Feasibility study protocol of the PainChek app to assess the efficacy of a social robot intervention for people with dementia

Pu, Lihui; Coppieters, Michel W.; Byrnes, Joshua; Jones, Cindy; Smalbrugge, Martin; Todorovic, Michael; Moyle, Wendy

published in
Journal of Advanced Nursing
2022

DOI (link to publisher)
10.1111/jan.15106

document version
Publisher's PDF, also known as Version of record

citation for published version (APA)
Pu, L., Coppieters, M. W., Byrnes, J., Jones, C., Smalbrugge, M., Todorovic, M., & Moyle, W. (2022). Feasibility study protocol of the PainChek app to assess the efficacy of a social robot intervention for people with dementia. *Journal of Advanced Nursing*, *78*(2), 587-594. https://doi.org/10.1111/jan.15106

WILEY

ENABLING DISCOVERY | POWERING EDUCATION | SHAPING WORKFORCES

Periodontitis E-learning Modules for Nurses

Periodontitis Knowledge Hub

Are you able to educate your patients with gum disease? Assess your your knowledge of gingivitis and periodontitis to enhance the treatment and care of patients with diabetes, cardiovascular disease, cognitive decline, and pregnancy.

"Gum disease is a threat to health that can cause serious complications. This site is an effective way to learn how vital good dental health is to patient health" Professor Debra Jackson AO RN PhD FRCSI SFHEA FCNA
Editor-in-Chief, *Journal of Advanced Nursing*

Visit the knowledge hub to access e-learning modules:

Pregnancy & Periodontitis

Cognitive Decline & Periodontitis

Cardiovascular Diseases & Periodontitis

Diabetes & Periodontitis

Access now

This Knowledge Hub is supported by Oral B.

Received: 22 September 2021 | Accepted: 5 November 2021

DOI: 10.1111/jan.15106

PROTOCOL

JAN Leading Global Nursing Research WILEY

Feasibility study protocol of the PainChek app to assess the efficacy of a social robot intervention for people with dementia

Lihui Pu[1,2] | Michel W. Coppieters[1,3] | Joshua Byrnes[1,4] | Cindy Jones[1,5] | Martin Smalbrugge[6] | Michael Todorovic[1,2] | Wendy Moyle[1,2]

[1]Menzies Health Institute Queensland, Griffith University, Brisbane, Queensland, Australia

[2]School of Nursing and Midwifery, Griffith University, Brisbane, Queensland, Australia

[3]Amsterdam Movement Sciences, Faculty of Behavioural and Movement Sciences, Vrije Universiteit Amsterdam, Amsterdam, The Netherlands

[4]Centre for Applied Health Economics, Griffith University, Brisbane, Queensland, Australia

[5]Faculty of Health Sciences & Medicine, Bond University, Brisbane, Queensland, Australia

[6]Department of General Practice and Elderly Care Medicine/EMGO + Institute for Health and Care Research, Amsterdam UMC, Amsterdam, The Netherlands

Correspondence
Lihui Pu, Menzies Health Institute Queensland, Griffith University, 0.12 Health Sciences (N48), 170 Kessel Rd, Nathan, Brisbane, Qld 4111, Australia.
Email: l.pu@griffith.edu.au

Funding information
This research was supported by a Menzies Health Institute Queensland Collaborative Interdisciplinary Grant 2021. Dr Lihui Pu is supported by the 2020 Griffith University Postdoctoral Fellowship.

Abstract

Aim: This study aims to test the feasibility of the PainChek app to assess pain for people with dementia living in residential aged care facilities (RACFs). It will also identify the optimal dosage and efficacy of a social robot (personal assistant robot [PARO]) intervention on chronic pain for people with dementia.

Design: This is a feasibility randomized controlled trial with three groups.

Methods: Forty-five residents living with dementia and chronic pain will be recruited from one RACF. The intervention consists of an individual 15-min non-facilitated session with a PARO robot twice a day (Group 1), a PARO robot once a day (Group 2), or a Plush-Toy (non-robotic PARO) once a day (Group 3) from Monday to Friday for 4 weeks. Participants will be followed at 4 and 8 weeks after baseline assessments. The primary outcome will be the feasibility of using the PainChek app to measure changes in pain levels before and after each session. Secondary outcomes include staff-rated pain levels, neuropsychiatric symptoms, quality of life and changes in psychotropic and analgesic medication use. Participants, staff and family perceptions of using PARO and the PainChek app will be collected after the 4-week intervention.

Discussion: This study will test the use of the PainChek app and PARO to improve pain management for people with dementia. Results from this study will help determine its usefulness, feasibility and acceptability for pain management in people with dementia living in RACFs.

Impact: As pain is a significant problem for people with dementia, this project will generate evidence on the use of the PainChek to measure the efficacy of a social robot intervention that has the potential to improve the quality of pain care in people with dementia.

Trial Registration: Australian and New Zealand Clinical Trials Registry number (ACTRN12621000837820) date registered 30/06/2021.

KEYWORDS
dementia, nursing, pain, social robot, technology

1 | INTRODUCTION

Dementia is considered a significant international public health issue. Currently, over 50 million people live with dementia globally, and this number is predicted to increase to 152 million by 2050 (Alzheimer's Disease International, 2019). Pain is one of the most common problems in people with dementia. Up to 80% of people living in residential aged care facilities (RACFs) experience chronic pain and around 50% of them are diagnosed with dementia (van Kooten et al., 2017).

Despite the high prevalence of pain among this group, it remains challenging to accurately assess pain in people with dementia due to their cognitive impairment and reduced ability to verbalize their pain experience (Knopp-Sihota et al., 2019). When self-reports are unattainable or absent, observation of pain-related behaviours, such as facial expressions, body movements, vocalization/verbalization and mental status change (Booker, 2016) or proxy reports from health care providers (Ersek et al., 2011) can be alternate ways for pain assessment. Although over 20 pain observational tools have been developed, there is a lack of widely accepted gold standards on the best observational tool for detecting pain in individuals with dementia in care home settings (Corbett et al., 2016). In addition, these tools are challenging to integrate into practice and often underused due to a lack of perceived value in pain assessment in persons with dementia (Lichtner et al., 2014). Thus, there is a need to develop alternative ways of pain assessment in people living with dementia.

Furthermore, there is a paucity of evidence for pain management strategies in dementia (Husebo et al., 2016), and robust evidence of effective interventions for this population is lacking (Corbett et al., 2016). Underestimation of pain has led to fewer analgesic medications prescribed for people with dementia than those without dementia (Liu & Leung, 2017; Malara et al., 2016). Undertreatment of pain is a significant contributor to behavioural and psychological symptoms of dementia (BPSD; Wei et al., 2021), and it is often misunderstood, untreated or mistreated with inappropriate use of antipsychotics (Rajkumar et al., 2017). Inadequately treated pain negatively impacts the quality of life and increases the risk of hospitalization, leading to high healthcare costs (Guliani et al., 2020). Therefore, more evidence-based research is warranted to better assess and manage pain for people with dementia (Achterberg et al., 2020).

2 | BACKGROUND

Advancements in technology offer new possibilities to support dementia care (Moyle, 2019). For example, a recently developed PainChek app (application, Figure 1) uses an artificial intelligence (AI)-based facial recognition technology to detect facial cues indicative of pain in people with dementia (Atee et al., 2018). PainChek has 42 items across six domains, including Face, Voice, Movement, Behaviour, Activity and Body. PainChek uses deep learning methods (i.e. automated facial recognition and analysis) to detect facial micro-expressions to indicate the presence of pain. The app then guides the assessor through checklists of pain behaviours related to the experience of pain. Each item has a clear operational definition to be rated on a binary level (Yes = present, No = absent). A total score across all domains between 0 and 6 represents no pain, 7–11 mild pain, 12–15 moderate pain and 16 and above severe pain. The assessment takes less than 3 min to complete, and assessment data is stored digitally in the PainChek cloud repository. Although PainChek has shown good concurrent validity and internal consistency for assessing pain in people with dementia (Atee et al., 2018; Hoti et al., 2018), preconditions for its broad clinical application to test the efficacy of interventions to manage pain in people with dementia living in RACFs (e.g. training, costs, implementation barriers, the acceptance of using the technology) need further research.

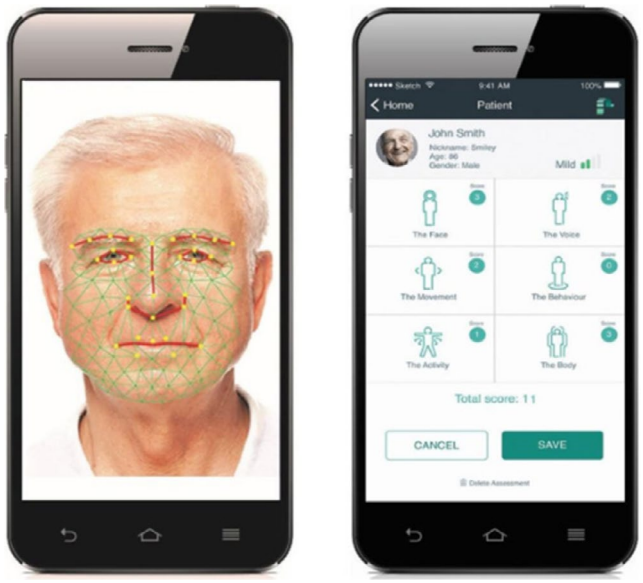

FIGURE 1 PainChek app (permission for image given by Professor Jeff Hughes, Chief Scientific Officer of PainChek Ltd, Australia)

Personal assistant robot (PARO, Figure 2), a therapeutic seal robot, has the appearance of a baby harp seal covered with artificial fur, which is soft and warm to the touch. Its fur is hypoallergenic and thus avoids allergic reactions commonly experienced with live animals. It has the following four senses: sight, hearing, balance, and tactile senses. PARO has two optical nose sensors to recognize the source of light and has a diurnal rhythm of sleep or movement according to the light sources and stimulation of the sensors. PARO also has three microphones in its ears to detect sound source direction and speech recognition, such as its name or greetings and several simple words. In addition, it contains a posture sensor to maintain balance and recognizes its posture when held by a user. It has seven silent intelligent actuators to open and close its eyes and move its neck and front and rear feet for motion. Thus, PARO combines these four senses to respond and communicate with users by moving or making a sound. PARO's voice was recorded from an actual baby harp seal (Wada et al., 2003). PARO can also learn users' preferences for its behaviours.

FIGURE 2 Personal assistant robot (PARO, permission for image given by Dr. Takanori Shibata, National Institute of Advanced Industrial Science and Technology, Japan)

Pharmacological treatment remains as the first-line treatment for underlying causes of pain in older adults; however, people with dementia are more susceptible to the potentially harmful side effects of polypharmacy (Achterberg et al., 2020). Moreover, the absence of effective and safe pharmacological treatment guidelines for chronic pain management in dementia care warrants closer investigation into alternative psychosocial approaches (Anderson et al., 2021; Pu et al., 2019). PARO has been reported as a promising therapeutic robot to reduce pain (Demange et al., 2019; Lane et al., 2016) and offers the potential to reduce pain medications in people with dementia (Petersen et al., 2017). Feasibility studies indicate that PARO can reduce acute pain associated with care procedures (Demange et al., 2019) and observational pain levels for hospitalized patients with dementia (Kelly et al., 2021). A pilot study with 15-min sessions of PARO intervention has shown significantly reduced observational pain levels and as needed medication use in people with dementia living in RACFs (Pu et al., 2020). Furthermore, pilot studies indicate that PARO might potentially alleviate pain for other groups such as paediatric patients (Okita, 2013) and patients with cancer (Eskander et al., 2013).

The analgesic effect of PARO may be explained by the active interactions with PARO (i.e. touching and stroking) that may lead to decreased sensitivity to pain. Geva et al. (2020) found that human-robot emotional touch with PARO effectively reduces experimentally induced pain ratings and improves mood in healthy young adults. This may be associated with a reduced salivary cortisol level (Pendry & Vandagriff, 2019) and the release of oxytocin as reported from animal-assisted interventions (Beetz et al., 2012). However, it remains uncertain what the appropriate human-robot intervention frequency is and whether there would be a larger effect on the reduction of pain if the treatment dosage were increased for people with dementia. Therefore, we aim to evaluate the feasibility of using the innovative PainChek app to identify the efficacy of different intervention frequencies of a daily PARO intervention for people with dementia living in RACFs.

3 | THE STUDY

3.1 | Aims

This study aims to determine the feasibility of using the PainChek app to measure pain in people with dementia and identify the optimal dosage and efficacy of a social robot intervention on pain management for people living with dementia. Furthermore, the study seeks to expand knowledge on how best to relieve pain using social robot interventions with improved pain measurement.

3.2 | Design/Methodology

This is a feasibility randomized controlled trial (RCT) with three groups.

3.3 | Participants

Participants will be recruited according to the following inclusion criteria: (1) aged 65 years and older; (2) diagnosed with dementia, or probable diagnosis of dementia with a mini-mental state examination score lower than 24 (Folstein et al., 1975); (3) assumed to experience chronic pain, e.g., prescribed with regular pain medications or with proxy reports of pain from care staff; (4) demonstration of perceptions to interact with PARO; (5) having lived in a RACF for more than 3 months.

Participants who meet at least one of the following criteria will be excluded: (1) Comorbidities that require residents to be admitted to hospital frequently, such as acute exacerbation of chronic obstructive pulmonary disease; (2) terminal illnesses where the resident is in the final palliative stage; (3) major mental illness, such as schizophrenia; (4) infectious diseases, such as acquired immune deficiency syndrome, COVID-19, or tuberculosis, or an open wound that is unable to be covered.

3.4 | Sample size

A formal sample size calculation is not required for a feasibility study, and literature shows that at least 12 participants per group are recommended (Julious, 2005). Therefore, a sample of 45 residents who meet the inclusion and exclusion criteria, accommodating 20% attrition rate, will be recruited from one large RACF with over 150 beds in South East Queensland, Australia.

3.5 | Recruitment and informed consent

The facility coordinator will (a) assist with identifying potential participants according to the study selection criteria and (b) seek permission from potential participants and their legally authorized

representatives to identify via email or phone calls whether they are willing to be contacted by the researcher. In addition, recruitment flyers and invitation letters will be sent out to promote recruitment. A person's capacity to provide consent will be first sought from facility care staff. Then, written informed consent will be obtained from participants or their legally authorized representatives. We will also obtain and record assent from participants before each session.

3.6 | Interventions and procedures

Following baseline assessment, an independent researcher who is not involved in this study will generate a randomization list of participants via an online website (https://www.random.org/). Participants will be then randomized into Intervention Group 1 receiving an individualized non-facilitated 15-min PARO intervention (two sessions/day) or intervention Group 2 with a 15-min PARO intervention (one session/day), or the control Group a 15-min Plush Toy (PT; one session/day)—a PARO with all robotic and AI capabilities disabled, from Monday to Friday for 4 weeks.

The intervention (Group 1 and 2 and Control Group) will be provided to a participant in their own bedroom. With the help of nursing staff, the participant will be guided to their bedroom whilst trying not to get them agitated. Participants will receive the intervention at a randomized schedule. All available 15-min periods between 9:00 am and 5:00 pm, excluding mealtimes, will be used to select a random time that the participant will be able to interact with the robot. The timing of the PARO and control intervention for the first week will be generated by a random number list. This time will then be rotated in the following weeks to ensure each participant receives the intervention at different times to avoid any confounding medication effect. If the participant is unable or unwilling to receive the intervention at the scheduled time, the robot or PT will be allocated to the next participant on the list. An attempt will be made to offer the intervention to the participant later in the day. Research assistants record the responses of participants towards the use of the PainChek app and PARO on the observational sheet. We will provide one PARO to the facility for 2 weeks following the trial for those in the control group to experience the robotic PARO.

3.7 | Primary outcomes

The primary outcome will be the feasibility of using the PainChek app. The Bowen feasibility framework (Bowen et al., 2009) will guide the feasibility outcome measures, including (1) acceptability (percentage of participants who adhere to the PainChek protocol), (2) implementation challenges (e.g. lighting issue, network, etc), (3) practicality (e.g. training, cost, etc) and (4) efficacy of the social robot intervention. The research assistants will be trained and practise using the PainChek app through web-based training programs. Inter-rater reliability among research assistants will be assessed and established during the training sessions. Moreover, the recruitment and consent rates of participants, cost of this study (e.g. labour, equipment, recruitment, training, intervention delivery, etc.) will be assessed by an audit of the study progress. A resource checklist and data collection matrix will be designed to calculate the potential cost offsets and appropriate data collection methods for a future cost-effectiveness analysis. In addition, key stakeholders (i.e. people with dementia, family carers and care staff) will be interviewed regarding their perceptions of using PARO and the PainChek app.

3.8 | Secondary outcomes

Measurements for secondary outcomes at baseline, week 4 and follow-up at week 8 include: (a) pain levels measured by the Abbey Pain Scale (Abbey et al., 2004); (b) neuropsychiatric symptoms measured using the Neuropsychiatric Inventory-nursing home version (Wood et al., 2000); (c) quality of life measured by a generic instrument EuroQoL 5-Dimensions (EQ-5D) questionnaire (Herdman et al., 2011) and a dementia-specific instrument Quality of Life in Alzheimer's disease (QoL-AD) questionnaire (Logsdon et al., 1999); and (d) scheduled and as needed psychotropic and analgesic medication use retrieved from residents' medical files.

3.9 | Data collection

The study data collected at each time point are summarized in Table 1. Participant's sociodemographic information, medical diagnosis, and health conditions will be collected from health medical records at baseline. Research assistants for outcome assessment will be blinded to the group allocation. They will be trained on collecting proxy assessments through structured interviews with the nursing staff. In addition, semi-structured interviews with people with dementia, family carers and care staff will be conducted at the end of the 4-week intervention. All the interviews will be audio-recorded.

3.10 | Ethics approval and trial registration

Institutional Review Board approval (Griffith University Human Ethics Committee, reference number: 2021/221) was received for this study protocol, and the study was prospectively registered with the Australian and New Zealand Clinical Trials Registry database (Trial ID: ACTRN12621000837820).

3.11 | Data management

Participants will have the protection of their privacy and confidentiality, with all data being de-identified when disseminated. All

TABLE 1 Data collection

Outcomes	Instruments	Time to complete (min)	Study process				
			Recruitment	Baseline Week 0	Inervention Week 1–Week 4	Post Week 4	Follow up Week 8
Screening							
Demographic[a]	Basic information	5	✓				
Cognition[b]	MMSE	10	✓				
Pain screening[c]	Comprehensive pain assessment	5	✓				
Medical diagnosis[a]	Medical records	5	✓				
Primary outcomes							
Feasibility[d]	PainChek app	5		✓	✓	✓	✓
Secondary outcomes							
Pain RN-reorted[c]	APS	5		✓		✓	✓
Neuropsychiatric symptoms[e]	NPI-NH	30		✓		✓	✓
Quality of life[e]	QoL-AD	20		✓		✓	✓
	EQ-5D	10		✓		✓	✓
Medication[a]	Medication charts	5		✓	✓	✓	✓
Interviews		20				✓	

Abbreviations: APS, Abbey Pain Scale; EQ-5D, the EuroQol 5-dimensions; MMSE, mini-mental state examination; NPI-NH, Neuropsychiatric Inventor-Nursing Home version; QoL-AD, quality of life in Alzheimer's disease; RN, registered nurse.

[a]Collected by reviewing the resident health records and medication charts.

[b]Completed by interviewing the participants.

[c]Completed by interviewing the registered nurses who are familiar with the participant.

[d]Completed by the research assistants before and after each session.

[e]Completed by interviewing the care staff who are familiar with the participant.

participants will be allocated a unique study identifier with participants' initials used for data collection. In addition, a project tracking spreadsheet will contain participant IDs and identifiable participant and project information, such as the participant's name to allow selected members of the research team to link the participant and the study treatment group. Paper-based de-identified data will be stored in locked filing cabinets in a locked office, and electronic de-identified data about the study will be stored on a password-protected computer. The project manager will undertake data entry. Access to the final data set will be available only to the research team. No plans have been arranged for data sharing.

3.12 | Analysis

Demographics and feasibility data will be analysed using descriptive statistics. Multiple imputations will be used to manage missing data, and an intention-to-treat approach will be applied for group comparisons. The weekly average changes in the pain score over 4 weeks will be compared among three groups using generalized estimated equations, accounting for between-individual variability and within-individual variability over time. The threshold of clinically meaningful improvement is estimated at a 20% reduction in pain scores (Guerriero & Reid, 2017). We will also calculate the numbers needed to treat between different groups. For secondary outcomes, a general linear model (GLM) with repeated measures will be used to determine differences between groups (with three levels: double dose intervention, single-dose intervention, control) and within groups over time (with three levels: baseline, end of intervention at week 4, follow-up at week 8). In addition, Cohen's *d* effect size will be calculated for the sample size estimation for a larger trial. Statistical significance will be set at the alpha level of 0.05. Analyses will be performed using IBM SPSS Statistics (version 27.0). Qualitative data will be transcribed into NVivo 11.0 and analysed using thematic analysis (Braun & Clarke, 2006).

4 | RESULTS

Funding for this study was obtained in March 2021. The trial is currently in data collection, and the participant recruitment started on 01 July 2021. The full results of this feasibility RCT, including data on the intervention in terms of the study feasibility and measurements for outcomes, are expected in the middle of 2022.

5 | DISCUSSION

The world population is ageing and alongside this is an increase in the population of people living with dementia in the community and RACFs. As a result, there is an increase in the burden on carers and the healthcare system. This project provides an innovative and unique opportunity to apply innovative technologies (PainChek app and PARO) to measure and appropriately manage chronic pain for older adults with dementia living in RACFs.

The findings from this feasibility RCT will draw recommendations for conducting a full-scale trial and determining which project modifications are necessary. This will include consultation with people with dementia and carers to explore facilitators and barriers toward using technology, the PainChek app and PARO. In addition to a large-scale RCT, other research activities could consist of an implementation study investigating the cost-effectiveness of using the PainChek app and PARO among people with dementia living in RACFs. Improvement in pain assessment and effective pain management will result in better care and quality of life in people with dementia, and this will potentially provide better care support for care staff with the potential to lower care burden and increase work satisfaction.

5.1 | Limitations

To our knowledge, this is the first RCT using the technology-based pain assessment tool—PainChek to evaluate the efficacy of the PARO intervention on pain management in residents with dementia living in RACFs. However, our study has limitations. First, the study participants are selected from a single RACF, and the small number of participants limits the validity of the findings. However, this is acceptable for a feasibility study. We will recruit more RACFs in a full-scale RCT if it is feasible. Second, it is impossible to blind the facility care staff who assist the research assistants with secondary outcomes measurement as they will be aware of the participants' group assignments during the intervention.

6 | CONCLUSION

Older adults with dementia living in RACFs are at risk of having their pain undertreated. Accurately assessing and managing pain in people with dementia is a challenge for aged care staff. Using innovative technologies with valid tools to assess and effectively manage pain is important for care professionals providing care to this population. This study will provide insights into the feasibility of using the PainChek app to explore the effect of different dosages of the PARO intervention compared to a PT control group. Study results will inform whether a full-scale RCT with cost-effective analysis is feasible and which modifications to the study design, process and intervention are needed. This study will provide research focused on better management of pain in people with dementia.

ACKNOWLEDGEMENT

We acknowledge the PainChek company that has provided the PainChek app for this research.

CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

AUTHOR CONTRIBUTIONS

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE*): (1) Substantial contributions to conception and design, acquisition of data or analysis and interpretation of data. (2) Drafting the article or revising it critically for important intellectual content. *http://www.icmje.org/recommendations/.

PEER REVIEW

The peer review history for this article is available at https://publons.com/publon/10.1111/jan.15106.

DATA AVAILABILITY STATEMENT

Research data are not shared with no participant permission to share data beyond this study.

ORCID

Lihui Pu https://orcid.org/0000-0003-0136-0940
Michel W. Coppieters https://orcid.org/0000-0002-3958-4408
Joshua Byrnes https://orcid.org/0000-0001-6562-711X
Cindy Jones https://orcid.org/0000-0002-7249-2580
Martin Smalbrugge https://orcid.org/0000-0003-0538-4843
Michael Todorovic https://orcid.org/0000-0003-0806-5610
Wendy Moyle https://orcid.org/0000-0003-3004-9019

REFERENCES

Abbey, J., Piller, N., De Bellis, A., Esterman, A., Parker, D., Giles, L., & Lowcay, B. (2004). The Abbey pain scale: A 1-minute numerical indicator for people with end-stage dementia. *International Journal of Palliative Nursing*, *10*(1), 6–13. https://doi.org/10.12968/ijpn.2004.10.1.12013

Achterberg, W., Lautenbacher, S., Husebo, B., Erdal, A., & Herr, K. (2020). Pain in dementia. *PAIN Reports*, *5*(1), e803. https://doi.org/10.1097/pr9.0000000000000803

Alzheimer's Disease International (2019). World Alzheimer report 2019: Attitudes to dementia. https://www.alz.co.uk/research/world-report-2019

Anderson, A. R., Hyden, K., Failla, M. D., & Carter, M. A. (2021). Policy implications for pain in advanced Alzheimer's disease. *Pain Management Nursing*, *22*(1), 3–7. https://doi.org/10.1016/j.pmn.2020.06.005

Atee, M., Hoti, K., & Hughes, J. D. (2018). A technical note on the PainChek™ system: A web portal and mobile medical device for assessing pain in people with dementia. *Frontiers in Aging Neuroscience*, *10*, 117. https://doi.org/10.3389/fnagi.2018.00117

Beetz, A., Uvnäs-Moberg, K., Julius, H., & Kotrschal, K. (2012). Psychosocial and psychophysiological effects of human-animal interactions: The possible role of oxytocin. *Frontiers in Psychology*, *3*, 234. https://doi.org/10.3389/fpsyg.2012.00234

Booker, S. Q., & Haedtke, C. (2016). Assessing pain in nonverbal older adults. *Nursing*, *46*(5), 66–69. https://doi.org/10.1097/01.NURSE.0000480619.08039.50

Bowen, D. J., Kreuter, M., Spring, B., Cofta-Woerpel, L., Linnan, L., Weiner, D., Bakken, S., Kaplan, C. P., Squiers, L., Fabrizio, C., & Fernandez, M. (2009). How we design feasibility studies. *American Journal of Preventive Medicine*, *36*(5), 452–457. https://doi.org/10.1016/j.amepre.2009.02.002

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101. https://doi.org/10.1191/1478088706qp063oa

Corbett, A., Nunez, K.-M., Smeaton, E., Testad, I., Thomas, A. J., Closs, S. J., Briggs, M., Clifton, L., Gjestsen, M. T., & Lawrence, V. (2016). The landscape of pain management in people with dementia living in care homes: A mixed methods study. *International Journal of Geriatric Psychiatry*, *31*(12), 1354–1370. https://doi.org/10.1002/gps.4445

Demange, M., Pino, M., Kerhervé, H., Rigaud, A.-S., & Cantegreil-Kallen, I. (2019). Management of acute pain in dementia: A feasibility study of a robot-assisted intervention. *Journal of Pain Research*, *12*, 1833–1846. https://doi.org/10.2147/JPR.S179640

Ersek, M., Polissar, N., & Neradilek, M. B. (2011). Development of a composite pain measure for persons with advanced dementia: Exploratory analyses in self-reporting nursing home residents. *Journal of Pain and Symptom Management*, *41*(3), 566–579. https://doi.org/10.1016/j.jpainsymman.2010.06.009

Eskander, R., Tewari, K., Osann, K., & Shibata, T. (2013). Pilot study of the PARO therapeutic robot demonstrates decreased pain, fatigue, and anxiety among patients with recurrent ovarian carcinoma. *Gynecologic Oncology*, *130*(1), e144–e145. https://doi.org/10.1016/j.ygyno.2013.04.410

Folstein, M. F., Folstein, S. E., & McHugh, P. R. (1975). "Mini-mental state": A practical method for grading the cognitive state of patients for the clinician. *Journal of Psychiatric Research*, *12*(3), 189–198. https://doi.org/10.1016/0022-3956(75)90026-6

Geva, N., Uzefovsky, F., & Levy-Tzedek, S. (2020). Touching the social robot PARO reduces pain perception and salivary oxytocin levels. *Scientific Reports*, *10*(1), 9814. https://doi.org/10.1038/s41598-020-66982-y

Guerriero, F., & Reid, M. C. (2017). New opioid prescribing guidelines released in the US: What impact will they have in the care of older patients with persistent pain? *Current Medical Research and Opinion*, *33*(2), 275–278. https://doi.org/10.1080/03007995.2016.1254603

Guliani, H., Hadjistavropoulos, T., Jin, S., & Lix, L. (2020). Utilization of health care resources by long-term care residents as a function of pain status. *The Clinial Journal of Pain*, https://doi.org/10.1097/ajp.0000000000000826

Herdman, M., Gudex, C., Lloyd, A., Janssen, M., Kind, P., Parkin, D., Bonsel, G., & Badia, X. (2011). Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of Life Research*, *20*(10), 1727–1736. https://doi.org/10.1007/s11136-011-9903-x

Hoti, K., Atee, M., & Hughes, J. D. (2018). Clinimetric properties of the electronic Pain Assessment Tool (ePAT) for aged-care residents with moderate to severe dementia. *Journal of Pain Research*, *11*, 1037–1044. https://doi.org/10.2147/JPR.S158793

Husebo, B. S., Achterberg, W., & Flo, E. (2016). Identifying and managing pain in people with Alzheimer's disease and other types of dementia: A systematic review. *CNS Drugs*, *30*(6), 481–497. https://doi.org/10.1007/s40263-016-0342-7

Julious, S. A. (2005). Sample size of 12 per group rule of thumb for a pilot study. *Pharmaceutical Statistics*, *4*(4), 287–291. https://doi.org/10.1002/pst.185

Kelly, P. A., Cox, L. A., Petersen, S. F., Gilder, R. E., Blann, A., Autrey, A. E., & MacDonell, K. (2021). The effect of PARO robotic seals for hospitalized patients with dementia: A feasibility study. *Geriatric Nursing*, *42*(1), 37–45. https://doi.org/10.1016/j.gerinurse.2020.11.003

Knopp-Sihota, J. A., Dirk, K. L., & Rachor, G. S. (2019). Factors associated with pain assessment for nursing home residents: A systematic review and meta-synthesis. *Journal of the American Medical Directors Association*, *20*(7), 884–892. https://doi.org/10.1016/j.jamda.2019.01.156

Lane, G. W., Noronha, D., Rivera, A., Craig, K., Yee, C., Mills, B., & Villanueva, E. (2016). Effectiveness of a social robot, "Paro," in a VA long-term care setting. *Psychological Services*, *13*(3), 292–299. https://doi.org/10.1037/ser0000080

Lichtner, V., Dowding, D., Esterhuizen, P., Closs, S. J., Long, A. F., Corbett, A., & Briggs, M. (2014). Pain assessment for people with dementia: A systematic review of systematic reviews of pain assessment tools. *BMC Geriatrics*, *14*, 138. https://doi.org/10.1186/1471-2318-14-138

Liu, J. Y. W., & Leung, D. Y. P. (2017). Pain treatments for nursing home residents with advanced dementia and substantial impaired communication: A cross-sectional analysis at baseline of a cluster randomized controlled trial. *Pain Medicine*, *18*(9), 1649–1657. https://doi.org/10.1093/pm/pnw242

Logsdon, R. G., Gibbons, L. E., McCurry, S. M., & Teri, L. (1999). Quality of life in Alzheimer's disease: Patient and caregiver reports. *Journal of Mental Health and Aging*, *5*(1), 21–32.

Malara, A., De Biase, G. A., Bettarini, F., Ceravolo, F., Di Cello, S., Garo, M., Praino, F., Settembrini, V., Sgro, G., Spadea, F., & Rispoli, V. (2016). Pain assessment in elderly with behavioral and psychological symptoms of dementia. *Journal of Alzheimer's Disease*, *50*(4), 1217–1225. https://doi.org/10.3233/jad-150808

Moyle, W. (2019). The promise of technology in the future of dementia care. *Nature Reviews Neurology*, *15*(6), 353–359. https://doi.org/10.1038/s41582-019-0188-y

Okita, S. Y. (2013). Self-other's perspective taking: The use of therapeutic robot companions as social agents for reducing pain and anxiety in pediatric patients. *Cyberpsychology, Behavior, and Social Networking*, *16*(6), 436–441. https://doi.org/10.1089/cyber.2012.0513

Pendry, P., & Vandagriff, J. L. (2019). Animal Visitation Program (AVP) reduces cortisol levels of university students: A randomized controlled trial. *AERA Open*, *5*(2), 1–12. https://doi.org/10.1177/2332858419852592

Petersen, S., Houston, S., Qin, H., Tague, C., & Studley, J. (2017). The utilization of robotic pets in dementia care. *Journal of Alzheimer's Disease*, *55*(2), 569–574. https://doi.org/10.3233/jad-160703

Pu, L., Moyle, W., Jones, C., & Todorovic, M. (2019). Psychosocial interventions for pain management in older adults with dementia: A systematic review of randomised controlled trials. *Journal of Advanced Nursing*, *75*(8), 1608–1620. https://doi.org/10.1111/jan.13929

Pu, L., Moyle, W., Jones, C., & Todorovic, M. (2020). The effect of using PARO for people living with dementia and chronic pain: A pilot randomised controlled trial. *Journal of the American Medical Directors Association*, *21*(8), 1079–1085. https://doi.org/10.1016/j.jamda.2020.01.014

Rajkumar, A. P., Ballard, C., Fossey, J., Orrell, M., Moniz-Cook, E., Woods, R. T., Murray, J., Whitaker, R., Stafford, J., Knapp, M., Romeo, R., Woodward-Carlton, B., Khan, Z., Testad, I., & Corbett, A. (2017). Epidemiology of pain in people with dementia living in care homes: Longitudinal course, prevalence, and treatment implications. *Journal of the American Medical Directors Association*, *18*(5), 453.e451–453.e456. https://doi.org/10.1016/j.jamda.2017.01.024

van Kooten, J., Smalbrugge, M., van der Wouden, J. C., Stek, M. L., & Hertogh, C. M. P. M. (2017). Prevalence of pain in nursing home residents: The role of dementia stage and dementia subtypes. *Journal of the American Medical Directors Association*, *18*(6), 522–527. https://doi.org/10.1016/j.jamda.2016.12.078

Wada, K., Shibata, T., Saito, T. & Tanie, K. (2003, 20-24 July). Psychological, physiological and social effects to elderly people by robot assisted activity at a health service facility for the aged. In Advanced Intelligent Mechatronics, 2003. AIM 2003. Proceedings. 2003 IEEE/ASME International Conference.

Wei, Y. J., Chen, C., Fillingim, R. B., DeKosky, S. T., Schmidt, S., Pahor, M., Solberg, L., & Winterstein, A. G. (2021). Uncontrolled pain and risk for depression and behavioral symptoms in residents with dementia. *Journal of the American Medical Directors Association*, *22*(10), 2079–2086.e5. https://doi.org/10.1016/j.jamda.2021.05.010

Wood, S., Cummings, J. L., Hsu, M.-A., Barclay, T., Wheatley, M. V., Yarema, K. T., & Schnelle, J. F. (2000). The use of the Neuropsychiatric Inventory in nursing home residents: Characterization and measurement. *The American Journal of Geriatric Psychiatry*, *8*(1), 75–83. https://doi.org/10.1097/00019442-200002000-00010

How to cite this article: Pu, L., Coppieters, M. W., Byrnes, J., Jones, C., Smalbrugge, M., Todorovic, M., & Moyle, W. (2022). Feasibility study protocol of the PainChek app to assess the efficacy of a social robot intervention for people with dementia. *Journal of Advanced Nursing*, 78, 587–594. https://doi.org/10.1111/jan.15106