Table 1- people with dementia

BPSD Review Project – In-Depth Systematic Review

Evidence Tables for Randomised Controlled Trials (RCTs) aimed at addressing BPSD and/or how carers deal with BPSD.

Total included: 68 studies (115 papers) plus 4 Qualitative studies (7 papers related   to 4 RCTS)

➢ **People with dementia (pwd);** (n=7 studies, 9 papers)
➢ **Dyads (People with dementia and carers)** (n=24 studies, 44 papers)- plus 1 qual study
➢ **Carers;** (n= 37 studies, 62 papers)- plus 4 qualitative studies (6 papers)

Outcomes of interest for the review

People with dementia: BPSD related (e.g. depression, agitation, etc), quality of life, daily function/activities, level of independence.
Carers (formal/informal): related to helping carers deal with BPSD, Carer burden/strain, distress, Quality of life related to BPSD management, carer depression, carer psychological health
Organisational: Related to move to care facility (e.g. delay in moving to long term care, moves to long term care), economic/resource, service use and costs

Process measures: relating to BPSD management and provision of care, process measures (e.g. relating to BPSD management and provision of care), acceptability/feasibility (e.g. acceptability of intervention)

Primary and secondary outcomes of the in-depth systematic review

Primary
• Changes (reductions) in the incidence, frequency or severity of behaviour problems (e.g. agitation) using standardized rating scales for BPSD or self-report from carers
• Carer strain/burden
• Carer depression
• Carer psychological health
• Quality of life

Secondary:
• Changes in the incidence or frequency of sleep-wake disturbances
• Change in level of independence (sustaining independence in activities of daily living such as nutrition and eating habits)
• Moves to long term institutions/care homes
• Delay in moving to care homes
• Resource implications, and where available, costs of intervention
• Impact of interventions on use of health and social care services, including voluntary sector and volunteer support, and informal caring
• Process measures relating to BPSD management and provision of care
• Experiences of people with dementia/carers in relation to the effectiveness and acceptability of BPSD management and quality of life

Effect sizes are calculated only where data were available, otherwise reported effects are extracted

Quality: Risk of bias

Overall quality score within a trial applied to main outcomes. Based on risk of bias assessment: low risk = 5 or more domains scored as low risk; unclear risk=low or unclear risk of bias for all domains; high risk: high risk of bias for one or more key domains; (Study is downgraded if randomisation, allocation and blinding of outcome assessment, incomplete data are unclear or high.)

Across trials: low risk = Most information is from trials at low risk of bias; unclear risk= Most information is from trials at low or unclear risk of bias; high risk of bias = The proportion of information from trials at high risk of bias is sufficient to affect the interpretation of results

Overall quality score= no of domains at low risk out of 6 domains assessed.

Instruments used for outcomes: applies to all the evidence tables

Abbreviation	Instrument/measure	Abbreviation	Instrument/measure	Abbreviation	Instrument/measure
ABID	The agitated behaviour inventory for dementia	FAB	Frontal Assessment Battery	PPA	The Physiological Profile Assessment
ABDS	Agitated Behaviours in Dementia ScaLe	FES-I-SF	Fall Efficacy Scale – International – Short Form	PSS	Perceived stress scale
ABMI	Agitated behaviour inventory	I FES-I	Iconographical Falls Efficacy Scale - International	PWI-ID	The personal well-being index – intellectual disability
ADA	Alzheimer's Disease Assessment	FLSAS	Functional Living Skills Assessment Scale	QOL-AD	Quality of life AD scale
ADAS-Cog	Alzheimer's Disease Assessment Scale-Cognitive subscale	GDS	Global Deterioration Scale	RAQ	Risk Appraisal Questionnaire adapted from REACH II
ADCS-ADL	Alzheimer's Disease Cooperation Study Activities of Daily Living Scale in AD	GDS/GDRS	Geriatric Depression/rating Scale	REHAB	Rehabilitation Evaluation Hall and Baker tool
ADL	Activities in Daily Life Inventory	GHQ	General Health Questionnaire	RSS	Relatives Stress Scale
ADS-R	Anxiety and Depression Scale - Reduced	HADS	Hospital anxiety and depression scale	RSCSES	Revised Scale for Caregiving Self-Efficacy Scale
AES	apathy evaluation	HST	The Hill Step Test	Rosenberg's SES	Rosenberg's Self Esteem Scale
AMT	Abbreviated Mental Test	IADL	Instrumental Activities of Daily Living	RMBPC	Revised memory and behaviour problem checklist
BACS	Beliefs about	IGT	Iowa Gambling Task	SCB	Screen for caregiver

Abbreviation	Instrument/measure	Abbreviation	Instrument/measure	Abbreviation	Instrument/measure
	caregiving scale				burden
BASQLD	The Bath Assessment of Subjective Quality of Life in Dementia	IPEQ-W	Incidental and Planned Exercise Questionnaire-Weekly for older people	SCQ	Sense of Competence Questionnaire
BMD	Behaviour and Mood disturbance scale	IMML	Index for Managing Memory Loss	STAI-S	State trait Anxiety Inventory - State
BRSD	Behavioural rating scale for dementia	IPEQ-W	Incidental and Planned Exercise Questionnaire-Weekly for older people	SUQ	Skill utilization questionnaire
CAN	Caregiver Need Assessment	MADRS	Montgomery and Asberg Depression Rating Scale	TB	Test – Barcelona
DAD	Disability assessment for dementia scale	MDS 2.0	Minimum Data Set 2.0 Questionnaire	TMSI	Task Management Strategy Index
DBD	dementia behaviour disturbance scale	MFEM	Memory Failures in Everyday Memory	VAS	Visual analogue scale
DDAD	Deterioration of Daily Activities in Dementia	MMSE	The Mini-Mental State Examination	VFT	Paced-overt Verbal Fluency Task
		MOSES	Multi-dimensional Observation Scale for Elderly Subjects		
DEMQOL	Quality of life in dementia	NPI	neuropsychiatric inventory	WMS III	Wechsler Memory Scale III
DES	Differential Emotions Scale	NTT	Near Tandem Test	WAIS III	Wechsler Adult Intelligence Test III
DSS	Decisional Support Scale	OARS	Older Americans resources and services multidimensional assessment questionnaire	ZBI	Zarit burden interview
EQ-5D	Euroqol -5D	PHQ-9	Patient health questionnaire		
ESASS	Emotional Support and Anticipated Support Scale	POMS	Profile of Mood States		

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Abbreviation	Full description	Abbreviation	Full description	Abbreviation	Full description
RCT	Randomised controlled trial	IG	Intervention group	MCI	Mild cognitive impairment
Pwd	People with dementia	CG	Control group	FU	Follow-up
QOL	Quality of life	RR	Risk ratio		
BPSD	Behavioural and psychological symptoms of dementia	OR	Odds ratio	ns	Not significant
AD	Alzheimer's disease	d	Cohen's d		
VD	Vascular dementia	MD	Mean difference		
F	Female	TF	Theoretical framework		
M	Male	ANCOVA	Analysis of variance, F test		
PC	Power calculation				

Table 1 – studies evaluating an intervention that includes BPSD symptoms as a component of the overall intervention delivered to people with dementia (pwd)

Effect size calculated only where data were available, otherwise reported effects are extracted.

Primary and secondary outcomes are indicated if reported and classified by the paper.

First Author, year And related papers	Research question/aim, and theoretical framework (TF) used	Study population setting, and country of study	Sample size Include PC if available	Description of intervention	Outcome variable(s) (measures in brackets)	Main results at follow up (FU; reported as IG vs CG unless otherwise specified) (95% confidence intervals are shown in brackets); ns=not significant	Evidence summary Quality (ROB=risk of bias No of domains 'low risk' out of 6; overall risk)	Applicability to the UK populations and settings Score 1-4*
Cognitive stimulation								
Cognitive stimulation therapy								
Buettner 2011 Fitzsimmons 2014 (in press)	To evaluate the effectiveness of Mentally Stimulating Activities (MSAs) on patient toutcomes and in engaging participants with apathy. TF: Marin's Model of Apathy-	Pwd, early stage AD or MCI with apathy. Mean age IG 78.6, mean age CG 81.2; >70% F , 23% African-American; Education: high in both groups, although 4/8 sites were low SES Exclusions: chronic and neurological illness, new	77 (IG 48, CG 29) No PC 2014 Study (multi site) IG: 66 CG 67	MSA aims to manage apathy. IG: Classroom style, variety of mentally stimulating activities, brief brain fitness exercises CG: Structured Early-Stage education and Social Support Program (SS). Model assumed that emotional apathy was addressed for both groups through the provision of similar amounts of social contact. **Duration & intensity**	Pwd outcomes: Apathy (AES) Depression (PHQ-9) QOL (Cornell Brown QOL) MMSE Executive function Engagement and time	FU: 12 weeks from BL (4 week significant) MD -7.80 (-10.5, -4.7), d=0.95 MD 3.41 (1.59, 5.23); f=6.75, p=0.011 MD -10.1 (-14.02,-6.12); F=7.5,p=0.007 ns significant improvement (p<0.001) IG: 99.9% engagement, time=57.1 mins CG: 94.1%; Time=34.7mins	MSA significantly reduced apathy, depression, improved QOL and maintained function.. IADL had mixed results. Increased engagement in the IG. Apathy is most common, complex to treat because it is mixed with other challenging behaviours and often confused with depression. No costs given but author claims it is an easy and cost effective intervention ideal for the skills and techniques of recreation	3

		psychoactive medication within the past 30 days (effect on apathy) **Setting:** home/community **Country:** USA		1hr twice a week for 4 weeks.(12 weeks for later study)- based on previous work that apathy and attention changed over 12 weeks **Providers** : Trained staff		Attrition high in CG (40%); IG (1.5%)	therapists which can be replicated Trained staff but implementation costs unclear. Active engagement may break the pattern of early stages. Recruitment in low SES was a problem ROB: 1/6 low Overall: high/unclear	
Emotional								
Reminiscence								
Tadaka 2007	Evaluate the effects of Reminiscence therapy TF: none	Pwd attending day care, with AD or VD Mean age IG 83, CG 82 70%F ; clinical dementia rating 1 or 2 (moderate), no speech or vision disorders **Setting**: Single day care (urban) **Country:** Japan	60 (IG 30, CG 30) PC not reported	Reminiscence therapy aims to improve daily function (defined as self care, disorientation, depression, irritability and withdrawal). CG: routine day care ; **Duration & intensity** 60-90 min session, once per week for 8 weeks. (for both) **Providers:** Groups of 6 with one care worker and 2 specialists (public health nurse or clinical psychologist).	Primary: Pwd outcomes: Carer reports & psychiatrist ADL – Self-care (MOSES) ADL - Disorientation (MOSES) Withdrawal (MOSES) Depression (MOSES) Irritability (MOSES)	FU: Immediate and 6 months Borderline improvement d=1.88, effect size 0.69, MD=-3.20, (-4.44, -1.97) p<.004 (for VD only)- immediate and 6 m d= 3.93, effect size 0.24, MD= -5.50, (-6.53, -4.48), p<.010 (for VD only) Not significant Not significant	Significant improvement in withdrawal and disorientation for patients with VD. No significant effects of intervention for those with AD. Reminiscence effective way to enhance remaining capacity and adaptation to daily life in older people with AD & VD, but sustained intervention may be required especially in older people with AD. ROB: 4/6 low Overall low/unclear – sample size small	3

Study	Aim	Population	N	Intervention	Outcomes	Follow-up	Findings	Score
					Secondary: Level of Cognition (MMSE)	Significant improvement (ns, long term)		
Multicomponent								
Exercise, cognitive therapy and support group								
Burgener 2008	To evaluate the feasibility and effects of a multimodal intervention TF: neurological functioning and regeneration	Pwd, irreversible early- middle stage. AD, Lewy Body, Frontal Lobe or mixed. <2 on CDR Mean age 77 IG 46%F, CG 47%F Education 15 yrs mean in both Co-morbidities mean 2.5 in both **Setting:** home/community **Country:** USA	43 (IG 24, CG 19) PC not reported, suggest low power	Multimodal intervention aims to improve cognitive functioning, physical functioning and behavioural outcomes. Consists of Taiji exercises, 1hr, 3 times per week for 40 weeks. CBT included small groups and individual counselling, 90 mins, bi-weekly for 40 weeks. Support group 90 mins, bi-weekly for 40 weeks CG: delayed treatment. Attention control education programme. Received treatment after 20 week treatment. **Providers:** Taiji instructors, social workers	<u>Pwd outcomes:</u> (self ratings) Depression (GDS) Self-esteem (Rosenberg's SES) Cognitive Functioning (MMSE) Physical Functioning, single leg stance, Berg balance, physical illness measure	FU: 20 and 40 weeks (10 m) No significant results	IG had stabilised depression at follow up.. IG had improved self esteem and mental stability at 20 weeks, but continued improvement in outcomes not observed at follow up. Gains in balance were evident. ROB: 2/6 low Overall unclear	2
Physical and structured								
Art therapy								
Hattori 2011	To evaluate the usefulness and psychological and cognitive effectiveness	Pwd with mild AD, limited to those showing recent memory impairment and disorientation.	39 (IG 20 , CG 19) PC not reported	Art Therapy aims to improve cognition, mood, vitality, behavioural impairment, and ADL Colouring patterns, line drawing of family objects	<u>Pwd outcomes:</u> Psychiatric symptoms of dementia, mental symptoms Mood (depression)	FU: 12 weeks (3m) Not significant	Significantly improved apathy and QOL. No other significant effects for pwd. Did not improve carer burden.	1

	of Art Therapy TF: none	Exclusions: MMSE>25, 19 or lower, speech impairment, age range 65-85 yrs. IG 55%F, CG 53%F mean age 74 **Setting**: Day hospital and home **Country:** Japan		CG: Calculation drill **Duration & intensity** 45 minutes once a week, x 12 weeks in day hospital – approximately 5 per group **Providers:** Delivered by authors (psychiatrist and speech therapist)	(GDS) Apathy (apathy scale) QOL (QOL short form SF-8) Behavioural abnormalities (DBD) Cognitive Function (MMSE) Carer outcomes: Burden (ZBI)	d= 0.125, (-3.23, 4.83) MD= 0.80, p=.0014 OR=5.54, p=.038 Not significant Not significant Not significant	ROB:3/6 low Overall unclear	
Individual functional enhancement								
Lam 2010b	To examine effects of individual functional enhancement on functional skills and mood TF: cognitive behavioural approach	pwd, mild-moderate dementia. mean age IG 83, CG 84 74%F Education IG: mean 3years, CG;1.5 yrs Exclusions: greatly impaired communication, bedbound **Setting**: social centres and old aged home for the elderly	74 (IG 37, CG 37). PC not reported	Functional enhancement (individualised occupational therapy) aims to modulate mood disturbances and functional deficits IG: Mapping functional profiles, enhance abilities to compensate for areas of deficiency, training activities selected from activities considered as important by the participants. Positive emotional experiences enforced and rehearsed throughout the sessions. Content of training is dynamic and adjusted to the changing needs of the demented person.	Primary: Pwd outcomes: Depressive mood, mood disturbances, mood symptoms Depression (NPI) Depression (CSDD) Apathy (NPI) Functional ability Secondary: Global Cognition	FU: 1 month and 4 months after intervention No significant results	Trend towards improved depression. Improved apathy post training but not at follow up. No significant results at follow up. ROB: 3/6 low Overall: high/unclear	3

		Country: Hong Kong		4-6 people with dementia/ group. CG: skills training **Duration and intensity** 45 mins twice per week for 8 weeks (both) **Providers**: occupational therapists.				
Sensory Enhancement & relaxation								
Multi sensory stimulation (MSS)								
Baker 2001 Baker 2003	To evaluate the effects of Multi sensory stimulation (MSS) on behaviour and mood TF: none Rationale: stimulating activities to be appropriate to their cognitive level in early stages; for advanced dementia, pwd may receive little stimulation	Pwd, moderate-severe AD, VD and mixed dementia, attending day care. Mean age = 78, 50%F, no major psychiatric comorbidities **Setting**: Day care (2001). Day hospital (UK), psycho-geriatric ward i.e. live on the ward (Netherlands and Sweden, 2003) **Country:** UK, Netherlands, Europe	50 (IG 25, CG 25) 80% power for MMSE scores 136 (N=94, UK) IG44 CG 50; Netherlands 26, Sweden 16 IG 65 CG 71	MSS aims to change behaviour, mood and cognition. CG: activity sessions IG: MSS: visual, auditory, tactile and olfactory stimulation in specially designed room and environment. Staff work one-to-one in non-directive, enabling approach. Encourage participants to engage in sensory stimuli of own choice. **Duration & intensity** One to one 8 sessions lasting 30 minutes, twice a week for 4 weeks **Providers**: keyworkers, day	Pwd outcomes: Behaviour before and immediately after sessions (Interact short) Behaviour during sessions (Interact) Change in behaviour at home (behaviour rating scale) Mood (BMD) Behaviour in day hospital (REHAB)	FU: 4 sessions, 8 sessions and 1 month after sessions No significant results at follow up. IG had significantly lower levels of behaviour at baseline	IG more attentive to their environment immediately after sessions, and improved in mood and behaviour. No long term benefits on mood and behaviour and behaviour declined sharply in the month follow up period. Also behaviour declined in the day hospital. Behaviour in UK remained stable during the trial and deteriorated once sessions stopped. ROB: 3/6 low Overall unclear/high on blinding outcomes	1

				hospital member of staff or OT or psychology assistant.				
Van Diepen 2002 (pilot study)	To evaluate the effects of Snozelen on agitated behaviours TF: none	Pwd, attending day hospital, with significant agitated behaviour. **Setting**: Day care **Country**: UK	10 (IG 5,CG 5) PC not reported	IG: MSS aims to improve agitated behaviour. CG: Reminiscence therapy **Duration & intensity** Up to 40 minutes, twice a week for 8 sessions **Providers**: experienced therapists, each with one participant	Pwd outcomes: BPSD Reported agitated behaviour (short form CMAI) Observed agitated behaviour (ABMI) Behaviour during sessions (Interact)	FU: 4 weeks with therapy and 4 weeks without No significant results	No significant results. Tendency for CMAI scores to be lower after therapy for both groups at follow up. ROB: 3/6 low Overall unclear/high (unblinded outcomes) Feasibility study of small numbers, limits validity of comparisons. Both instruments for apathy easy to use	1

 *Applicability score:

 1 = Applicable across a broad range of populations and settings

 2 = Applicable across a broad range of populations and settings assuming appropriately adapted

 3 = Applicable only to populations or settings included in the studies, and broader applicability is uncertain

 4 = Applicable only to settings or populations included in the studies