Appendix 5: Methodology used in the literature review

Approach

A Clinician's BPSD Guide: Understanding and helping people experiencing changed behaviours and psychological symptoms associated with dementia (Clinician's BPSD Guide, 2023) was developed to replace and update the original document *Behaviour Management - A Guide to Good Practice: Managing Behavioural and Psychological Symptoms of Dementia (BPSD Guide, 2012)*. The approach to the review and update was 3-pronged:

- Experienced clinicians, researchers, industry representatives and relevant stakeholders were consulted.
- The academic literature (2012-2021) was comprehensively reviewed, and outcomes were synthesised with recommendations from the most recent expert clinical guidelines.
- An expert Advisory Group met on three occasions during the project to provide advice and feedback.

Sections of the *BPSD Guide 2012*, outlining additional considerations in relation to Aboriginal and Torres Strait Islander peoples, and people from culturally and linguistically diverse backgrounds, were retained where the information remains relevant and current (see *Acknowledgements*). These sections were supplemented with updated resources and literature.

Literature Review

A systematic literature review was undertaken to examine the evidence for psychosocial, environmental, biological and pharmacological interventions for supporting people who present with behavioural and psychological symptoms associated with dementia (BPSD). Databases searched included Medline, PsycINFO, Embase and PubMed. MeSH terms were checked.

Search terms

BPSD OR behav* psychological symptoms dementia OR challenging behav* OR disturbing behav* OR difficult behav* OR disruptive behav* OR behav* concern OR agitat* OR restles* OR pacing OR resist* OR apathy OR social* disinhibiti* OR sexual* disinhibiti* OR catastrophic reaction OR verbal outbursts OR screaming OR delusion OR hallucination OR anxiety OR depression OR neuropsychiatr* symptoms AND psychosocial management OR psychosocial intervention OR psychosocial treatment OR pharmacological management OR pharmacological intervention OR pharmacological treatment OR nonpharmacological management OR nonpharmacological intervention OR nonpharmacological treatment AND dementia OR alzheim* OR lewy bod* OR fronto-temporal OR frontotemporal.

Our initial search identified more than 8,000 potentially relevant papers. Articles were considered for inclusion if they were available in English and full text. Duplicates were removed and abstracts were screened. Articles relevant to updating the content of *Clinician's BPSD Guide, 2023* as well as intervention studies relevant to BPSD were retained, resulting in a total of some 5,000 articles. Of these, intervention studies were then reviewed and the reference lists of more than 600 relevant review articles hand searched. Intervention studies met our inclusion criteria if they included participants with a diagnosis of dementia and reported BPSD outcomes. Conference abstracts and studies that included people with brain-related conditions other than dementia were excluded.

Study designs included randomised controlled trials (RCTs), cluster RCTs, controlled non-randomised trials, comparison-group studies, interrupted time series studies, repeated

measures studies, cross-sectional studies, comparative cohort studies and observational studies. Individual case study/series were excluded. All care settings were eligible, and studies were included from residential, acute, primary care and community care settings. Participants living in residential care were receiving fulltime care and participants from community settings were recruited from in-home care, carer support services, primary care, hospital outpatients (e.g. memory clinic) and/or day respite centres.

Over-the-counter products such as vitamins and herbal products were not excluded. Where two or more articles based on similar studies by the same authors and reporting the same BPSD outcomes were available, the better or best study was selected for inclusion. This decision was made according to the most recent, most relevant and/or most complete study or those with a greater number of participants. A total of 420 studies of psychosocial and environmental interventions, and 221 studies of biological and pharmacological interventions were retained for further review and rating of the evidence quality. Some BPSD were very limited in the amount of literature available e.g., wandering and vocal disruption. In contrast, the search yielded far more intervention studies for depression and agitation in dementia.

Overall, the published research relating to interventions to support people living with dementia who experience BPSD has increased dramatically in volume and quality since 2012. A greater focus on nonpharmacological/psychosocial interventions, rather than pharmacological, was evident. Studies using psychotropic medications, particularly antipsychotics, have noticeably decreased since 2012.

Quality Criteria

To better guide clinical practice, all intervention studies reported in the modules and outlined in the intervention tables (*Appendix 2: psychosocial/environmental* and *Appendix 3: biological/pharmacological)* were rated for research quality to determine the strength of the evidence for the findings reported. The tool used to assess the quality of the studies[1] was developed by considering, adapting and combining aspects of a number of published scales[2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12] to reflect the dementia research landscape. Total scores on the quality rating tool ranged from 0 to 16. See table below for specific criteria. Effect sizes were also calculated where possible, to provide an indication of clinically meaningful change.

The increased number and quality of the intervention studies published since 2012 required revised inclusion criteria from that used in the original *BPSD Guide* (2012). Based on the total quality rating score for each intervention study, the strength of the evidence presented was grouped into the following revised categories:

- **Strong:** total score of 13-16 inclusive
- **Moderate:** total score of 10-12 inclusive
- **Modest:** total score of 7-9 inclusive

Studies rated with a quality score of six or less were excluded. The decision was made to report on only those studies providing moderate to strong quality evidence in the *Clinician's BPSD Guide 2023.* In all, 348 studies of psychosocial/environmental interventions and 178 studies of pharmacological/biological interventions, published between 2012-2021 were included. Studies rated as providing modest quality evidence are summarised and retained in *Appendices 2 and 3* for information purposes only. Clinicians should be aware that outcomes from these modest quality studies have not been considered in any recommendations included in the updated *Guide*.

A limited number of RCTs from the *BPSD Guide* (2012) were retained in the *Clinician's BPSD Guide 2023* where they included a minimum of twenty participants and rated as strong in

quality. Studies reporting outcomes based on subscale scores only or those that did not adjust for multiple comparisons were also excluded.

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Criteria for rating the quality of intervention studies

Design

- Randomised
- Randomised according to Delphi specifications i.e., must be unpredictable e.g., coin toss, table of random numbers, computer generated, etc *(allocation by DOB, admission date, MRN, coin toss of clusters or similar do not qualify)*
- Control or comparison group *(credit for repeated measures)*
- Blinded ratings *(partial blinding OK if primary outcome is blinded)*

Subjects

- Groups similar at baseline regarding most important prognostic indicators *(credit for ≤20% difference. Must include: age, gender & baseline BPSD score or an indication that there is no significant difference in these. Where groups are not matched but baseline BPSD scores are used as a covariate in analysis is OK. Behaviour change scores only do not qualify)*
- Eligibility criteria specified i.e., could the study be replicated based on only the information reported?
- Use of standardised diagnostic criteria i.e., GDS, MMSE, DSM ICD, etc *(no credit where criteria not reported e.g., 'written in notes by dr' or 'diagnosed by dr', etc)*
- All subjects accounted for/withdrawals reported

Outcomes

- Well-validated, reliable measures *(known or reported as validated, those that are published generally qualify)*
- Objective outcome i.e., based on observations, not self-rated
- Follow-up assessment 6 months or beyond i.e., follow-up period must be from cessation of intervention to qualify

Statistics

- Point estimates and measures of variability presented for primary outcome measures i.e., both means + SDs or effect sizes or SEs provided
- Statistical significance considered and reported
- Adjustment for multiple comparisons e.g., adjusted p-value, Bonferroni, Scheffe, Tukey's, post hoc, hierarchical linear modelling *(no credit where not reported)*
- Evidence of sufficient power i.e., stated or large sample size n ≈ 100
- Intention-to-treat analysis of BPSD outcomes i.e. all randomised participants are included in analysis *(no credit where study is described as "ITT" but no evidence provided).* For non-randomised studies, all participants enrolled are included in analysis.

Total score for quality of the evidence reported = 1 point for each of above criterion met