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The effectiveness of the Program to Enhance Adjustment to Residential Living (PEARL) in reducing depression in newly admitted nursing home residents

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ABSTRACT

Background: Depression is common in nursing homes, particularly among newly admitted residents. This cluster randomised controlled trial evaluated the effectiveness of the Program to Enhance Adjustment to Residential Living (PEARL) in reducing depression in this group.

Methods: Participants were 219 newly-admitted residents (mean of 4.4 weeks since admission) in 42 nursing homes in Melbourne, Australia, with a mean age of 85.5 years (SD = 7.3). Nursing homes were randomly allocated to the intervention or standard care condition. Level of depressive symptoms was evaluated at baseline (T1), one week post-intervention (T2), 2 months post-intervention (T3, primary end point), and 6 months post-intervention (T4). Changes in depressive symptoms in the intervention and control groups over time were compared using a multilevel model, with nursing homes modelled as random intercept.

Results: In intention to treat analyses, depressive symptoms reduced from T1 to T3 to a greater degree in the intervention condition (M_{change}=2.56, SD_{change}=5.71) than in the control (M_{change}=0.63, SD_{change}=5.25), with a significant, small-medium treatment effect size (p=.035; Cohen's d=0.36). The reduction in depressive symptoms from T1 to T4 was not significant (p=.369; Cohen's d=0.32).

Limitations: The findings require replication, particularly comparing PEARL with an active control condition.

Conclusions: PEARL is a simple, brief program that was effective in reducing symptoms of depression in newly admitted nursing home residents.

Key words: Depression, adjustment, residential aged care, nursing homes, long term care, psychological treatment

1. Introduction

Depression rates are high in nursing homes (also known as residential aged care or long-term care facilities), with a review of international studies reporting a median prevalence of Major Depressive Disorder (MDD) of 10% (Seitz et al., 2010). Australian population data have indicated that over half (52%) of all routinely assessed nursing home residents had significant symptoms of depression (Australian Institute of Health and Welfare, 2013), based on a cut-off score of 9 and above on the screening tool used in Australia (Davison et al., 2012), the Cornell Scale for Depression in Dementia (Alexopoulos et al., 1988). These high estimations are concerning, given the association between depression and multiple adverse outcomes such as increased mortality, functional disability, poor quality of life, and greater health care utilisation (Abrams et al., 1992; Beekman et al., 2002; Beerens et al., 2013; Meeks et al., 2011).

Researchers have determined a significant association between transition to a nursing home and depressive symptoms, even when controlling for established risk factors that are common in this setting, such as multiple medical comorbidity, functional decline and cognitive impairment (Anstey et al., 2007; Pot et al., 2005). Depressive symptoms are commonly present at the point of entry (Achterberg et al., 2006; McSweeney and O'Connor, 2008), and are enduring, with researchers reporting persistence rates of significant levels of depression in nursing homes of 45% to 75% over 5 to 12 month periods (Barca et al., 2010; McSweeney and O'Connor, 2008; Smalbrugge et al., 2006; Sutcliffe et al., 2007). In addition, new cases

emerge in the post-admission period. US population data indicated that more than half of nursing home residents had a diagnosis of depression in their medical records made during their first year: 32.8% at admission and a further 21.6% during the subsequent twelve months (Hoover et al., 2010). Thus, newly admitted residents appear to be at a high risk of depression during the transition period, whether associated with pre-admission factors, the admission process, or the initial months of life in a nursing home. However, to our knowledge, there are no published interventions designed specifically to address mental health and wellbeing during this high-risk period.

Although there is widespread recognition of the extent of the problem of depression in nursing homes, there have been few prevention or treatment advances over recent years. There is a continued reliance on pharmacological treatment for depression in nursing homes, despite the absence of clear evidence for the effectiveness of antidepressants in this setting (Boyce et al., 2012), and concerns about medication side-effects and poor effectiveness in people with dementia (Farina et al., 2017; Nelson and Devanand, 2011). A multidisciplinary approach that includes structured assessment in nursing homes has been found to reduce depression prevalence (Leontjevas et al., 2013), and there are promising indications that psychological interventions are effective for depression in nursing homes (Cody and Drysdale, 2013). However, we lack a consistent body of evidence based on high quality trials to guide practices in this setting (Simning and Simons, 2017), and interventions rarely target known risk and protective factors for depression in nursing homes.

However, there are indications from prospective longitudinal studies to guide the development of tailored nonpharmacological approaches. For example, loneliness (Smalbrugge et al., 2006) and poor social support (Chau et al., 2019) were identified as risk

factors for a subsequent increase in depressive symptoms among nursing home residents, while engagement in activities with social components was associated with fewer depression symptoms (Knippenberg et al., 2019). In addition, cross-sectional research has suggested that low levels of perceived environmental mastery, autonomy, and social support are associated with greater levels of depression among nursing home residents (Davison et al., 2012; Paque et al., 2017).

The above findings are consistent with Self-Determination Theory, which postulates that psychological wellbeing throughout the lifespan is dependent on three basic needs being satisfied: autonomy, competence and relatedness (Ryan and Deci, 2000). Persistent deprivation of any of these psychological needs is proposed to have negative consequences for mental health (Deci and Ryan, 2000). There is evidence to support this proposal in the nursing home setting, with poor satisfaction of residents' basic needs associated with higher levels of depression 5-8 months later (Kloos et al., 2019). A recent meta-analysis found evidence for a relationship between basic need satisfaction and both positive and negative indicators of well-being, including depression, among older adults across a variety of settings (Tang et al., 2020). However, to date, there have been no interventions developed to satisfy older people's needs for competence, autonomy and relatedness.

The Program to Enhance Adjustment to Residential Living (PEARL) addresses this gap. The program aims to reduce the risk of depression through the implementation of tailored care approaches to satisfy residents' basic psychological needs (autonomy, competence and relatedness). Recognising that newly admitted residents are at particular risk of depression, this program is designed specifically for implementation during residents' initial period of institutional care. The program employs a collaborative approach, with the clinician working

closely with both the resident and an identified staff member in the facility to identify and implement strategies that are feasible and sustainable following the end of the formal program sessions.

The aim of this study was to determine the effectiveness of PEARL in reducing depressive symptoms in newly admitted nursing home residents, compared to standard care. It was hypothesised that PEARL plus standard care ('intervention condition') would be superior to standard care alone ('control condition'). Subgroup analyses were conducted to determine whether PEARL had an equivalent effect in reducing depressive symptoms for (i) residents with and without MDD at baseline, and (ii) residents with normal cognitive function and with mild-moderate cognitive impairment. While this study was designed to assess changes in depressive symptoms, supplementary analyses were conducted to examine changes in the frequency of MDD during the course of the study.

2. Methods

2.1. Trial Design

This study was a two-armed, parallel-design, cluster randomised controlled trial, which has been described in a protocol paper (Davison et al., 2020). Clusters were nursing home facilities in Melbourne, Australia. Participants were newly admitted residents in these facilities. The PEARL intervention delivery involved staff, and so to avoid contamination, facilities were randomised rather than individual participants. Analyses were carried out at the level of individual participants.

This trial was approved by university ethics committees and registered with the Australian and New Zealand Clinical Trial Registry in December 2016 (Reference: 12616001726448).

2.2. Clusters

Managers from a convenience sample of nursing homes in Melbourne, Australia were invited to express interest in the trial. Potential facilities from the authors' existing networks were approached, as were providers with multiple nursing homes across Melbourne. Discussions commenced with managers of 74 facilities, 12 of whom declined to participate. Three facilities that were exclusively dementia-specific or only admitted residents from a non-English language group were excluded. Managers from the remaining 59 facilities consented to participate. These facilities were randomised prior to data collection by a statistician who was not involved in intervention delivery or data collection, using a web-based random allocation sequence generator (Haahr, 2020). Randomisation was stratified by the facilities' size (<100 and ≥100 beds) and provider (i.e., the organisation that owns and runs the nursing home), with a separate randomisation schedule generated for each stratum. While the residents were not informed which condition their facility was allocated to during recruitment, there was no practicable means of ensuring staff blinding.

2.3. Participants

Following randomisation, facility staff were asked to refer potential participants. Staff were instructed to refer only newly admitted permanent residents with fluency in English and an absence of severe dementia. Staff from 51 nursing homes referred 608 residents, who were screened by the research team, and, if eligible and willing, provided informed consent to participate. Inclusion criteria were aged 60 years or older and admitted to the facility during the previous four weeks as a permanent resident. Residents with any level of depression or no depression were eligible for this study. Exclusion criteria were: an acute medical condition likely to compromise participation; moderate-severe cognitive impairment [Mini Mental

State Examination (MMSE) score of less than 15 (Folstein et al., 1975; Tombaugh and McIntyre, 1992)]; previous residence in another nursing home; non-fluency in English; and admitted for temporary respite. If potential participants scored less than 24 on the MMSE, consent was sought from their next of kin. A total of 219 eligible residents from 42 facilities consented to participate in the trial (see CONSORT flowchart in Figure 1).

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Insert Figure 1 approximately here

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2.4. Intervention

All participants received the standard care offered to nursing home residents, including assistance with activities of daily living, medical care, access to scheduled group activities run at the facility, and any psychotropic medications prescribed by a medical practitioner.

Participants in the intervention condition received PEARL in addition to standard care. PEARL was delivered individually to residents, usually in their rooms, by a clinician in five one-hour sessions over a seven-week period, using a structured manual (see Davison et al., 2020 for more details). The first three sessions were delivered weekly and were designed to identify and implement tailored strategies to satisfy residents' needs for autonomy, competence and relatedness. The clinician met with a key facility staff member (e.g., nurse or care assistant) prior to and following each session, to collaborate in finalising and implementing the strategies. Two 'booster' sessions were provided, each delivered after a two-week gap, which were attended by the key staff member and resident. Booster sessions were designed to review progress, apply a problem-solving approach to address any barriers in implementing the tailored strategies, and plan for the future. Six clinicians delivered 457

intervention sessions to 99 participants. Ninety-two participants completed the intervention (see Figure 1).

Clinicians were post-graduate trained clinical psychologists or social workers, with previous experience delivering psychological interventions to older adults. Clinicians received training in implementing PEARL and ongoing group clinical supervision.

2.5. Adherence fidelity

Adherence fidelity for individual sessions was assessed by audio-recording a random selection of 12 intervention sessions. A checklist was developed for each of the five sessions, to identify if essential elements were covered, as well as any commission errors, based on the approach of Moncher and Prinz (1991). An independent reviewer listened to the audio-recordings and determined whether each criterion on the checklist was met in the session. An overall adherence rate of 93% was determined.

2.6. Data Collection

Data collection took place between February 2017 and December 2019. Trial data were collected at baseline (T1), 4 weeks after participants entered the facility (M=4.4 weeks, SD=0.9); one week post-intervention (T2, M=8.2 weeks after baseline, SD=0.6); two months post-intervention (T3, M=16.1 weeks after baseline, SD=0.6) and six months post-intervention (T4, M=31.0 weeks after baseline, SD=1.4). T3 (two months post-intervention) was established as the primary end-point prior to trial commencement (Davison et al., 2020).

The five research assistants collecting data had at least a four-year degree in Psychology and received extensive training prior to collecting data independently and ongoing supervision

throughout data collection. Despite efforts to ensure the research assistants were blind to the condition to which facilities had been randomised, they were unblinded on thirteen occasions in relation to nine facilities. This occurred when participants or staff mentioned their involvement in the PEARL intervention or when a research assistant's and clinician's visits to a facility coincided.

2.7. Measures

Unless otherwise specified, all measures were administered to participants at all four time points. Facility-level data were collected once during the course of the study, including the facility size (number of beds) and whether or not the nursing home was not-for-profit.

The following participant demographic data were collected at T1 only: Gender, date of birth, country of birth, first language, and date of admission to facility.

The primary outcome was level of depressive symptoms, assessed with the Cornell Scale for Depression in Dementia (Alexopoulos et al., 1988). This scale is suitable for use with older people with and without dementia and has been validated for use in nursing homes (McCabe et al., 2006). The scale was administered and scored according to the author's guidelines, but with additional prompts to assist in determining the presence and severity of symptoms. Separate clinical interviews were conducted with the participant and with a staff informant. Information collected in these interviews were integrated with behavioural observations made by the research assistant to determine an overall score for each item (0 = absent, 1 = mild or intermittent, 2 = severe). Item scores were summed to create the final total score, which ranged from 0 to 38, with higher scores indicating more symptoms of depression. Australian

guidelines suggest that scores of less than 9 indicate no or minimal symptoms (Davison et al., 2012).

The Structured Clinical Interview for DSM-5 Disorders – Clinician Version (SCID-5-CV) was used to determine if participants met criteria for MDD (First et al., 2016). Extra prompts were added to the interview schedule to assist in identifying depressive symptoms in this elderly cohort. Further, modifications recommended by Davison et al. (2009) were made to the instrument to enable it to be used to assess criteria from the perspective of a staff informant, and to record observations made by the assessor. Information from all sources was integrated to determine if each criterion was present.

Participants' medication charts at the facility were reviewed to determine whether or not they had been prescribed any kind of psychotropic medication throughout the trial, from the following medication classes: antidepressants, anxiolytics, benzodiazepines, other hypnotics, mood stabilisers, antipsychotics, and cholinesterase inhibitors. Participants' cognitive function was assessed using the MMSE (Folstein et al., 1975) at the eligibility screen only. Higher scores on this measure are indicative of higher cognitive function.

2.8. Statistical analyses

A description of the power considerations has been published in the protocol paper (Davison et al., 2020). In all analyses, alpha level of 0.05 was used to infer statistical significance.

The characteristics of the nursing homes randomised to the intervention and control arms of the study were compared using the χ^2 test for categorical variables and one-way analysis of variance for continuous variables. Similarly, characteristics of the participants in the two

arms were compared using logistic regression for categorical data and one-way analysis of variance for continuous data. The participant's facility was included as a co-variate in these models, to account for clustering. These analyses were completed with IBM SPSS, version 26 (IBM Corp, 2019).

Analyses of the outcomes were completed with Stata/SE 16 (StataCorp, 2019). The primary analyses were intention to treat. The aim was to include all the participants in these analyses; however, it was only possible to include 216 of 219 participants because two withdrew from the study and requested that their data not be used, and the data from another participant were considered unreliable, based on the perception of the assessor that the participant did not understand the questions. Supplementary per-protocol analyses were also conducted, to determine the effect of the intervention only in participants who completed the protocol as intended. Data from participants who had provided data at T1, T2, and T3 were included in per protocol analyses, and in addition, participants in the intervention condition must have completed at least four of the five intervention sessions to be included (see Figure 1).

We initially intended to undertake multilevel longitudinal modelling to analyse changes in depressive symptoms in the intervention and control groups over time, focusing on the time by group interaction (Davison et al., 2020). However, this approach resulted in model non-convergence when combined with multiple imputation. We therefore opted for the simplified but equivalent approach of analysing change at each time point. A multilevel regression analysis (Model 1) was used to compare changes in the level of depressive symptomology in the intervention and control groups between T1 and T3, our primary endpoint. Given our interest in determining longer-term outcomes, we conducted a second regression analysis

(Model 2), comparing changes in depressive symptomology between T1 and T4. In each model, level one was the individual and level two was the facility. The models included condition (intervention/control), which was of primary interest, as a fixed factor. The following covariates were also included: level of depressive symptoms at T1, total number of beds in the facility, and use of psychotropic medication at each time point[1]. Facility was modelled as a random intercept.

Two sets of subgroup analyses were conducted. First, analyses were conducted to examine whether the impact of the PEARL intervention on depressive symptoms varied as a function of the residents' cognitive functioning. A predictor was included in Model 1 indicating presence (MMSE < 24) or absence of cognitive impairment (MMSE ≥ 24) at screening. A two-way interaction was examined: condition (intervention/control) by cognitive functioning. Second, analyses were conducted to determine whether the impact of PEARL on depressive symptoms was different for those with and without MDD at baseline. A predictor indicating baseline MDD/no MDD was added to Model 1, and the interaction between condition (intervention/control) and baseline MDD/no MDD was examined.

Supplementary analyses were conducted to compare the changes in MDD status in the intervention and control groups over time, using a multilevel logistic regression (Model 3). This model allowed us to account for within-facility clustering of participants and the repeated measures design of the study. Level one was assessment time point, level two was the individual, and level three was the facility. The models included condition (intervention/control), assessment time (T1, T2, T3 and T4), and condition by time

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[1] We originally intended to include organisational climate variables in the models as additional covariates (see Davison et al., 2020). However, these variables made a negligible contribution to the models and were omitted from our final analyses. Data are available from the authors upon request.

interaction (of primary interest) as fixed factors. The following covariates were also included: number of beds in the facility and use of psychotropic medication at each time point. Facility was included as a random intercept.

Multiple imputation was used to mitigate the potential of bias arising from missing data. Separate imputation models were used for each outcome, with the missing values derived via 20 imputations using the chained equations approach (Azur et al., 2011). All predictors used in analyses were included in the imputation models and clustering was accounted for by including facility and the unique subject identifier as factor variables (Eddings and Marchenko, 2020).

3.0. Results

The characteristics of the nursing homes involved in the study are described in Table 1. No significant differences were detected between those randomised to the intervention and control conditions. As detailed in the flowchart (Figure 1), several facilities either failed to refer residents (2 facilities in intervention, 6 in control), or only referred residents who were ineligible or did not consent to participate (3 facilities in intervention, 6 in control). While there was greater attrition of facilities in the control condition, we did not detect differences in the characteristics of facilities with participating residents in the intervention or the control condition at the end of the trial (see Table 1). Finally, we did not detect differences in the characteristics of facilities where recruitment occurred and where no recruitment occurred.

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Insert Table 1 approximately here

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Baseline sample characteristics for each condition are provided in Table 2. Participants in the intervention condition had significantly lower cognitive functioning than those in the control. No other characteristics were significantly different between the conditions, including baseline level of depressive symptoms or proportion of the sample with MDD. Table 2 also contains a comparison of the baseline characteristics of participants who did and did not complete the trial. The only significant difference detected was that those who withdrew had more depressive symptoms at baseline.

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3.1 Depressive symptoms

The effects of the intervention on level of depressive symptoms between T1 and T3 were explored using Model 1 (see Table 3). Symptom levels reduced over time for residents in both conditions; however, the reduction was greater in the intervention condition (Figure 2). In both the intention to treat and per protocol analyses, condition (intervention/control) contributed significantly to Model 1 (intention to treat $p=.035$, per protocol $p=.022$), indicating that the changes in the level of depressive symptoms differed significantly between the control and intervention conditions. Based on Cohen's (1988) guidelines, the effect size of the intervention was in the small-medium range from T1 to T3 (intention to treat $d=0.36$ and per protocol $d=0.37$). The contribution of the other covariates to the model is described in Table S1 (see supplementary materials).

The effects of the intervention on level of depressive symptoms between T1 and T4 were explored using Model 2 (see Table 3). Condition did not make a significant contribution to either the intention to treat model ($p=.369$) or the per-protocol model ($p=.291$), although there

was a small to medium effect size (intention to treat $d=.32$ and per protocol $d=.29$). It was notable that in Model 1, the facility variable effected the model very slightly (intention to treat facility intraclass correlation [ICC] for the intention to treat analyses = .03) while in Model 2 this variable had a much greater impact (intention to treat facility $ICC=.24$).

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3.2 Subgroup analyses

To examine whether the PEARL intervention had a differential effect on depressive symptoms in participants with and without cognitive impairment at screening, an additional predictor (mild-moderate/no cognitive impairment) was added to Model 1, and a two-way interaction examined (mild-moderate/no cognitive impairment by condition). Neither the predictor (intention to treat: $p=.467$; per protocol: $p=.340$) nor the two-way interaction (intention to treat: $p=.064$; per protocol: $p=.074$) contributed significantly. While the interaction effect did not reach $p=.05$, a review of group means suggests that those with no cognitive impairment tended to have a greater reduction of depressive symptoms following the PEARL intervention than did those with mild-moderate cognitive impairment (see Table S2 in supplementary materials).

To examine whether the PEARL intervention had a differential effect on depressive symptoms in participants with and without MDD at baseline, an additional predictor (presence/absence of MDD at T1) was added to Model 1 and a two-way interaction examined (presence/absence of MDD at T1 by condition). The predictor made a significant contribution to the model (intention to treat: $p=.014$; per protocol: $p=.001$). The means indicate that the magnitude of change in depressive symptoms between T1 and T3 was greater for those who

initially had MDD than for those who did not (see Table S2 in supplementary materials). However, the two-way interaction did not contribute significantly to the model (intention to treat: $p=.710$; per protocol: $p=.303$).

3.3 Supplementary analyses: Presence or absence of Major Depressive Disorder

Preliminary data on the effect of the intervention on the presence or absence of MDD were explored using Model 3 (Table S3). The rate of MDD in each condition ranged from 9.3%-16.7% over the four time points. No significant time by group interaction was observed for MDD in either the intention to treat analysis ($p=.571$) or the per protocol analysis ($p=.343$). The other included variables failed to contribute significantly to Model 2 (see Table S4 in supplementary materials).

To gain a clearer picture of study outcomes for participants with MDD, changes in diagnosis from baseline to the primary endpoint (T3) were reviewed for the subset of 25 participants who met criteria for MDD at baseline. There were 12 participants in the intervention group with MDD at baseline. At T3, 2 participants continued to present with MDD, while 6 participants no longer met criteria (data were missing for 4 participants). There were 13 participants with MDD in the control group at baseline. At T3, 8 participants continued to present with MDD, while 2 participants no longer met criteria (data were missing for 3 participants).

New cases of MDD that emerged during the study were also reviewed to determine if the intervention provided a protective effect, examining 177 participants who did not meet criteria for MDD at baseline. At T3, there were 4 new cases of MDD in the intervention group and 6 new cases of MDD in the control group.

4. Discussion

This trial adds to our knowledge of effective nonpharmacological interventions to reduce symptoms of depression in nursing homes. This is one of the few published trials of an intervention demonstrating a significant improvement in the mental health in newly admitted residents, compared to a control condition. While the effect size was modest, given the major challenges that residents face relocating to an institutional environment (Brownie et al., 2014; Sury et al., 2013) and the high level of depressive symptoms typically found in this setting, a simple, five-session intervention that reduces symptoms represents a clinically important outcome. The mean scores on the Cornell Scale reduced during the trial from a level indicative of causing mild interference with the person's ability to participate in their regular activities to a level indicative of minimal or no symptoms, according to Australian guidelines (Davison et al., 2014). The treatment effect was established when using an intention to treat approach analysing outcomes for all residents enrolled in the study, as well as when restricting analyses to those who completed the trial protocol, increasing confidence in the findings. This trial controlled for the size of nursing home and prescription of psychotropic medications, which could also impact on changes in depression. Few residents had any indication of another non-pharmacological treatment in their medical records.

Previous nursing home trials of psychological interventions for depression have reported mixed findings (Simning & Simons, 2017). There is some indication that interventions involving facility staff in an integrated care approach may be more effective (Cody & Drysdale, 2013). Clinicians in our trial reported that engagement with staff was critically important in introducing changes to the resident's day to day activities and care plans, in order to address their needs for autonomy, relatedness, and competence. Anecdotally, both residents and staff reported the benefits of an opportunity to engage with each other around

residents' psychological needs. This was particularly helpful given the common concern expressed by residents in our study of being seen to be 'too demanding' or 'bothering' busy staff, a concern that has been previously reported in this cohort (Mellor et al., 2008). In the PEARL intervention, staff were encouraged to provide reassurance to residents that tailoring care to their psychological needs was a core part of their role.

While PEARL was designed to address factors previously associated with depressive symptoms (Kloos et al., 2019), and had a positive effect on level of symptoms, the trial did not demonstrate a significant decline in the probability of residents in the intervention group presenting with MDD, compared to the control group. This may indicate that the intervention is insufficient to resolve clinical cases. However, the trial was not powered to assess diagnostic changes and the data should be considered as preliminary. It is important to note that the trial sample was non-clinical, with only 12% of participants meeting DSM-5 criteria for MDD at baseline. An examination of this subgroup revealed that 6 of the 12 cases with MDD in the intervention group had resolved by the primary endpoint, compared with only 2 of the 13 cases in the control group. Given the small number of clinical cases at baseline and their high attrition rate, this trend is suggestive only and a future trial with a clinical sample is required to examine the impact of the intervention on resolving cases of MDD. Of interest, subgroup analyses demonstrated that PEARL was similarly effective in reducing symptoms of depression in those with and without MDD at baseline.

We also attempted to assess the effectiveness of PEARL in preventing the onset of new clinical cases, but this was not possible given the very small numbers of participants developed MDD during the course of the trial.

4.1. Limitations

There are a number of important limitations in this trial. We invited a convenience sample of nursing homes to participate, rather than a random sample of all homes across Melbourne, Australia. Slightly fewer homes participating in our study were not-for-profit than the national average; however, larger homes in Australia are more likely to be managed by private organisations (AIHW, 2020). While we did not collect information on the proportion of new nursing home admissions who were referred by staff, or how these referrals differed from those not referred, characteristics of participants in this study appeared to be representative of the broader nursing home population in Australia, in terms of age and gender (see AIHW, 2020). However, residents with limited English fluency were unable to participate. Future studies should seek opportunities to offer the program in other languages or employ interpreters, to determine if this approach is also effective with linguistically diverse older people. Similarly, those with moderate-severe and severe cognitive impairment were excluded from this trial. While presence of mild-moderate cognitive impairment did not have a statistically significant effect on the impact of the intervention on depressive symptoms, there was a trend indicating that the reduction of symptoms may be greater in residents with normal cognition. This requires replication in additional trials recruiting larger numbers of residents with cognitive impairment.

As detailed in Figure 1, just over one quarter of newly admitted residents who were referred to the trial (168/608) either declined to participate or their family members declined on their behalf, with indications that some residents felt overwhelmed post-admission. This raises the possibility of self-selection bias, with the result that participants in this trial may have presented with fewer symptoms of depression at baseline than do newly admitted residents in

general. Further research may determine whether uptake could be improved by offering the program to residents at a slightly later point after admission.

While a significant effect of PEARL on depressive symptoms was demonstrated, it is possible that this effect was the result of residents receiving five visits from a clinician, who engaged the resident in discussion and showed an interest in their feelings and experiences. Future studies should control for this non-specific social or attentional effect, for example, by comparing intervention outcomes with a condition involving 'friendly visits', which previous research has indicated may reduce symptoms of depression, at least while the visits are continuing (Tsai et al., 2008; Wilson et al., 2010).

In this study, we demonstrated a significant treatment effect of PEARL on depressive symptoms from baseline to the primary endpoint, two months post-intervention. However, the effect on symptoms from baseline to 6-month follow-up was not significant. This was despite a similar treatment effect size to that found in the T1 to T3 analysis. Examination of intraclass correlation coefficients suggested that there was a much stronger clustering effect from T1 to T4, with more similarity in the degree of changes in depression within an individual facility over the longer time period. This may be due to the impact of the shared physical, social or care environment on resident depression over time. In our models, this clustering effect likely impacted on the p-value for the effect of study condition. In addition, there was greater attrition over the longer period. Further research is required to determine the longer-term outcomes of this brief intervention, with larger sample sizes to account for the clustering effect and participant attrition.

5. Conclusions

PEARL is effective in reducing the level of depressive symptoms among residents newly admitted to nursing homes. In this trial the intervention was implemented by experienced clinicians and it is recognised that in many nursing homes clinicians are not readily available to deliver psychological programs (Stargatt et al., 2017). In order to disseminate the program into standard care across nursing homes, for use with all newly admitted residents, alternative implementation models may be required. Further research is required to determine if PEARL can be implemented by nursing home staff in situ, and to identify the training and continuing support that is required for this model to be effective. Alternatively, clinicians may target their limited resources to treating higher need nursing home residents, with more research evaluating PEARL for use with residents with higher levels of depression symptoms warranted.

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