Internal consistency: 0.827 Cronbach α |
| | Gazoni, F. M, et. al | A | Interrater reliability: 85.2% (ICC -type not reported)<br>Test-retest reliability: 64.3% (ICC- type not reported)<br>Reliability: k=0.381 |
| **FLACC** | | | |
| | Fox MA et al. | C | Interrater reliability: 0.41-0.57 (ICC -type not reported) |
| | Moon Y et. al. | A | Test-retest reliability: 0.73 (ICC -type not reported) |
| **ESCID** | | | |
| | López-López C et. al. | F | Interrater reliability: k >0.84 |
| | Latorre-Marco, I., et. al | F | Internal consistency: 0.85 Cronbach α<br>No significant intrarater differences ($p$ = 0.241)<br>Interrater reliability: difference of 0.0 or 0.1 points between the two observers |
| **Algoplus** | | | |
| | Pickering G. et. al. | G | Internal consistency: >0.6 (KR20s)**<br>Test-retest reproducibility: k=0.69 to 0.84<br>Interrater reliability: k=0.69 to 0.84 |
| | Pickering, et. al | J | Internal consistency: 0.51 Cronbach alpha α |
| **BPS** | | | |
| | Al Darwish ZQ, et. al. | F | Internal consistency: 0.77-0.95 (ICC -type not reported) |
| | Latorre-Marco, I., et. al | F | Interrater reliability: "High" (difference of 0.0 or 0.1 points between the two observers) |
| | Chanques, G, et. al. | | Interrater reliability: k=0.81<br>Internal consistency: 0.80 Cronbach α |
| | Rahu MA, et. al. | F | Test-retest reliability tested during rest and procedure: $r$ = 0.71 at rest and $r$ = 0.50 during procedure<br>Internal consistency: 0.94 Cronbach α |
| **CPOT** | | | |
| | Al Darwish ZQ, et. al. | F | Internal consistency: 0.95 Cronbach α<br>Interrater reliability: r=0.74-0.99; k=0.81 |
| | Paulson-Conger M, et. al. | I | Internal consistency reliability: 0.72 Cronbach α |
| | Linde SM, et. al. | F | Interrater reliability: 0.87 (weighted Kappa) |
| | Vázquez M, et. al | F | Interrater reliability: k=0.79-1; 97-100% |
| | Gélinas, C., et. al. | I | Interrater reliability: 86-100% |
| **NVPS** | | | |

| | | |
|---|---|---|
| Al Darwish ZQ, et. al. | F | Internal consistency: 0.86 Cronbach α |
| Chanques, G, et. al. | I | Interrater reliability: k=0.71<br>internal consistency: 0.76 Cronbach α |
| **ANVPS** | | |
| Rahu MA, et. al. | F | Internal consistency: 0.78 Cronbach α |
| **COMFORT** | | |
| Rahu MA, et. al. | F | Internal consistency: 0.90 Cronbach α |
| **NOPPAIN** | | |
| Ford B, et. al. | A | Interrater reliability: r = 0.7 -1.0<br>Test-retest reliability: r = 0.68-0.95<br>Internal consistency: 0.80-0.97 Cronbach α |
| Sheu E, et. al. | A | Interrater reliability: k=0.23 |
| **PADS** | | |
| Shinde SK,et. al | H | Interrater reliability: r= 0.82 |
| **FACS** | | |
| Shinde SK,et. al | H | Interrater agreement: 93% |
| Benromano T et. al. b) | C | Interrater agreement: 0.67-0.92 (ICC -not reported) |
| **PAINAD** | | |
| Muñoz-Narbona, L, et. al. | D,E | Internal consistency: 0.72-0.75 Cronbach α<br>Interrater reliability: k=>0.80 ; 0.97-0.98 (ICC -not reported) |
| Paulson-Conger M, et. al. | I | Internal consistency reliability: 0.80 |
| Sheu E, et. al. | A | Interrater reliability: k=0.15-0.42 |
| **APS** | | |
| Sheu E, et. al. | A | Interrater reliability: k=0.07-0.31 |
| Neville, C, et. al. | A | Test-retest reliability: 0.61-0.68 Cronbach α<br>Internal consistency: 0.65-0.79 Cronbach α<br>Interrater reliability: 0.70-0.75 (ICC -type not reported); 0,33-0.47 (weighted Kappa) |
| Gregersen, M et al. | G | Interrater reliability: 0.84 (ICC -not reported)<br>Internal consistency: 0.52 Cronbach α |
| **Mahoney Pain Scale** | | |
| Sheu E, et. al. | A | Interrater reliability: k=0.30-0.32 |
| **Doloplus-2** | | |
| Sheu E, et. al. | A | Interrater reliability: k=0.04-0.38 |
| Neville, C, et. al. | A | Test-retest reliability: 0.70 Cronbach α<br>Internal consistency: 0.85-0.86 Cronbach α<br>Interrater reliability: 0.73-0.81 (ICC -type not reported); 0,42-0.50 (weighted Kappa) |
| **CNPI** | | |
| Neville, C, et. al. | A | Test-retest reliability: 0.44-0.56 Cronbach α<br>Internal consistency: 0.75-0.82 Cronbach α<br>Interrater reliability: 0.58-0.71 (ICC -type not reported); 0,43-0.53 (weighted Kappa) |
| **Pain Indicators for Brain-Injured Patients*** | | |
| Roulin MJ, et. al. | D | Internal consistency: 95% Confindence Interval |

** Items selected from CPOT and BPS;** (KR20s): Kuder-Richardson's α coefficient ***ICC: intraclass correlation coefficient (different types added when reported); ICC 2,1: two-way random absolute agreement; ICC 1, k: One-way random, average measures.*

*ICC<0.5 = poor reliability, ICC 0.5-0.75 = moderate reliability, ICC 0.75- 0.9 = good reliability, ICC > 0.90 = excellent reliability [80]*
*A: Elderly with dementia; B: Post stroke aphasia; C: Cerebral palsy; D: Brain injury; E: Cancer patients; F: Mechanically ventilated patients; G: Elderly with Communication Disorders; H: Intellectual disability; I: Critical patients; J: Acute pain; K: Vegetative/minimum consciousness*

*Table S6. Methodological quality of the studies included in the meta-analysis.*

| | CASPE Score | SIGN Level of evidence |
|---|---|---|
| Soares CD et. al.,, 2018 | 8 | 2+ |
| Chatelle C et. al., 2012 | 6 | 2- |
| López-López C et. al., 2018 | 7 | 2- |
| Al Darwish ZQ, et. al., 2016 | 7 | 2- |
| Rahu MA, et. al., 2015 | 7 | 2+ |
| Rahu MA et. al., 2013 | 6 | 2- |
| Vázquez M et.al, 2011 | 7 | 2- |

*CASPe: Critical Appraisal Skills Program tool Spanish (range 1-11). SIGN: Scottish Intercollegiate Guidelines Network (range 1++- 4)*