

# Home-based family caregiver-delivered music and reading interventions for people living with dementia (HOMESIDE trial): an international randomised controlled trial



Felicity Anne Baker,<sup>a,b,\*</sup> Vanessa Pac Soo,<sup>d,e</sup> Jodie Blaska,<sup>c</sup> Laura Blauth,<sup>h</sup> Anna A. Bukowska,<sup>i</sup> Libby Flynn,<sup>a</sup> Ming Hung Hsu,<sup>c</sup> Edyta Janus,<sup>i</sup> Kjersti Johansson,<sup>b</sup> Tone Kvamme,<sup>b</sup> Nicola Lautenschlager,<sup>f,g</sup> Hayley Miller,<sup>a</sup> Jonathan Pool,<sup>c</sup> Agnieszka Smrokowska-Reichmann,<sup>i</sup> Karette Stensæth,<sup>b</sup> Kate Teggelove,<sup>a</sup> Sven Warnke,<sup>h</sup> Thomas Wosch,<sup>h</sup> Helen Odell-Miller,<sup>c</sup> Karen Lamb,<sup>d,e</sup> Sabine Braat,<sup>d,e</sup> Tanara Vieira Sousa,<sup>a</sup> and Jeanette Tamplin<sup>a</sup>



<sup>a</sup>Creative Arts and Music Therapy Research Unit, The University of Melbourne, Australia

<sup>b</sup>Centre for Research in Music and Health, Norwegian Academy of Music, Norway

<sup>c</sup>Cambridge Institute for Music Therapy Research, Anglia Ruskin University, United Kingdom

<sup>d</sup>Centre for Epidemiology and Biostatistics, Melbourne School of Population and Global Health, The University of Melbourne, Australia

<sup>e</sup>MISCH (Methods and Implementation Support for Clinical Health) Research Hub, Faculty of Medicine, Dentistry and Health Sciences, The University of Melbourne, Melbourne, Australia

<sup>f</sup>Academic Unit for Psychiatry of Old Age, Department of Psychiatry, Melbourne Medical School, The University of Melbourne, Melbourne, Victoria, Australia

<sup>g</sup>North Western Mental Health, Royal Melbourne Hospital, Melbourne, Victoria, Australia

<sup>h</sup>Institute for Applied Social Sciences, Music Therapy Lab, Technical University of Applied Sciences Würzburg-Schweinfurt, Germany

<sup>i</sup>Institute of Applied Sciences, University of Physical Education in Krakow, Poland

## Summary

**Background** Music interventions provided by qualified therapists within residential aged care are effective at attenuating behavioural and psychological symptoms (BPSD) of people with dementia (PwD). The impact of music interventions on dementia symptom management when provided by family caregivers is unclear.

**Methods** We implemented a community-based, large, pragmatic, international, superiority, single-masked randomised controlled trial to evaluate if caregiver-delivered music was superior to usual care alone (UC) on reducing BPSD of PwD measured by the Neuropsychiatric Inventory-Questionnaire (NPI-Q). The study included an active control (reading). People with dementia (NPI-Q score  $\geq 6$ ) and their caregiver (dyads) from one of five countries were randomly allocated to caregiver-delivered music, reading, or UC with a 1:1:1 allocation stratified by site. Caregivers received three online protocolised music or reading training sessions delivered by therapists and were recommended to provide five 30-min reading or music activities per week (minimum twice weekly) over 90-days. The NPI-Q severity assessment of PwD was completed online by masked assessors at baseline, 90- (primary) and 180-days post-randomisation and analysed on an intention-to-treat basis using a likelihood-based longitudinal data analysis model. [ACTRN12618001799246](https://doi.org/10.1016/j.eclinm.2023.102224); [ClinicalTrials.gov](https://doi.org/10.1016/j.eclinm.2023.102224) NCT03907748.

**Findings** Between 27th November 2019 and 7th July 2022, we randomised 432 eligible of 805 screened dyads (music  $n = 143$ , reading  $n = 144$ , UC  $n = 145$ ). There was no statistical or clinically important difference in the change from baseline BPSD between caregiver-delivered music ( $-0.15$ , 95% CI  $-1.41$  to  $1.10$ ,  $p = 0.81$ ) or reading ( $-1.12$ , 95% CI  $-2.38$  to  $0.14$ ,  $p = 0.082$ ) and UC alone at 90-days. No related adverse events occurred.

**Interpretation** Our findings suggested that music interventions and reading interventions delivered by trained caregivers in community contexts do not decrease enduring BPSD symptoms.

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\*Corresponding author. 234 St Kilda Rd, The University of Melbourne, Southbank, Melbourne, 3006, Australia.

E-mail address: [felicity.baker@unimelb.edu.au](mailto:felicity.baker@unimelb.edu.au) (F.A. Baker).

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### Research in context

#### Evidence before this study

The 2018 Cochrane review found music interventions in aged care reduced behaviour and psychological symptoms (BPSD), though evidence quality was moderate. No community caregiver-delivered studies were included. On 6th June 2023, we updated the search since the Cochrane review on 19th June 2017. We used the search strings in CINAHL Plus, PsycINFO, Web of Science, PubMed, MEDLINE (Dementia\* OR Alzheimer\* OR neurodegenerative disease\* OR memory loss OR cognitive impairment) AND (music OR musical OR music intervention OR music therap\*) with no language limits. After removing duplicates and studies not conducted in the community, we found 17 studies. Only two randomised controlled trials with 89 and 100 participants involved the elements of caregiver-delivered music interventions at home. Both trials showed positive effects on anxiety, depression, cognition, quality of life and caregiver stress. However, the main focus of these two trials was to examine the effects of group sessions of singing, music listening, and music-with-movement delivered by trained interventionists or music therapists. As part of these group sessions, family caregivers received some coaching and support to use music activities at home. This differed from our study, which solely examined the effectiveness of individually tailored training for caregivers and caregiver-delivered activities. Despite the previous findings, little is known about how effective caregiver-

delivered music interventions are in managing other behavioural and psychological symptoms, such as agitation, apathy, and psychosis, for community-dwelling individuals with dementia.

#### Added value of this study

No significant long-term improvements in BPSD resulted from the intervention, but activities used were safe with no adverse events. Short-term effects were noted by caregivers. Subgroup analysis suggests severe symptoms and vascular dementia patients were more responsive to caregiver-delivered music intervention.

#### Implications of all the available evidence

As per the 2020 Lancet Commission on dementia, addressing modifiable causes is the primary approach for BPSD management. Though caregiver-delivered music intervention by trained therapists didn't create lasting BPSD changes, it was safe. Immediate and short-term measures better capture music intervention impact, aiding daily dementia care. Such interventions are vital during exceptional circumstances like COVID-19, when community-care access is limited. Responder profile differences in dementia patients can guide prioritisation of caregiver-delivered music interventions with limited training resources.

### Introduction

Dementia is a global public health issue, with the healthcare sector calling for evidence-based approaches to enable people living with dementia (PwD) to live at home wherever possible.<sup>1</sup> Family caregivers provide vital community care for PwD; however, behavioural and psychological symptoms of dementia (BPSD), such as agitation, depression, apathy, and aggression, can override caregivers' capacity to cope, increasing their risk of developing physical or psychological illnesses.<sup>2</sup> With the escalating lifetime costs of care, there is an urgent need to implement affordable, accessible, and effective non-pharmacological approaches to BPSD management that can be delivered by caregivers. Clinic-based caregiver programs that adopt cognitive-behavioural or psycho-educational interventions are ineffective in managing BPSD and caregiver wellbeing because of low attendance at training sessions.<sup>3</sup> It is yet to be determined whether home-based caregiver training programs have higher attendance and result in better management of BPSD.

Music interventions provided by qualified music therapists reduce the severity of BPSD and associated

distress experienced by caregivers,<sup>4,5</sup> including clinically significant effects (Cohen's  $d = 2.32$ ).<sup>4</sup> Suggested mechanisms for the positive effects of music in dementia care include activation of neuroplastic and neurochemical processes, auditory-motor coupling, neural entrainment, arousal-mood pathways, and autobiographical and implicit memory.<sup>6</sup> A preliminary study of family caregivers trained in targeted music use suggested the interventions were feasible.<sup>7</sup> However, it has yet to be determined whether family caregivers implementing music interventions in the home context can reduce BPSD. Such reductions in BPSD may have flow on effects such as: enabling PwD to live at home longer, improving life and relationship quality for both caregiver and PwD, and may be a cost-effective approach to support PwD to remain living in their home. Home-based music programs might prevent or delay care home or hospital admissions.

HOMESIDE is a translation of the research evidence for music therapy in a residential aged care context to a home-care context, and instead of music interventions being directly delivered by qualified therapists,

caregivers provide therapy-informed music interventions, following training from qualified therapists.<sup>8,9</sup> We asked, whether caregiver-delivered music interventions decrease BPSD after 90 days in dementia patients, in comparison to standard care (UC). In addition, we assessed the effects of caregiver-delivered music on depression and quality of life of the PwD, as well as caregiver distress derived from BPSD, depression, resilience, sense of caregiver competence, and quality of life and caregiver-PwD relationship quality (secondary outcomes). We also examined whether an active control (reading intervention delivered by caregivers) influenced the same primary and secondary outcomes. Reading was chosen as an active control intervention due to preliminary indications of its positive impact on BPSD.<sup>10</sup>

## Methods

### Study design

HOMESIDE was an international, pragmatic, three-arm, parallel-group, randomised controlled trial. Community-dwelling people with dementia (PwD) and their co-habiting caregiver (dyads) in Australia, United Kingdom (UK), Norway, Poland and Germany, were randomised to one of the three arms: music, reading or UC alone. We hypothesised that caregiver-delivered music would be superior to UC alone in reducing BPSD at 90-days post-randomisation (primary comparison). Online assessments were administered at baseline, 90- and 180-days post-randomisation, and three online training sessions were delivered at weeks 1, 3 and 6 post-randomisation. The study protocol, music intervention protocol, and statistical analysis plan were published prior to database lock.<sup>8,9,11</sup> The trial was approved by ethics committees at The University of Melbourne (no.1852845) and local approvals were obtained for each country.<sup>8</sup> Protocol changes made prior to and post-enrolment of the first participant are detailed in [appendix p 2](#). The trial is reported according to the CONSORT-CONSERVE guidelines. [ACTRN12618001799246](#) (Registered 5th November 2018); [ClinicalTrials.gov](#) [NCT03907748](#) (Registered 9th April 2019).

### Participants

Eligibility criteria were defined as 1) community-dwelling, co-habiting dyads close in relationship, 2) residing in either Australia, Germany, Poland, Norway, and the UK, 3) where the person has a dementia diagnosis, 4) was scoring  $\geq 6$  on the Neuropsychiatric Inventory Questionnaire (NPI-Q) at the time of screening,<sup>12</sup> and 5) where consent/assent was given by caregiver and PwD. Each team explored different options for recruitment, including paid advertising, social media (targeted Facebook groups), commercial media (TV, radio, newspapers, magazines), YouTube recruitment videos, live presentations at aged care events,

direct contact with aged care organisations, and accessing research databases (Join Dementia Research [UK] and StepUp for Dementia Research [Australia]). The UK team also had recruitment support from the National Institute for Health Research (NIHR) Clinical Research Network, including nine National Health Service Trusts (NHS) research sites and two participant identification centres. A full description of inclusion criteria, screening processes, and recruitment strategies is described elsewhere.<sup>8,11,13</sup>

### Randomisation and masking

Dyads were randomly allocated to one of the three intervention groups with a 1:1:1 allocation using a computer-generated schedule of randomly permuted blocks, stratified by site (Northern Australia, Southern Australia, Germany, Norway, Poland, and the UK) and was uploaded by an independent statistician to a randomisation module in the Research Electronic Data Capture trial database hosted at The University of Melbourne. Randomisation occurred after baseline assessment was completed; assessors and statisticians were masked to group allocation throughout the trial; participating dyads could not be masked due to the nature of the interventions. When accidental unmasking occurred, a new masked assessor was assigned to continue until trial completion.

### Interventions

The music training program involved a 2-h home-based session in which a qualified music therapist instructed the caregiver on receptive (music listening) and active (singing, movement to music, instrument playing) music methods.<sup>9</sup> Guidance was provided on targeted use of music to regulate arousal and to stimulate autobiographical memories. A standardised manual for training was developed prior to implementation. Once trained, caregivers were recommended to use music five times per week for approximately 30 min over 12 weeks, with a minimum of two sessions per week. Minimum dosage was determined based on findings from the most recent Cochrane Review<sup>4</sup> where 13 studies found treatment effects from two music therapy sessions per week. As we anticipated that a higher dose of five times per week, where possible, would lead to greater change in BPSD, we recommended that caregivers provide five sessions per week, however we used the minimum dose as two sessions per week. After each session, caregivers diarised ([appendix p 4](#)) their experiences, documenting duration, types of activities used, and whether they perceived a positive impact on BPSD (agitation, distress, lucidity, awareness) immediately post-music use and for the rest of the day. At weeks 3 and 6 post-randomisation, caregivers were provided with additional 2-h training sessions with a qualified music therapist to extend their knowledge and skills, troubleshoot emerging issues, and encourage adherence. Fortnightly phone calls were

conducted to record music use, mitigate risk of non-completion, maximise participant engagement, retention, and adherence, and document adverse events.

The reading training program (3 sessions at weeks 1, 3 and 6 post-randomisation) was implemented using the same structure (including fortnightly phone calls) as the music intervention. Occupational therapists trained caregivers in use of receptive (listening to audiobooks) and active (reading aloud, playing word games, discussing texts) reading activities. Caregivers allocated to the UC condition were instructed to care for the PwD in their usual manner. To control for the potential influence of psychosocial support on NPI-Q distress that those in music and reading may derive from phone calls, those in UC also received fortnightly phone calls.

Initially, the music and reading training were provided in person; however, in May 2020, home visits were cancelled after 21 (4.9% of actual sample size) randomised dyads due to lockdowns associated with the COVID-19 pandemic, and the training sessions moved to online delivery for the remainder of the trial. No unmasked data were seen before these changes. The trial protocol and registration were amended at the time of the change.<sup>11</sup>

Therapists and assessors received local monthly supervision and bi-monthly international supervision to promote intervention fidelity, support consistent administration of assessments, and improve data quality. 20% of video recordings of music and reading training sessions from each site were randomly selected for review using a customised fidelity checklist ([appendix p 5](#)).

## Outcomes

The assessment visit schedule is detailed in the statistical analysis plan.<sup>11</sup> At baseline, dyad demographics and dementia diagnostic data were collected. All outcomes were assessed at baseline, 90- and 180-days except for the Mini-Mental State Examination (MMSE),<sup>14</sup> collected at baseline and 90-days. The primary outcome of BPSD was assessed using the severity subscale of the NPI-Q. The NPI-Q is the most highly regarded and used measure for determining the severity of BPSD in clinical trials.<sup>15</sup> The 12-item scale is used to assess the behaviour of PwD across 12 domains of commonly displayed BPSD - hallucinations, delusions, depression, anxiety, disinhibition, agitation, elation, apathy, irritability, aberrant motor behaviour, sleep and appetite. The 12 items each describe a specific symptom and caregivers are asked to rate these from 1 (mild) to 3 (severe) as well as rate their associated distress from 0 (not distressing) to 5 (extreme or very severe distress). Total severity scores range from 0 to 36; higher values are indicative of higher severity. Distress scores range from 0 to 60; higher values represent higher levels of distress. The scale has 3 subscales: 1) Agitation/aggression (agitation/aggression, disinhibition, irritability/lability, motor disturbance,

scores between 0 and 12); 2) Mood (depression/dysphoria, anxiety, irritability/lability, scores between 0 and 9); Frontal (elation/euphoria, apathy/indifference, disinhibition, irritability/lability, scores between 0 and 12). Caregivers self-completed the NPI-Q with guidance from the assessor when required. The NPI-Q has been translated into >40 languages, has been cross-validated against the NPI as the gold standard ( $r = 0.73$ ), and has demonstrated good validity (sensitivity = 74.1%, specificity = 79.5%), internal reliability ( $\alpha = 0.783$ ), and excellent test-retest reliability ( $r = 0.99$ ).<sup>12,16</sup>

Detailed descriptions of secondary outcome measures, including reliability and validity data, are reported in the protocol.<sup>8</sup> For the PwD, secondary measures were: 1) depression (Montgomery Asberg Depression Rating Scale, MADRS),<sup>17</sup> 2) quality of life (Quality of Life-Alzheimer's Disease, QoL-AD),<sup>18</sup> and 3) cognition (MMSE).<sup>14</sup> Caregiver wellbeing measures comprised: 1) distress derived from BPSD (NPI-Q distress subscale),<sup>12</sup> 2) depression (Patient Health Questionnaire-9, PHQ-9),<sup>19</sup> 3) resilience (Resilience Scale-14),<sup>20</sup> 4), sense of competence in caregiving (Short Sense of Competence Questionnaire),<sup>21</sup> 5) quality of life (Assessment of Quality of Life-6D instrument),<sup>22</sup> and 6) caregiver perception of quality of the caregiver and PwD relationship (Quality of Caregiver-Patient Relationship).<sup>23</sup>

Adverse events were captured during assessment sessions, training sessions, and fortnightly phone calls; classified as serious or not serious; and related or unrelated to the intervention. COVID-19 infections and death were also captured as adverse events.

## Statistical analysis

The statistical analysis was outlined in a detailed plan prior to database lock.<sup>11</sup> Changes made post-unmasking are detailed in [appendix p 2](#). A total of 495 dyads (165 per arm) were needed to detect an absolute mean difference of 3-points in the NPI-Q severity score between the music and UC arm at 90-days, assuming a conservative standard deviation (SD) of 7.5 points, no correlation between baseline and post-baseline measurements (conservative), and including 20% attrition (90% power, two-sided alpha 5%).

All available data was included according to the randomised assignment of the dyad (i.e. intention-to-treat). The NPI-Q severity score of the PwD was analysed using a likelihood-based longitudinal data analysis model<sup>24</sup> to obtain an estimate of the intervention effect (i.e., absolute mean difference between arms in the change from baseline to 90-days) irrespective of the dyad's adherence or experienced intercurrent events, except for death, in which case the worst possible score was assigned to the subsequent visit. The model included site and used an unstructured variance-covariance among the repeated measurements. In an additional analysis, the pre-specified potential

prognostic variables dementia type, gender of PwD, and caregiver's relationship with PwD were added to the primary model. A further analysis including all randomised dyads provided an estimate of the intervention effect among those dyads who adhered to their randomised intervention using a complier average causal effect (CACE) analysis.<sup>25</sup> Adherence (yes/no) was derived for the music and reading groups using diary and phone call data. As the primary model provides valid inference under the missing-at-random assumption, multiple imputation was performed before conducting the CACE analysis. A post-hoc analysis based on the delta-adjustment method to assess sensitivity to NPI-Q data missing not at random was added. Continuous secondary outcomes were analysed using a model similar to the primary model of the primary outcome. Adverse events were summarised by actual intervention group. Perceived effects (positive, neutral/unsure, or negative) and durations of music and reading intervention sessions recorded in the participant diaries were summarised by intervention group, country, and type of activity as a post-hoc analysis.

Point estimates and two-sided 95% confidence intervals are provided alongside two-sided P values. The comparison of music vs UC and reading vs UC occurred at the 5% level of significance. The comparison of music with reading was planned only if music vs UC was statistically significant (i.e., P value <0.05). No adjustment for multiple testing was planned. Eight pre-specified subgroup analyses were performed for the NPI-Q severity score of the PwD using baseline characteristics: gender of the PwD, gender of the caregiver, dementia type, dementia severity, time of onset of dementia, caregiver's relationship to PwD, country, length of time living with dementia (continuous) and four post-hoc subgroup analyses consisting of current use of music and reading in daily life (PwD and caregiver) at baseline. Analyses were performed in Stata/SE, version 16.1 (Stata Corporation, College Station, TX, USA).

The trial was overseen by an independent data safety and monitoring board, no interim analyses were conducted.

### Role of the funding source

The study was undertaken independently of any input from funding bodies. Funders have had no role in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the paper for publication. Public and Participant Involvement (PPI) was embedded throughout the study with an overarching international committee and active PPI committees for public engagement for each country, including people with lived experience. All authors had access to the data and contributed to interpreting the data, revising the manuscript, and approving the final version of the

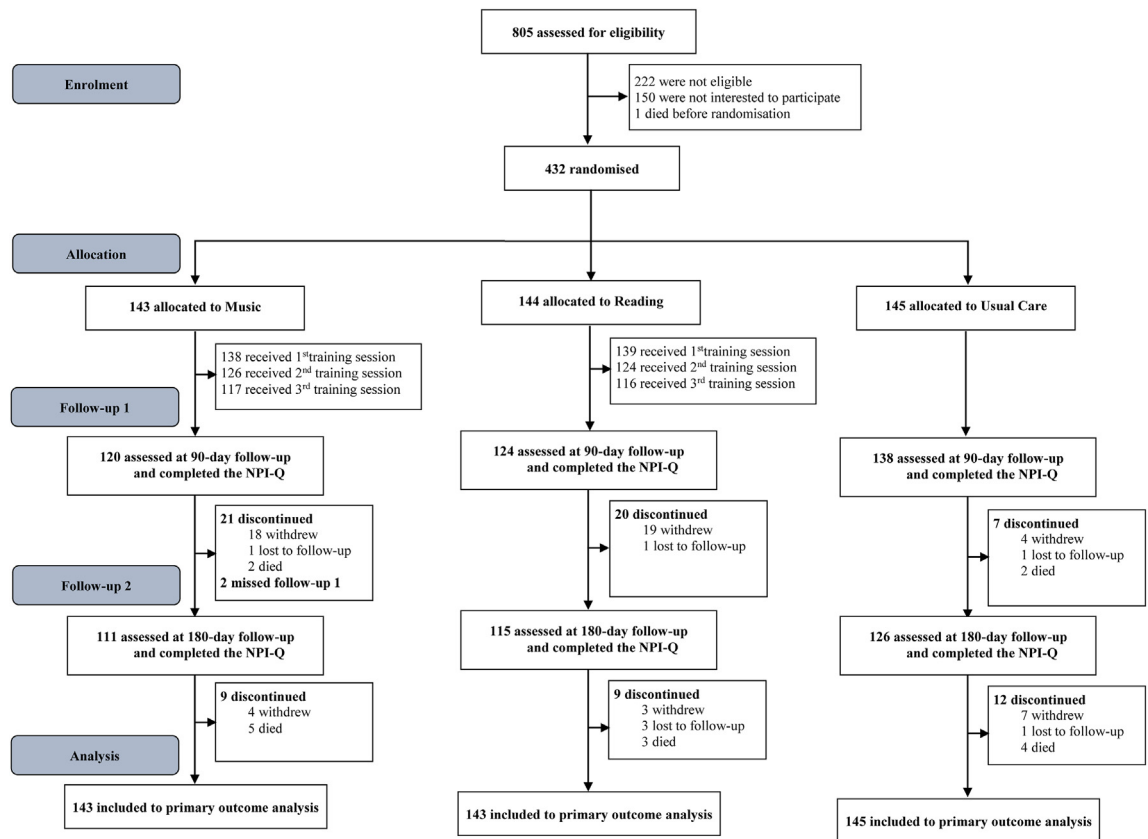
manuscript. All authors had final responsibility for the decision to submit for publication.

### Results

Recruitment commenced in October 2019, with the first randomisation on 27th November 2019 and the last on 7th July 2022.<sup>13</sup> 432 of 805 dyads met the inclusion criteria, consented to participate, and were randomised to music, reading or UC (Fig. 1). Table 1 shows baseline demographic and clinical characteristics of PwD and caregivers. Groups were similar at baseline. 45% (195) of PwD were female, 81% (351) of caregivers were female. A total of 61% (262) of PwD had a neurodegenerative dementia diagnosis (Alzheimer's Disease, Frontotemporal, Lewy Body); 23% (74) had no cognitive impairment (>23 MMSE), 28% (89) had mild impairment, 34% (109) had a moderate impairment, and 15% (48) had severe impairment (Table 1, appendix p 6). More participants were lost in the music (32 [22%]) and reading (29 [20%]) groups compared with UC (19 [13%]). Most dyads received all three music (117 [82%]) and reading (116 [81%]) training sessions (Fig. 1). Assessment of compliance of the training sessions to the protocol according to the fidelity checklist was high (music 37 of 41 [90%]; reading 30 of 32 [94%]) (appendix p 9). A total of 67% (96) of caregivers allocated to music and 63% (90) allocated to reading met minimum adherence defined as allocated interventions having been provided to PwD at least twice weekly sessions for 10 weeks during the 12-week intervention period (appendix p 10). Use of music and reading in daily life at baseline, follow-up at 90- and 180-days post-randomisation, irrespective of the randomised intervention, are reported by treatment group (appendix p 11). Overall, 332 (77%) of the PwDs and 91 (21%) of the caregivers took medication (appendix p 12). Initiation of new medication post-baseline was uncommon (i.e.<3%). There were 11 instances of accidental unmasking of the assessor at 90-day assessments. Successful replacement of a second masked assessor was achieved for eight dyads; two were fully unmasked, and one withdrew at the time of unmasking.

In PwD, change from baseline NPI-Q severity was not superior for dyads randomly assigned to music compared to UC at 90-days (-0.15, 95% CI -1.41, 1.10,  $p = 0.81$ ) or at 180-days (0.18, 95% CI -1.54, 1.91,  $p = 0.84$ ) irrespective of post-randomisation events (Table 2, appendix p 16, p 17). Reading was also not superior to UC at 90-days (-1.12, 95% CI -2.38, 0.14,  $p = 0.082$ ) but was at 180-days (-1.81, 95% CI -3.54, -0.09,  $p = 0.039$ ); changes in NPI-Q were not clinically meaningful.<sup>26</sup> The adjusted analysis confirmed the unadjusted analysis results and the findings were also similar in the complier average causal effect analysis and under the assumption of a different missing data mechanism (appendix p 18). Analyses of secondary





**Fig. 1: Trial profile.** Abbreviations: NPI-Q = Neuropsychiatric Inventory-Questionnaire; PwD = Person with Dementia. The figure illustrates the trial profile detailing participant allocation and withdrawals across intervention groups (music, reading, and usual care). Initially, 805 dyads were assessed for eligibility. Among these, 432 dyads meeting inclusion criteria and giving consent were randomised into music, reading, or usual care groups. In the music intervention group, 30 dyads discontinued the trial, citing Caregivers’ burden or health deterioration (6), PwD health deterioration or transition to Residential Aged Care (7), PwD death (7), allocation refusal (1), lost to follow-up (1) and other reasons (5). Two participants within the music group missed the 90-day follow-up assessment but completed the 180-day follow-up. Similarly, within the reading group, 25 dyads withdrew due to caregivers’ burden or health deterioration (7 dyads), PwD health deterioration or transitioning to Residential Aged Care (8 dyads), PwD death (3), allocation refusal (2 dyads), and other reasons (5 dyads), plus 4 dyads were lost to follow-up. Most dyads in the music (117 dyads, 82%) and reading (116 dyads, 81%) groups completed all three training sessions. Across the interventions, attrition was higher in music (30 dyads, 22%) and reading (29 dyads, 20%) groups compared to usual care (19 dyads, 13%).

outcomes for PwD found no significant differences in the change from baseline in QoL at 90- and 180-days for music and reading compared to UC, with QoL decreasing over time in all three randomised groups (Table 2, appendix p 16 p 17). Compared to UC, no differences were found for change from baseline in depression or cognition for either music or reading at 90- or 180-days (Table 2, appendix p 16).

In caregivers, analyses of secondary outcomes found that music and reading were not superior to UC at 90-days, except for resilience (music, 1.76, 95% CI 0.01, 3.52,  $p = 0.049$ ). At 180-days, there was no significant difference in change from baseline in caregivers of dyads randomised to music compared to UC in any of the secondary outcomes. Reading was superior to UC at lowering the experience of caregiver distress caused by BPSD ( $-2.24$ , 95% CI  $-4.16$ ,  $-0.31$ ,  $p = 0.023$ ; Table 2,

appendix p 20, 21, NPI-Q distress) and significantly better in increasing resilience (2.58, 95% CI 0.59, 4.58,  $p = 0.011$ ), while significantly worse at improving QoL ( $-1.69$ , 95% CI  $-3.20$ ,  $-0.19$ ,  $p = 0.027$ ) at 180-days.

A post-hoc investigation comparing the duration of daily use of music and reading activities indicated that dyads allocated to the music spent more time (45.9 min per session, SD 37.2) using the proposed intervention activities than those in reading (34.1 min, SD 22.3). For the music group, listening to music, combined with at least one other activity, was more prevalent (1957 of 4849, 40%) than other music activities, and showed positive effects on the dyads’ shared experiences (1780 of 1957, 91%) and on dementia symptoms (agitation, distress, lucidity, awareness) for the rest of the day (1428 of 1877, 76%). Reading aloud together was the most frequently used activity by the reading group. A

	Person with dementia				Caregiver			
	Music	Reading	Usual care	Total	Music	Reading	Usual care	Total
	N = 143	N = 144	N = 145	N = 432	N = 143	N = 144	N = 145	N = 432
Age (years)	76.6 (8.6)	76.7 (9.1)	77.2 (8.7)	76.8 (8.8)	63.1 (12.6)	63.9 (11.2)	65.1 (12.0)	64.0 (12.0)
Sex								
Male	78/143 (55%)	79/144 (55%)	80/145 (55%)	237/432 (55%)	25/143 (17%)	27/144 (19%)	29/145 (20%)	81/432 (19%)
Female	65/143 (45%)	65/144 (45%)	65/145 (45%)	195/432 (45%)	118/143 (83%)	117/144 (81%)	116/145 (80%)	351/432 (81%)
Site								
Northern Australia (NSW, QLD, ACT)	19/143 (13%)	18/144 (13%)	19/145 (13%)	56/432 (13%)	19/143 (13%)	18/144 (13%)	19/145 (13%)	56/432 (13%)
Southern Australia (Rest of Australia)	18/143 (13%)	17/144 (12%)	17/145 (12%)	52/432 (12%)	18/143 (13%)	17/144 (12%)	17/145 (12%)	52/432 (12%)
United Kingdom	37/143 (26%)	38/144 (26%)	37/145 (26%)	112/432 (26%)	37/143 (26%)	38/144 (26%)	37/145 (26%)	112/432 (26%)
Germany	35/143 (24%)	36/144 (25%)	37/145 (26%)	108/432 (25%)	35/143 (24%)	36/144 (25%)	37/145 (26%)	108/432 (25%)
Norway	18/143 (13%)	20/144 (14%)	19/145 (13%)	57/432 (13%)	18/143 (13%)	20/144 (14%)	19/145 (13%)	57/432 (13%)
Poland	16/143 (11%)	15/144 (10%)	16/145 (11%)	47/432 (11%)	16/143 (11%)	15/144 (10%)	16/145 (11%)	47/432 (11%)
Marital status								
Married or De Facto	108/142 (76%)	101/139 (73%)	112/145 (77%)	321/426 (75%)	127/140 (91%)	124/138 (90%)	125/144 (87%)	376/422 (89%)
Single, divorced or separated	3/142 (2%)	7/139 (5%)	5/145 (3%)	15/426 (4%)	11/140 (8%)	13/138 (9%)	17/144 (12%)	41/422 (10%)
Widowed	31/142 (22%)	31/139 (22%)	28/145 (19%)	90/426 (21%)	2/140 (1%)	1/138 (1%)	2/144 (1%)	5/422 (1%)
PwD's dementia diagnosis								
Neurogenerative diseases (Alzheimer's disease, Frontotemporal dementia, Lewy body disease)	79/143 (55%)	92/144 (64%)	91/145 (63%)	262/432 (61%)	-	-	-	-
Mixed (Vascular dementia, Mixed dementia)	38/143 (27%)	26/144 (18%)	23/145 (16%)	87/432 (20%)	-	-	-	-
Other (other or unknown)	26/143 (18%)	26/144 (18%)	31/145 (21%)	83/432 (19%)	-	-	-	-
Severity of dementia								
No cognitive impairment (MMSE: 24-30)	25/111 (23%)	28/106 (26%)	21/103 (20%)	74/320 (23%)	-	-	-	-
Mild cognitive impairment (MMSE: 19-23)	33/111 (30%)	23/106 (22%)	33/103 (32%)	89/320 (28%)	-	-	-	-
Moderate cognitive impairment (MMSE: 10-18)	36/111 (32%)	39/106 (37%)	34/103 (33%)	109/320 (34%)	-	-	-	-
Severe cognitive impairment (MMSE: <10)	17/111 (15%)	16/106 (15%)	15/103 (15%)	48/320 (15%)	-	-	-	-
Time of onset dementia								
Early (under 65 years old)	24/143 (17%)	28/144 (19%)	23/145 (16%)	75/432 (17%)	-	-	-	-
Late (≥65 years old)	119/143 (83%)	116/144 (81%)	122/145 (84%)	357/432 (83%)	-	-	-	-
Caregiver's relationship with PwD								
Spouse/partner	-	-	-	-	92/143 (64%)	93/144 (65%)	89/145 (61%)	274/432 (63%)
Child	-	-	-	-	48/143 (34%)	46/144 (32%)	52/145 (36%)	146/432 (34%)
Other	-	-	-	-	3/143 (2%)	5/144 (3%)	4/145 (3%)	12/432 (3%)
Length of relationship with PwD (years)	-	-	-	-	45.0 (35.0-57.0)	50.0 (36.0-56.0)	50.0 (43.0-58.0)	50.0 (38.0-57.0)
Highest level of education								
No formal schooling/Primary school	12/141 (9%)	11/144 (8%)	19/145 (13%)	42/430 (10%)	2/143 (1%)	0/144 (0%)	0/145 (0%)	2/432 (0%)
Secondary or high school	30/141 (21%)	41/144 (28%)	39/145 (27%)	110/430 (26%)	22/143 (15%)	21/144 (15%)	30/145 (21%)	73/432 (17%)
Trade, community or TAFE college	39/141 (28%)	37/144 (26%)	30/145 (21%)	106/430 (25%)	31/143 (22%)	42/144 (29%)	32/145 (22%)	105/432 (24%)
Bachelors degree	31/141 (22%)	28/144 (19%)	28/145 (19%)	87/430 (20%)	47/143 (33%)	35/144 (24%)	42/145 (29%)	124/432 (29%)
Masters degree	23/141 (16%)	24/144 (17%)	23/145 (16%)	70/430 (16%)	40/143 (28%)	39/144 (27%)	36/145 (25%)	115/432 (27%)
PhD	6/141 (4%)	3/144 (2%)	6/145 (4%)	15/430 (3%)	1/143 (1%)	7/144 (5%)	5/145 (3%)	13/432 (3%)
Current or last job/occupation <sup>a</sup>								
Manager	20/143 (14%)	15/143 (10%)	18/143 (13%)	53/429 (12%)	21/142 (15%)	19/141 (13%)	15/144 (10%)	55/427 (13%)
Professional	48/143 (34%)	60/143 (42%)	47/143 (33%)	155/429 (36%)	68/142 (48%)	69/141 (49%)	72/144 (50%)	209/427 (49%)
Technicians and associate professionals	19/143 (13%)	13/143 (9%)	21/143 (15%)	53/429 (12%)	21/142 (15%)	20/141 (14%)	19/144 (13%)	60/427 (14%)
Clerical support workers	13/143 (9%)	7/143 (5%)	12/143 (8%)	32/429 (7%)	10/142 (7%)	10/141 (7%)	15/144 (10%)	35/427 (8%)
Service and sales workers	15/143 (10%)	13/143 (9%)	13/143 (9%)	41/429 (10%)	16/142 (11%)	18/141 (13%)	17/144 (12%)	51/427 (12%)

(Table 1 continues on next page)

	Person with dementia				Caregiver			
	Music	Reading	Usual care	Total	Music	Reading	Usual care	Total
	N = 143	N = 144	N = 145	N = 432	N = 143	N = 144	N = 145	N = 432
(Continued from previous page)								
Craft and related trade workers	10/143 (7%)	11/143 (8%)	13/143 (9%)	34/429 (8%)	0/142 (0%)	1/141 (1%)	1/144 (1%)	2/427 (0%)
Other	14/143 (10%)	15/143 (10%)	18/143 (13%)	47/429 (11%)	6/142 (4%)	4/141 (3%)	5/144 (3%)	15/427 (4%)
Never worked professionally	4/143 (3%)	9/143 (6%)	1/143 (1%)	14/429 (3%)	0/142 (0%)	0/141 (0%)	0/144 (0%)	0/427 (0%)
Main source of income								
Own income/Savings	23/143 (16%)	23/143 (16%)	20/145 (14%)	66/431 (15%)	57/142 (40%)	59/141 (42%)	56/145 (39%)	172/428 (40%)
Pension	102/143 (71%)	106/143 (74%)	112/145 (77%)	320/431 (74%)	52/142 (37%)	49/141 (35%)	55/145 (38%)	156/428 (36%)
Government benefits	8/143 (6%)	6/143 (4%)	5/145 (3%)	19/431 (4%)	7/142 (5%)	10/141 (7%)	9/145 (6%)	26/428 (6%)
Family help	2/143 (1%)	2/143 (1%)	0/145 (0%)	4/431 (1%)	1/142 (1%)	1/141 (1%)	0/145 (0%)	2/428 (0%)
The same income from PwD	-	-	-	-	4/142 (3%)	4/141 (3%)	3/145 (2%)	11/428 (3%)
Other	8/143 (6%)	6/143 (4%)	8/145 (6%)	22/431 (5%)	21/142 (15%)	18/141 (13%)	22/145 (15%)	61/428 (14%)
Currently use music in daily life								
Never	3/140 (2%)	6/139 (4%)	5/131 (4%)	14/410 (3%)	1/142 (1%)	3/143 (2%)	4/144 (3%)	8/429 (2%)
Rarely (less than once per week)	13/140 (9%)	15/139 (11%)	17/131 (13%)	45/410 (11%)	17/142 (12%)	10/143 (7%)	15/144 (10%)	42/429 (10%)
Sometimes (about once per week)	30/140 (21%)	24/139 (17%)	22/131 (17%)	76/410 (19%)	33/142 (23%)	20/143 (14%)	23/144 (16%)	76/429 (18%)
Often (several times per week but less than every day)	45/140 (32%)	36/139 (26%)	45/131 (34%)	126/410 (31%)	43/142 (30%)	43/143 (30%)	45/144 (31%)	131/429 (31%)
Very often (once or more per day)	49/140 (35%)	58/139 (42%)	42/131 (32%)	149/410 (36%)	48/142 (34%)	67/143 (47%)	57/144 (40%)	172/429 (40%)
Currently use reading in daily life								
Never	18/140 (13%)	17/139 (12%)	22/131 (17%)	57/410 (14%)	4/142 (3%)	5/143 (3%)	5/144 (3%)	14/429 (3%)
Rarely (less than once per week)	20/140 (14%)	26/139 (19%)	21/131 (16%)	67/410 (16%)	16/142 (11%)	19/143 (13%)	16/144 (11%)	51/429 (12%)
Sometimes (about once per week)	20/140 (14%)	23/139 (17%)	22/131 (17%)	65/410 (16%)	21/142 (15%)	15/143 (10%)	17/144 (12%)	53/429 (12%)
Often (several times per week but less than every day)	22/140 (16%)	28/139 (20%)	27/131 (21%)	77/410 (19%)	31/142 (22%)	28/143 (20%)	30/144 (21%)	89/429 (21%)
Very often (once or more per day)	60/140 (43%)	45/139 (32%)	39/131 (30%)	144/410 (35%)	70/142 (49%)	76/143 (53%)	76/144 (53%)	222/429 (52%)
Length of time having dementia (years)	2.3 (1.5-4.1)	3.0 (1.5-5.0)	3.0 (2.0-5.0)	3.0 (2.0-5.0)	-	-	-	-

Data are presented as Mean (SD) or Median (IQR) for continuous measures and n/N (%) for categorical measures. NSW = New South Wales; QLD = Queensland; ACT = Australian Capital Territory; PwD = Person with dementia; MMSE = Mini Mental State Examination; TAFE = Technical and Further Education; PhD = Doctor of Philosophy; SD = Standard Deviation; IQR = Interquartile range (25th to 75th percentile); - = Not Applicable. Participants without a MMSE score were categorised clinically as severe (if deemed so) or not assessable. As a result, 21/32 (66%), 27/38 (71%), 25/42 (60%) and 73/112 (65%) of those with a missing MMSE score were additionally categorised as having severe cognitive impairment, thus bringing the total of participants with severe cognitive impairment to 38/132 (29%), 43/133 (32%), 40/128 (31%) and 121/393 (31%) in the music, reading, usual care groups and overall respectively. Baseline measurements obtained at the enrolment visit between 32 days before to just prior to allocation are considered as baseline values. <sup>a</sup>Last job/occupation only for persons with dementia.

**Table 1: Baseline characteristics (Intention-To-Treat Population).**

combination of reading activities was also reported as having a more positive effect on shared experience (320 out of 367, 87%) that remained present during the day (215 out of 360, 60%) (appendix p 22, 23).

Pre-specified subgroup analyses were performed for NPI-Q at 90- (Fig. 2, appendix p 24) and 180-days post-randomisation (appendix p 25, p 26). Compared with UC, PwD with moderate to severe cognitive impairment with a mixed diagnosis tended to be more responsive to music at 90-days but not at 180-days, although the interaction was not statistically significant. For the reading intervention, similar tendencies were evident at 90-days but less so at 180-days (Fig. 2). The treatment effects by gender of the PwD and caregiver, time of onset of dementia, caregiver relationship to PwD, country, and (continuous) length of time having dementia were not statistically different (appendix p

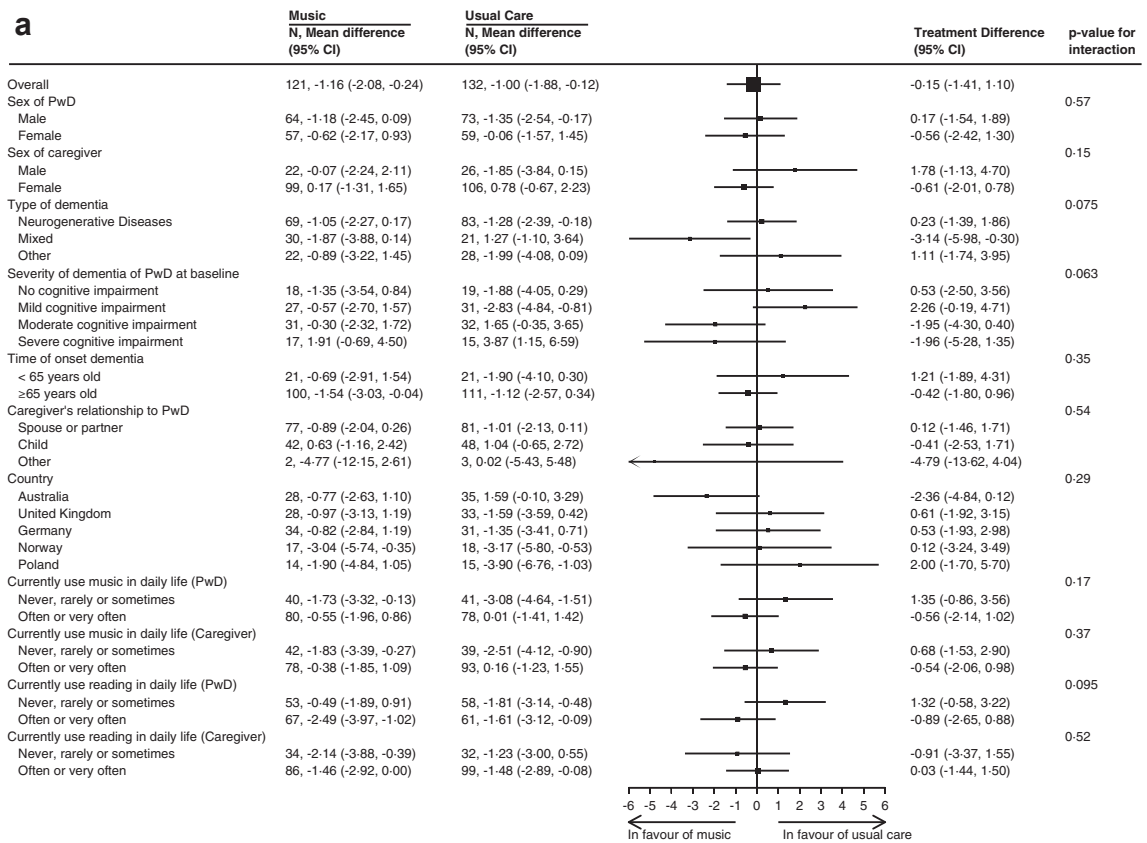
24–26), however forest plots suggest that when PwD were cared for by female caregivers, the PwD were more responsive to the music interventions; however these subgroup differences by sex of the caregiver were not evident in the reading condition. Fig. 2 shows that Australian participants were more responsive to the music intervention than other participants in other countries, largely driven by a greater increase in the NPI-Q (indicating worsening symptoms) in the UC group (appendix p 24). In the post-hoc analysis of participants' diaries, Australian caregivers engaged in music sessions for longer durations (54.2 min, SD 47.3 compared to 45.9 min, SD 37.2 across the whole sample), while caregivers from Poland engaged PwD in reading sessions for longer durations (40.7, SD 34.1 compared to 34.1, SD 22.3 across the whole sample, appendix p 22). When comparing the music



	Music (N = 143)	Reading (N = 144)	Usual care (N = 145)	Music vs usual care Mean difference (95% CI)	P value	Reading vs usual care Mean difference (95% CI)	P value
<b>Person with dementia</b>							
NPI-Q severity score (proxy)							
Baseline	142, 11.5 (4.2)	137, 11.6 (4.9)	142, 11.9 (5.0)	-	-	-	-
90 days	122, 10.5 (6.0)	121, 9.5 (5.2)	134, 10.8 (6.8)	-0.15 (-1.41, 1.10)	0.81	-1.12 (-2.38, 0.14)	0.082
180 days	116, 11.7 (8.2)	116, 9.8 (6.9)	132, 11.6 (7.7)	0.18 (-1.54, 1.91)	0.84	-1.81 (-3.54, -0.09)	0.039
Quality of life (QoL-AD instrument)							
Self							
Baseline	109, 36.2 (5.2)	106, 36.1 (5.5)	106, 35.5 (5.9)	-	-	-	-
90 days	86, 35.3 (6.9)	78, 36.8 (5.9)	91, 35.1 (6.8)	-0.38 (-1.80, 1.04)	0.60	1.27 (-0.18, 2.72)	0.087
180 days	78, 33.0 (8.4)	72, 35.8 (7.1)	84, 34.1 (7.8)	-1.00 (-3.04, 1.03)	0.33	1.23 (-0.84, 3.29)	0.25
Proxy							
Baseline	142, 30.6 (5.4)	141, 30.4 (5.0)	144, 30.4 (5.4)	-	-	-	-
90 days	120, 29.7 (5.7)	121, 30.2 (5.7)	129, 29.4 (5.7)	0.19 (-0.85, 1.24)	0.72	0.54 (-0.50, 1.59)	0.31
180 days	114, 28.7 (6.5)	113, 30.2 (6.4)	126, 28.6 (6.5)	0.03 (-1.30, 1.37)	0.96	1.18 (-0.16, 2.52)	0.085
Depression (MADRS instrument)							
Baseline	142, 16.4 (7.2)	138, 16.5 (8.0)	142, 16.6 (8.1)	-	-	-	-
90 days	119, 16.4 (9.0)	118, 15.5 (7.8)	127, 16.9 (9.8)	-0.47 (-2.29, 1.35)	0.61	-1.22 (-3.05, 0.60)	0.19
180 days	111, 19.5 (12.5)	111, 16.7 (10.5)	125, 18.4 (11.5)	0.73 (-2.00, 3.46)	0.60	-1.85 (-4.58, 0.89)	0.19
Cognition (MMSE instrument)							
Baseline	111, 17.6 (7.3)	106, 17.7 (7.4)	103, 17.7 (7.2)	-	-	-	-
90 days	80, 17.4 (7.9)	75, 19.0 (6.3)	82, 18.1 (7.8)	-0.35 (-1.45, 0.74)	0.53	-0.11 (-1.21, 0.99)	0.84
<b>Caregiver</b>							
NPI-Q distress							
Baseline	142, 13.3 (7.1)	137, 12.8 (7.5)	142, 13.7 (8.7)	-	-	-	-
90 days	120, 11.8 (7.0)	121, 11.1 (8.1)	132, 11.9 (9.0)	-0.18 (-1.77, 1.41)	0.83	-0.38 (-1.97, 1.21)	0.64
180 days	109, 12.3 (8.1)	113, 10.4 (8.3)	128, 12.7 (10.0)	-0.37 (-2.31, 1.57)	0.71	-2.24 (-4.16, -0.31)	0.023
Quality of life (AQoL-6D instrument)							
Baseline	143, 35.4 (7.2)	141, 35.1 (8.3)	143, 36.0 (7.5)	-	-	-	-
90 days	119, 35.4 (7.1)	121, 35.5 (8.2)	125, 36.1 (7.8)	-0.58 (-1.76, 0.61)	0.34	-0.26 (-1.45, 0.93)	0.67
180 days	107, 35.1 (6.7)	110, 35.0 (8.6)	121, 37.4 (8.9)	-1.43 (-2.94, 0.08)	0.064	-1.69 (-3.20, -0.19)	0.027
Depression (PHQ-9 instrument)							
Baseline	142, 4.7 (3.9)	141, 4.6 (4.3)	143, 5.0 (4.1)	-	-	-	-
90 days	118, 4.4 (3.4)	121, 4.4 (4.2)	126, 4.9 (4.4)	-0.50 (-1.18, 0.19)	0.16	-0.43 (-1.11, 0.25)	0.22
180 days	107, 4.6 (4.0)	111, 4.4 (4.2)	123, 5.0 (4.4)	-0.33 (-1.20, 0.54)	0.46	-0.52 (-1.38, 0.34)	0.24
Resilience (RS-14 instrument)							
Baseline	138, 80.9 (9.5)	139, 80.8 (10.7)	142, 82.5 (9.9)	-	-	-	-
90 days	115, 80.7 (9.1)	120, 80.6 (12.3)	126, 81.0 (11.1)	1.76 (0.01, 3.52)	0.049	1.10 (-0.63, 2.84)	0.21
180 days	106, 80.6 (8.9)	109, 81.6 (11.5)	119, 80.3 (12.8)	1.97 (-0.05, 3.98)	0.056	2.58 (0.59, 4.58)	0.011
Sense of competence (SSCQ instrument)							
Baseline	141, 25.1 (5.2)	141, 25.4 (4.6)	142, 25.5 (4.8)	-	-	-	-
90 days	118, 25.6 (4.7)	120, 25.7 (5.0)	124, 25.6 (5.3)	0.57 (-0.44, 1.58)	0.27	0.16 (-0.85, 1.16)	0.76
180 days	106, 25.5 (4.6)	111, 25.6 (5.3)	120, 25.3 (5.5)	0.49 (-0.57, 1.54)	0.37	0.45 (-0.59, 1.50)	0.39
Quality of caregiver-patient relationship (QCPR instrument)							
Baseline	137, 54.8 (8.7)	134, 54.0 (8.3)	137, 53.9 (9.2)	-	-	-	-
90 days	113, 54.3 (8.6)	117, 54.2 (9.0)	121, 52.9 (9.0)	1.26 (-0.15, 2.66)	0.080	1.05 (-0.35, 2.45)	0.14
180 days	104, 53.1 (8.9)	108, 55.0 (9.3)	117, 52.6 (10.6)	0.04 (-1.61, 1.70)	0.96	1.47 (-0.17, 3.11)	0.078

Data are presented as N, Mean (SD). CI = Confidence Interval; NPI-Q = Neuropsychiatric Inventory Questionnaire; QoL-AD = Quality of Life-Alzheimer's Disease; MADRS = Montgomery Asberg Depression Rating Scale; MMSE = Mini Mental State Examination; AQoL-6D = Assessment of Quality of Life-6D instrument; PHQ-9 = Patient Health Questionnaire-9; RS-14 = 14-item Resilience Scale; SSCQ = Short Sense of Competence Questionnaire; QCPR = Quality of the Caregiver Patient Relationship; SD = Standard Deviation; - = Not Applicable. Intervention visit = 90 (±31) days; Follow-up visit = 180 (±31) days. NOTE: For the person with dementia, a negative mean difference in NPI-Q severity score and depression (MADRS instrument) or a positive mean difference in quality of life (QoL-AD instrument) and cognition (MMSE instrument) means that the intervention group is associated with a better outcome compared to the usual care group. For the caregiver, a negative mean difference in NPI-Q distress score, quality of life (AQoL-6D instrument) and depression (PHQ-9 instrument) or a positive mean difference in resilience (RS-14 instrument), sense of competence (SSCQ instrument) and quality of caregiver-patient relationship (QCPR instrument) means that the intervention group is associated with a better outcome, compared to the usual care group.

**Table 2: Study outcomes for the person with dementia and caregiver (Intention-To-Treat Population).**



**Fig. 2: Effectiveness of music (2a) and reading (2b) interventions on people with dementia (Intention-To-Treat Population).** Abbreviations: PwD = Person with Dementia; UC = usual care. Pre-specified subgroup analyses were conducted for NPI-Q at 90 days. While not statistically significant, PwD with moderate to severe cognitive impairment and a mixed diagnosis showed a trend toward greater responsiveness to music compared to UC. Similar tendencies were observed for the reading intervention at 90 days. Treatment effects based on sex, time of dementia onset, caregiver relationship, country, and length of time with dementia were not statistically different. However, forest plots suggested that PwD cared for by female caregivers exhibited enhanced responsiveness to music interventions, whereas this trend was not seen in the reading group. Australian participants displayed heightened responsiveness to music intervention, particularly due to increased NPI-Q scores in the UC group. No significant heterogeneity of treatment effect in PwDs and caregivers was observed when comparing music intervention to UC at 90 days. Generally, moderate evidence indicated that PwD were more responsive to reading compared to UC when they or their caregiver frequently used music or reading, as opposed to never.

intervention to UC alone, no statistically significant heterogeneity of treatment effect in PwDs and caregivers was found at 90 and 180 days. In general, there was moderate evidence that the PwD was more responsive to reading compared to UC when the PwD or caregiver used music or reading often or very often, compared to never.

Among those who received the intervention, a total of 4 (1%) PwD died (music: 2 [1%], reading: 0 [0%], UC: 2 [1%]) and no caregivers died during the 90-day intervention period. There were slightly more PwD who reported at least one hospitalisation in music (12 [9%]) compared to reading (8 [6%]) and UC (5 [3%]). Both music (23 [17%]) and reading (25 [18%]) reported more participants with at least one adverse event (including COVID-19 infections, hospitalisation, and death) than UC (12 [8%]). There were no related adverse events for

the PwD or caregiver in any treatment group during the entire trial period (Table 3, appendix p 30). The history of COVID-19 lockdowns by country are reported in the appendix (p 31), noting that Australia had substantially longer lockdowns than all other countries.

### Discussion

In an international study in five countries across Australia and Europe, a 3-month caregiver-delivered music intervention in people living with dementia did not show a statistically significant or clinically important reduction (3-point difference) in BPSD compared with UC at the end of the intervention period. Similarly, no effect was seen after a 3-month reading intervention compared to UC alone. Secondary outcomes in PwD and caregivers did not reveal any clinically relevant

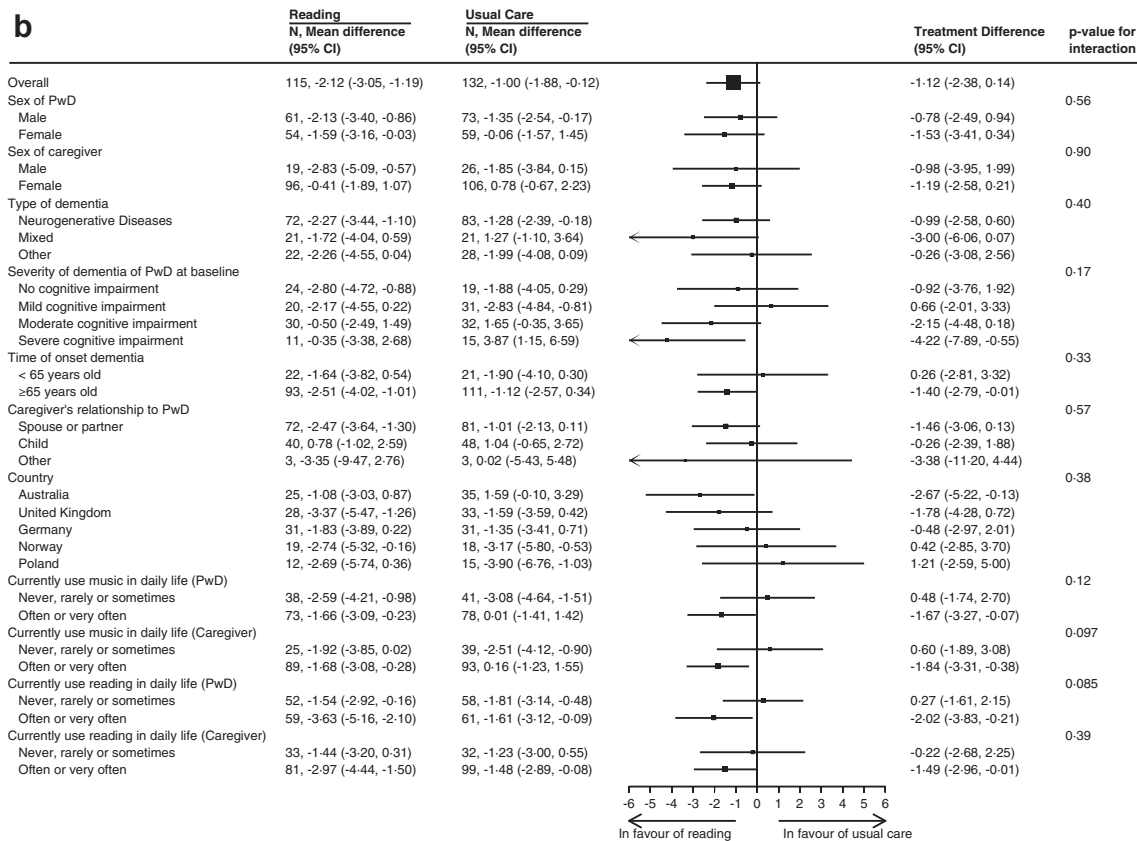


Fig. 2: Continued.

differences between music or reading and UC. No intervention-related adverse events were reported.

Our findings do not align with the most recent Cochrane review of music-based interventions for dementia care, where a standard mean difference of  $-0.23$  (95% CI  $-0.46$  to  $-0.01$ ) favouring music was found for reduction in BPSD. However, the Cochrane findings are not directly comparable as reviewed studies were situated in residential care, and music interventions were delivered in individual or small groups by qualified music therapists. In HOMESIDE, music interventions were home-based and provided by trained family caregivers. The contrasting findings between our trial and the Cochrane review suggest that family caregivers may not be as effective as trained music therapists at providing music interventions targeting BPSD or required more than three training sessions and more support from a music therapist to be sufficiently skilled in music use to effect change. Post-hoc analysis of the diary entries (recorded on the same day of intervention delivery where recall bias is likely to be less evident) showed positive immediate and short-term rest-of-the-day effects of music on BPSD symptoms. Further, these in-the-moment and short-term effects on BPSD confirm

previous findings with PwD in residential aged care that the effects of music on BPSD were short-lived.<sup>27</sup> This indicates a need to move away from examining the impact of music interventions on long-term changes in this progressive condition. Rather, examining its short-term effects of music engagement, either to preemptively minimise the severity or delay the onset of BPSD that typically escalate later in the day, or as a pro re nata (as needed) when caregivers need immediate assistance with symptom management.

Our study also found that the caregiver-delivered reading intervention was not effective in reducing BPSD or other secondary outcomes at 90-days. These results do not align with previous studies suggesting that reading is an accessible, feasible and effective approach to managing BPSD. However, our findings are not comparable to existing reading studies, which are of low quality, underpowered, with interventions delivered by healthcare professionals, and provided in residential aged care settings.<sup>10</sup>

With the global focus on enabling PwD to live at home,<sup>1</sup> feasible and acceptable non-pharmacological approaches that family caregivers can safely implement are needed. Our music interventions resulted in

	Person with dementia			Caregiver		
	Music (N = 143)	Reading (N = 144)	Usual care (N = 145)	Music (N = 143)	Reading (N = 144)	Usual care (N = 145)
<b>0-90 days</b>						
Participants at risk	138	139	145	138	139	145
At least one adverse event	23 (17%)	25 (18%)	12 (8%)	17 (12%)	12 (9%)	14 (10%)
At least one related adverse event	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
At least one serious adverse event	13 (9%)	8 (6%)	7 (5%)	3 (2%)	2 (1%)	7 (5%)
Hospitalisation	12 (9%)	8 (6%)	5 (3%)	3 (2%)	2 (1%)	7 (5%)
Death	2 (1%)	0 (0%)	2 (1%)	0 (0%)	0 (0%)	0 (0%)
At least one non-serious adverse event	10 (7%)	20 (14%)	5 (3%)	14 (10%)	10 (7%)	7 (5%)
<b>90-180 days</b>						
Participants at risk	122	124	140	122	124	140
At least one adverse event	13 (11%)	11 (9%)	16 (11%)	7 (6%)	8 (6%)	15 (11%)
At least one related adverse event	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
At least one serious adverse event	7 (6%)	6 (5%)	10 (7%)	2 (2%)	2 (2%)	5 (4%)
Hospitalisation	3 (2%)	5 (4%)	7 (5%)	2 (2%)	2 (2%)	4 (3%)
Death	5 (4%)	3 (2%)	3 (2%)	0 (0%)	0 (0%)	1 (1%)
At least one non-serious adverse event	6 (5%)	7 (6%)	6 (4%)	5 (4%)	6 (5%)	11 (8%)
<b>0-180 days</b>						
Participants at risk	138	139	145	138	139	145
At least one adverse event	35 (25%)	32 (23%)	26 (18%)	21 (15%)	19 (14%)	26 (18%)
At least one related adverse event	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
At least one serious adverse event	20 (14%)	14 (10%)	15 (10%)	4 (3%)	4 (3%)	10 (7%)
Hospitalisation	15 (11%)	13 (9%)	11 (8%)	4 (3%)	4 (3%)	10 (7%)
Death	7 (5%)	3 (2%)	5 (3%)	0 (0%)	0 (0%)	1 (1%)
At least one non-serious adverse event	16 (12%)	23 (17%)	11 (8%)	17 (12%)	16 (12%)	18 (12%)

Data are presented as n (%). PwD = Person with dementia. At 0-90 days, a total of 72 events were reported in 60 PwD participants and a total of 44 events were reported in 43 caregiver participants. At 90-180 days, a total of 45 events were reported in 40 PwD participants and a total of 31 events were reported in 30 caregiver participants. At 0-180 days, a total of 117 events were reported in 93 PwD participants and a total of 75 events were reported in 66 caregiver participants. A related adverse event is defined as an adverse event likely or very likely occurred due to the intervention. A non-serious adverse event is any adverse event that is not hospitalisation or death. Adverse events include COVID-19 infections. Participants at risk is the total number of participants randomised and treated (0-90 and 0-180) and additionally still participating in the study (90-180 days) per group. Adverse event data was collected at post-randomisation visits 1-, 21-, 42-, 90- and 180-days. Intervention period = 0-90 days (relative to intervention visit); Follow-up period = 90-180 days (relative to follow-up visit).

**Table 3: Number (%) of persons with dementia and caregivers with at least one adverse event (Safety Population).**

no intervention-related adverse events, confirming its safety. However, poor caregiver adherence to music delivery meant that a large proportion of our PwD did not receive the minimum dose we hypothesised would lead to reductions in BPSD. Therefore, questions remain as to whether the dose was too low to reduce BPSD by the clinically important difference of 3-points. The possible impact of a dose-effect response is supported by subgroup analyses of country effects and the session durations of music use. Here, changes in BPSD favouring music were pronounced in Australia, and the Australian dyads' durations of music use were significantly longer than across the whole sample. This supports other studies proposing that there is likely a complex interaction between disease severity, dose, and efficacy of music interventions.<sup>28</sup>

Despite the positive BPSD benefits reported by caregivers in the diary entries, the low adherence in

implementing music and reading could imply that it was burdensome for them. We expected that delivering twice weekly sessions (minimum adherence) would not be overly onerous for them, however more participants in music and reading withdrew from the study, compared with UC, suggesting that adding music and reading to their existing caregiver responsibilities was burdensome. This level of burden of implementing music interventions is further supported by the fact that caregivers used the easier-to-implement music listening activities to a greater degree than other active forms of music engagement.

Caregiver-delivered music interventions resulted in a statistically significant improvement in caregiver resilience at 90-days; however, these improvements were not clinically meaningful. As levels of caregiver resilience were high at baseline, this reduced the potential for a clinically meaningful change (ceiling effects).

Nevertheless, positive immediate and rest-of-the-day effects on some BPSD symptoms may have positively impacted caregiver coping. This study has underscored the need to explore whether immediate and short-term improvements in BPSD have a flow on effect to immediate and short-term health outcomes for caregivers. It should be noted that the resilience of caregivers who used music was relatively stable, which is noteworthy given that the study was conducted during COVID-19 pandemic where caregiver burden typically increased.<sup>28,29</sup>

Our post-hoc investigation of the diary data highlighted that while receptive music listening was used the most frequently, and resulted in more minutes of music engagement, its immediate and rest-of-the-day effects were less frequently positive than the effects of active music engagement (ie. singing, instrument playing, movement to music). This reflects existing literature that suggests that music listening may have some immediate effects but tends to be short-lived (20 min).<sup>27</sup> It also supports recent research that highlights active music interventions as more effective than receptive music interventions at improving cognition, behaviour, and functional state in PwD living in residential aged care.<sup>30</sup> Understanding the differences in therapeutic benefits of active vs receptive music activities (or their combination) in dementia care is of ongoing interest. Receptive approaches are easy to implement and less taxing on a caregiver than active approaches but do perhaps not address the relational needs of PwD in the same way as singing, dancing, or making music together do.<sup>31</sup> Given that active approaches had better immediate effects in our study, future training programs should include explanations of the potential differences between implementing active and receptive approaches so that caregivers can make more informed choices of where and when to expend the extra effort involved in implementing active approaches.

Subgroup analyses suggest that people with moderate to severe dementia were more responsive to the music interventions than those with no or mild cognitive impairment, although this lacked statistical evidence for interaction. This tendency supports previous study findings<sup>28</sup> where people with moderate to severe dementia had larger enduring symptom reductions in response to music compared with those with milder symptoms. Differences in responsiveness to reading in people with severe cognitive impairment were less pronounced than in music. The tendency for those with no cognitive impairment to be responsive to reading (where music was not) is likely related to more intact semantic memory.<sup>32</sup> Reading may also be viewed as an easy activity to implement for caregivers because it is familiar and easy for the caregiver to integrate and sustain within their daily routine.

Responsiveness to the interventions tended to differ between dementia types. Those with vascular and mixed

dementia tended to be more responsive to music (and to a lesser extent, reading) than those with Alzheimer's disease which may be explained by differences in the cognitive profile and BPSD symptoms of vascular dementia and Alzheimer's disease. People with vascular dementia are usually less impaired in episodic memory and more impaired in semantic memory than those with Alzheimer's disease. As music stimulates autobiographical recall, for those with vascular dementia, the music may have functioned as an added primer to stimulate episodic memory. This, combined with a lower reliance on language to engage actively in music, may explain why people with vascular dementia were more responsive to music than those with Alzheimer's disease.<sup>32</sup> Further, people with vascular dementia display significantly more agitation, sleep disturbances, depression, and aberrant motor behaviours than Alzheimer's disease,<sup>33,34</sup> suggesting that music, and to a lesser extent reading, may have a greater opportunity to affect one or more of these symptoms for people with vascular dementia. While high quality studies of reading are lacking, it is known that music interventions can reduce depression<sup>28</sup> and affect the mood and frontal subscales of the NPI-Q<sup>28</sup>; however, effects by dementia type need further investigation.

The sex of the caregiver also highlighted some possible explanations in the potential effects of reading and music. PwD had more positive responses to music interventions when the intervention was provided by a female caregiver, when compared with male caregivers, however these sex differences were not apparent in those allocated to the reading condition. This might suggest that male caregivers were less able to use music effectively but equally competent to females in providing reading activities. Further exploration of the effects by sex of the caregiver is needed given that less than 20% of caregivers were male. Another possible factor impacting the findings is the educational level of PwD and their use of reading and music across all study arms. Our study sample was biased because a high number of PwD had attained a Bachelor degree or higher. At the time of study enrolment, more than 50% of participants were already using music and reading at least several times per week and continued to use it for the duration of the study, irrespective of study arm. It is known that music and reading are beneficial in maintaining cognition,<sup>35,36</sup> so continued regular use may have contaminated the treatment effect.

The context of extended COVID-19 lockdowns in Australia, may explain why music was favoured over UC for Australia only. These lockdowns exacerbated BPSD,<sup>29</sup> and this tendency is reflected in the Australian UC sample where the mean NPI-Q increased. However, the Australian music sample remained stable. This suggests that intentional music use may support maintenance of symptoms when people are isolated for extended periods. It is possible that the fortnightly



phone calls to UC by the other countries, provided greater caregiver support, thereby contaminating the control. This might explain why BPSD for UC were less severe at 90-days in these countries.

Major strengths of this trial include the assessor-masked, pragmatic randomised controlled design, and implementation across five countries. It tested the effects of complex interventions which are safe and suitable for implementation in real-world settings. Therapists who trained caregivers received standardised training, were supervised by experienced clinicians, and achieved high intervention protocol fidelity. We successfully recruited a hard-to-reach group, compounded by the challenges of implementing this trial during COVID-19, and retained 96% of our target participant sample at the end of the intervention period. Assessors and therapists reported that many caregivers (including those allocated to UC) appreciated opportunities to talk about their day-to-day lives beyond those related to trial involvement because lockdowns limited opportunities for external social support. This may be one reason we retained a high proportion of participants. Therefore, this underscores the need for caregivers and PwD to receive regular check-ins and external support by healthcare professionals, especially during a pandemic.

Our study was designed to have caregivers trained at home and in person. However, the onset of the COVID-19 pandemic led to a pragmatic decision to shift the training to online, which may have impacted the learning of participants and therefore the effectiveness of the interventions. Further, the psychological impact of lockdowns, isolation, and fear of contracting the disease have impacted participant implementation of, adherence to, and responsiveness to the interventions, and is known to be positively correlated with accelerated decline in cognitive functioning, increased BPSD (especially anxiety, depression, and hallucinations),<sup>37</sup> and increased caregiver burden.<sup>33</sup> Collectively, these stressors may have influenced the therapeutic potential of the HOMESIDE interventions. Important questions remain as to whether caregiver-delivered music interventions when used during periods not marked by such extenuating circumstances, have the same effect.

As a pragmatic trial, we intentionally kept our inclusion criteria broad to be inclusive of all dementia diagnoses and levels of severity, to support family caregivers who sought out interventions to better manage BPSD. This resulted in a heterogeneous sample with half of the participants having no or mild cognitive impairments (according to MMSE scores) and mild BPSD. Research findings reported after commencement of our trial suggest that NPI-Q >11, would have been a more appropriate minimum NPI score.<sup>38</sup> We also achieved a lower than planned sample size. Further, our sample may be biased because a substantial proportion of people from Australia and UK were recruited through databases of people who had

already expressed an interest in participating in research. Combined, this may have limited the opportunity to detect a difference on the NPI-Q (ceiling effects). Subgroup analyses showed trends that participants with moderate to severe BPSD were more responsive to the music interventions. To explore this further, future research might limit inclusion criteria to PwD with severe symptoms only. Conversely, our results may suggest that the NPI-Q is not sensitive to capturing subtle changes in BPSD that make a meaningful difference to PwD and their caregivers. The inclusion of participants with all forms of dementia resulted in low homogeneity, which may have masked the true effects of the intervention for some dementia types. It was noted from subgroup analyses that people with vascular dementia tended to be more responsive. Limiting the target sample to those with vascular dementia only may have led to different results.

In conclusion, our study showed that neither music or reading interventions delivered by trained family caregivers, were beneficial in managing enduring BPSD or other health outcomes for community-dwelling PwD during the intervention period. However long-term but not clinically meaningful effects were found for reading. There is some suggestion that those who were engaging in both reading and music activities even outside of the protocol were more responsive, suggesting that both used in combination may be more effective than one or the other approach. Additional investigations are required to determine the profile of responders to both music and reading interventions, whether similar effects are achieved outside of the context of a pandemic, or when a combination of online and in person training sessions are provided. Further exploration is also needed into why a caregiver-delivered music intervention did not achieve the same effects as previous research on music interventions implemented directly by trained music therapists.

#### Contributors

Conceptualisation and funding: FAB initiated the study. FAB, HOM, KS, AB, and TW obtained funding.

Methodology: FAB, HOM, KS, AB, JT, JB, MH, TK, NTL, SB, TVS and TW designed the study. It was further developed and refined by LB, LF, EJ, KJ, KL, ASR, KT, and SW.

Project Management: TVS managed the trial, including monitoring activities across all international sites. JB, LB, LF, KJ, MH, JP, EJ, and HM implemented the study, including recruitment and data collection.

Supervision: FAB maintained oversight and leadership for the whole trial. HOM (United Kingdom), KS (Norway), AB (Poland), JT (Australia), and TW (Germany) led trial supervision at each of the trial sites. TK, KS, ASR, HOM supervised the therapists and HOM led the International Participant and Public Involvement Committee. NTL led clinical decision-making processes.

Data curation: TVS managed and monitored data including data cleaning and preparation of the database for analysis and later reuse.

Formal analysis: SB, KL, and VPS formulated the statistical analysis plan and applied statistical analyses to the dataset. SB, VPS and TVS verified all underlying data.

Visualisation: VPS, TVS and JP prepared figures and tables with support from SB and FAB.

FAB drafted the initial manuscript supported by JT and HOM. All authors had access to the data and contributed to interpreting the data, revising the manuscript, and approving the final version of the manuscript. All authors had final responsibility for the decision to submit for publication.

#### Data sharing statement

Study data will not be publicly available. De-identified data and data dictionaries can be made available to any researcher interested after completing a data request form and signing a data transfer agreement. Requests for access to the HOMESIDE study data should be sent to [felicity.baker@unimelb.edu.au](mailto:felicity.baker@unimelb.edu.au). The study protocol and statistical analysis plan have been published online.

#### Declaration of interests

All authors declared no conflicts of interest.

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#### Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.eclinm.2023.102224>.

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