Care Interventions for People With Dementia (PWD) and Their Caregivers

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What We Will Cover Today:

- Brief highlights of methods
- Results
- Discussion
- Thoughts for Future Research

Objective

To assess the evidence for care interventions for PWD and their informal and formal caregivers for potential for broad dissemination and implementation.

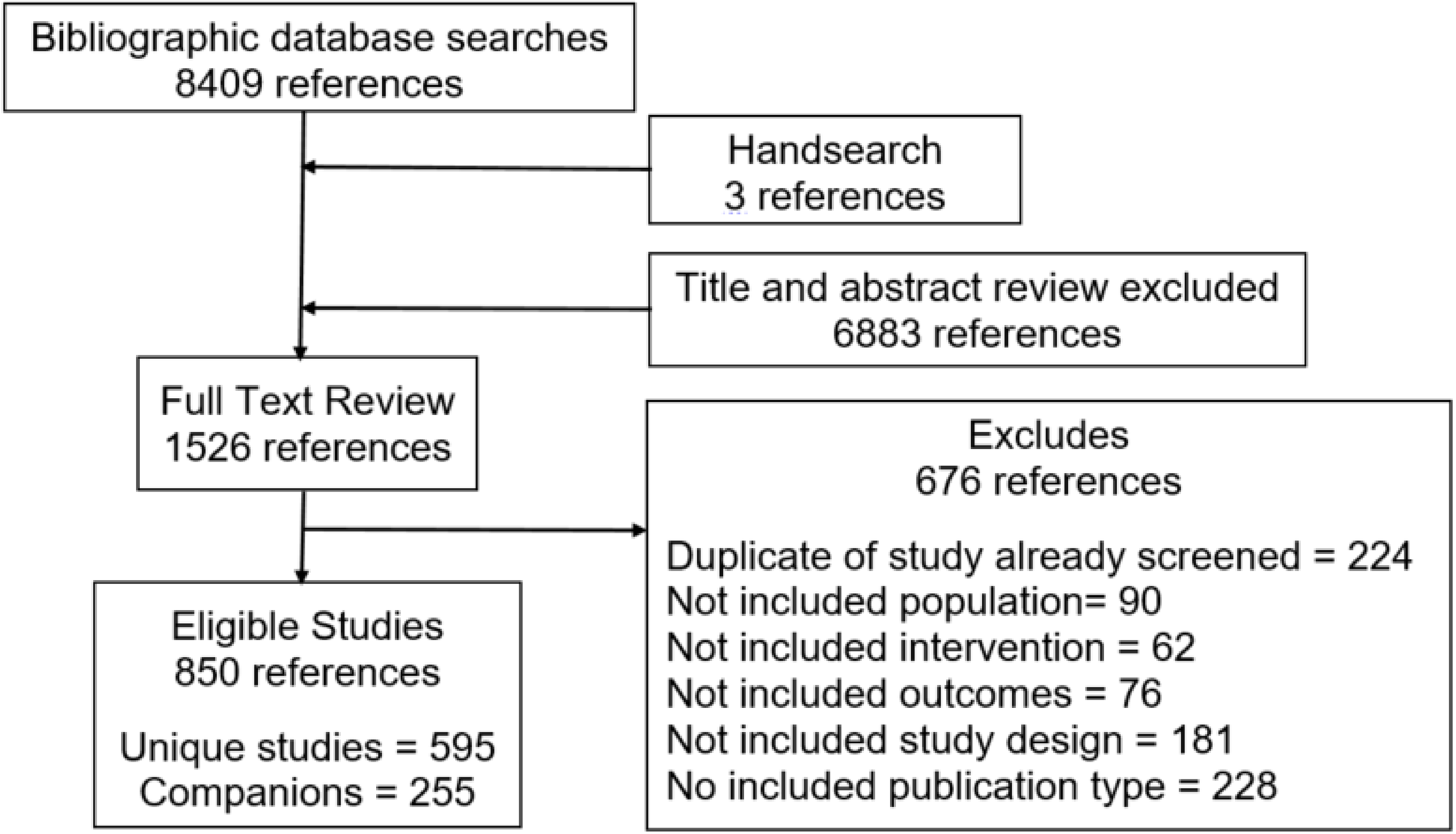
Data Sources for literature

Ovid Medline, Ovid Embase, Ovid PsycINFO, and the Cochrane Central Register of Controlled Trials (CENTRAL) to identify trials with comparator arms or single arm studies with appropriate methods (e.g., intermittent time series) indexed in bibliographic databases from inception to October 2019

Categorization

- To support readiness for broad dissemination decisions, used NIH Stage Model as a framework for categorizing studies to focus on those best designed to look for real-world effects.
- Modified PRECIS-2 tool to assist with assessment
    - Stage 0-2 categorized as pilot
    - Stage 3 categorized as “explanatory”
    - Stage 4 categorized as “pragmatic”

Results



Bibliographic database searches
8409 references

Handsearch
3 references

Title and abstract review excluded
6883 references

Full Text Review
1526 references

Excludes
676 references

Duplicate of study already screened = 224
Not included population= 90
Not included intervention = 62
Not included outcomes = 76
Not included study design = 181
No included publication type = 228

Eligible Studies
850 references

Unique studies = 595
Companions = 255

Results

96 studies in the **analytic set:** the set of studies not judged to be pilots or have a high potential for bias that might have interfered with the ability of the study to answer its research question.

499 studies in the **evidence map:** the set of studies that did not undergo synthesis. Summarizes what has been studied and facilitates identifying future research needs.

Clarification

An assessment of insufficient evidence does not mean that the intervention is determined to be of no value. Rather, it means that due to the uncertainty of the evidence we could not draw meaningful conclusions at this time.

Managing Behavioral and Psychological Symptoms of Dementia (BPSD) (Ch 4)

Intervention	Total Unique Studies	# Analytic Set	# Evidence map	# non-U.S.
Assisted Therapy	12	1	11	11
Multi-Sensory Stimulation/Snoezelen	9	2	7	6
Complementary and Alternative Medicine (CAM) Therapies	20	5	15	18
Bright Light Therapy	8	0	8	4
Psychosocial Therapies for BPSD	6	0	6	1
Multicomponent Interventions for BPSD	9	0	9	5
Chapter 4 TOTAL	**64**	**8**	**56**	**45**

Managing BPSD in PWD

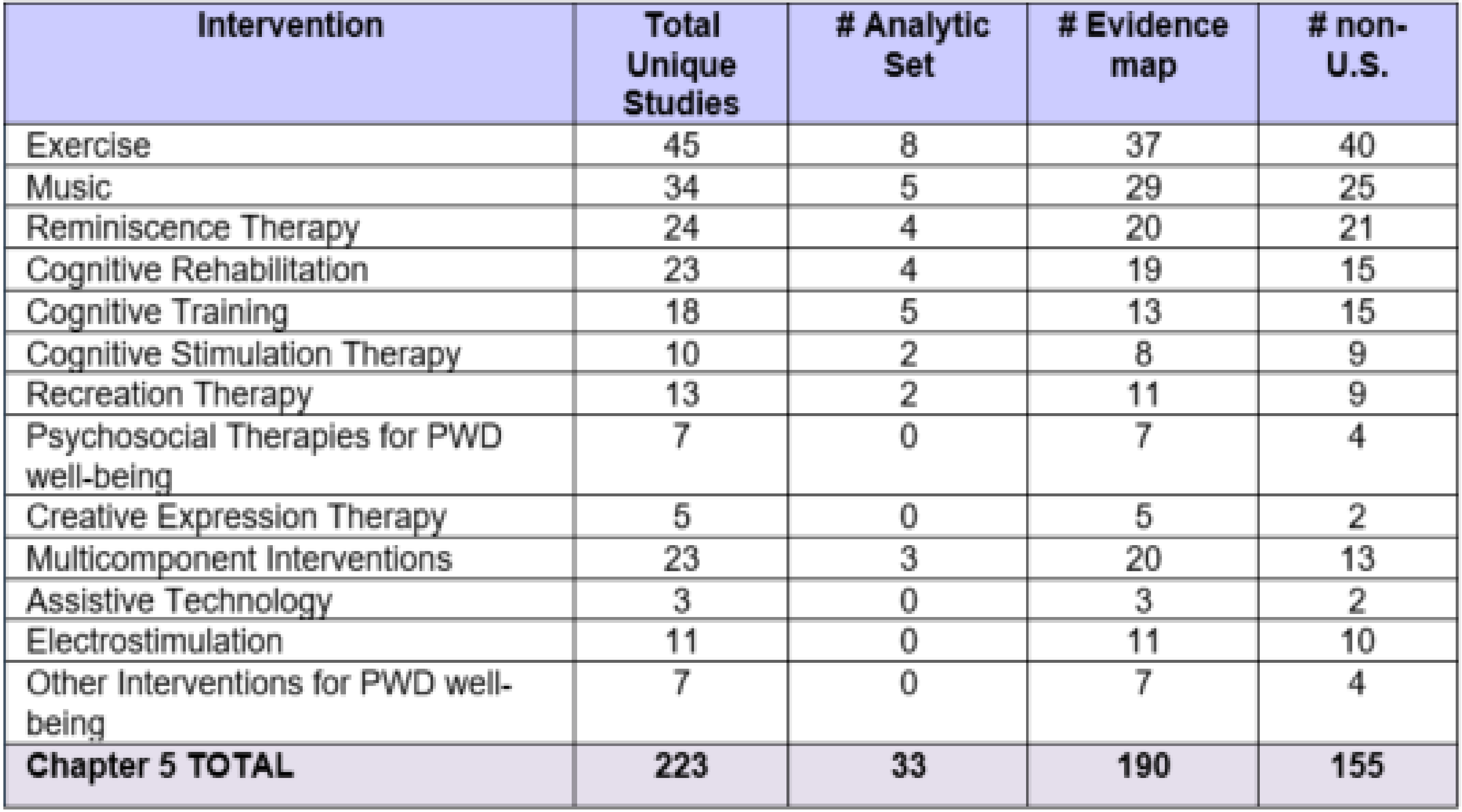
Evidence was insufficient to draw conclusions

- Robot-assisted therapy
- Multi-sensory stimulation/Snoezelen
- Aromatherapy or foot massage interventions (CAM)

Evidence that did not advance to analysis

- Live animal- or doll-assisted therapy
- Bright light therapy
- Psychosocial therapies
- Multicomponent interventions

Care Interventions for PWD Well-being (Ch 5)



Intervention	Total Unique Studies	# Analytic Set	# Evidence map	# non-U.S.
Exercise	45	8	37	40
Music	34	5	29	25
Reminiscence Therapy	24	4	20	21
Cognitive Rehabilitation	23	4	19	15
Cognitive Training	18	5	13	15
Cognitive Stimulation Therapy	10	2	8	9
Recreation Therapy	13	2	11	9
Psychosocial Therapies for PWD well-being	7	0	7	4
Creative Expression Therapy	5	0	5	2
Multicomponent Interventions	23	3	20	13
Assistive Technology	3	0	3	2
Electrostimulation	11	0	11	10
Other Interventions for PWD well-being	7	0	7	4
Chapter 5 TOTAL	**223**	**33**	**190**	**155**

Care Interventions for PWD Well-being

Evidence was insufficient to draw conclusions

- Exercise
- Music
- Reminiscence
- Cognitive rehabilitation
- Cognitive training
- Cognitive stimulation therapy
- Recreation therapy
- Multicomponent interventions

Care Interventions for PWD Well-being

Evidence was insufficient to draw conclusions

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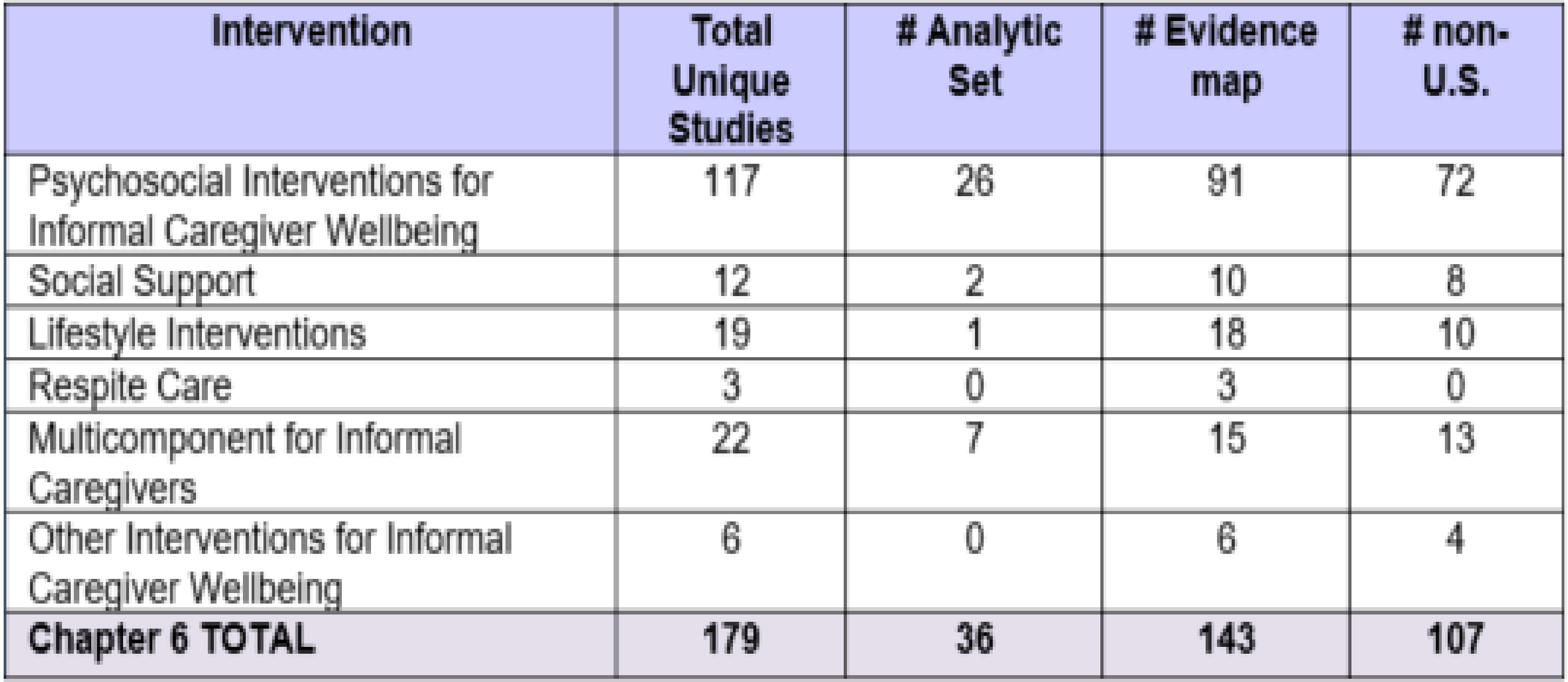
PWD Well-being (cont.)

Evidence that did not advance to analysis

- Psychosocial therapy
- Creative expression therapy
- Assistive technology
- Electrostimulation
- Other interventions

Interventions for Informal Caregiver Well-being (Ch 6)



Intervention	Total Unique Studies	# Analytic Set	# Evidence map	# non-U.S.
Psychosocial Interventions for Informal Caregiver Wellbeing	117	26	91	72
Social Support	12	2	10	8
Lifestyle Interventions	19	1	18	10
Respite Care	3	0	3	0
Multicomponent for Informal Caregivers	22	7	15	13
Other Interventions for Informal Caregiver Wellbeing	6	0	6	4
Chapter 6 TOTAL	**179**	**36**	**143**	**107**

Interventions for Informal Caregiver Well-being

Low-strength evidence

- Intensive multicomponent intervention with education, group discussion, in-home and phone support sessions, and caregiver feedback for informal caregiver support (REACH II), improved informal caregiver depression at 6 months.

Caregiver Well-being (cont.)

Evidence was insufficient to draw conclusions

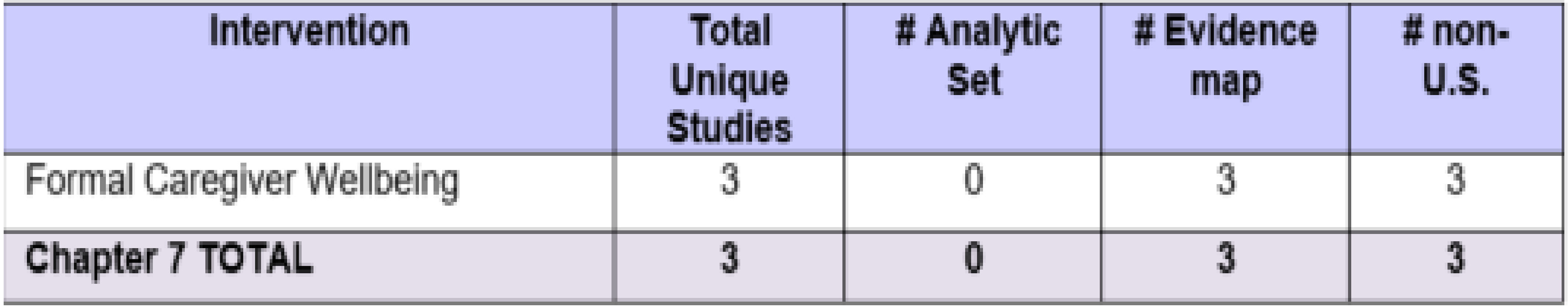
- Psychosocial interventions
- In-person social support
- Mindfulness, meditation, spiritually-focused activities
- Most forms of multicomponent interventions

Caregiver Well-being (cont.)

Evidence that did not advance to analysis

- Phone-based social support
- Physical activity or other lifestyle interventions
- Respite care
- Other interventions

Interventions for Formal Caregivers (Ch 7)



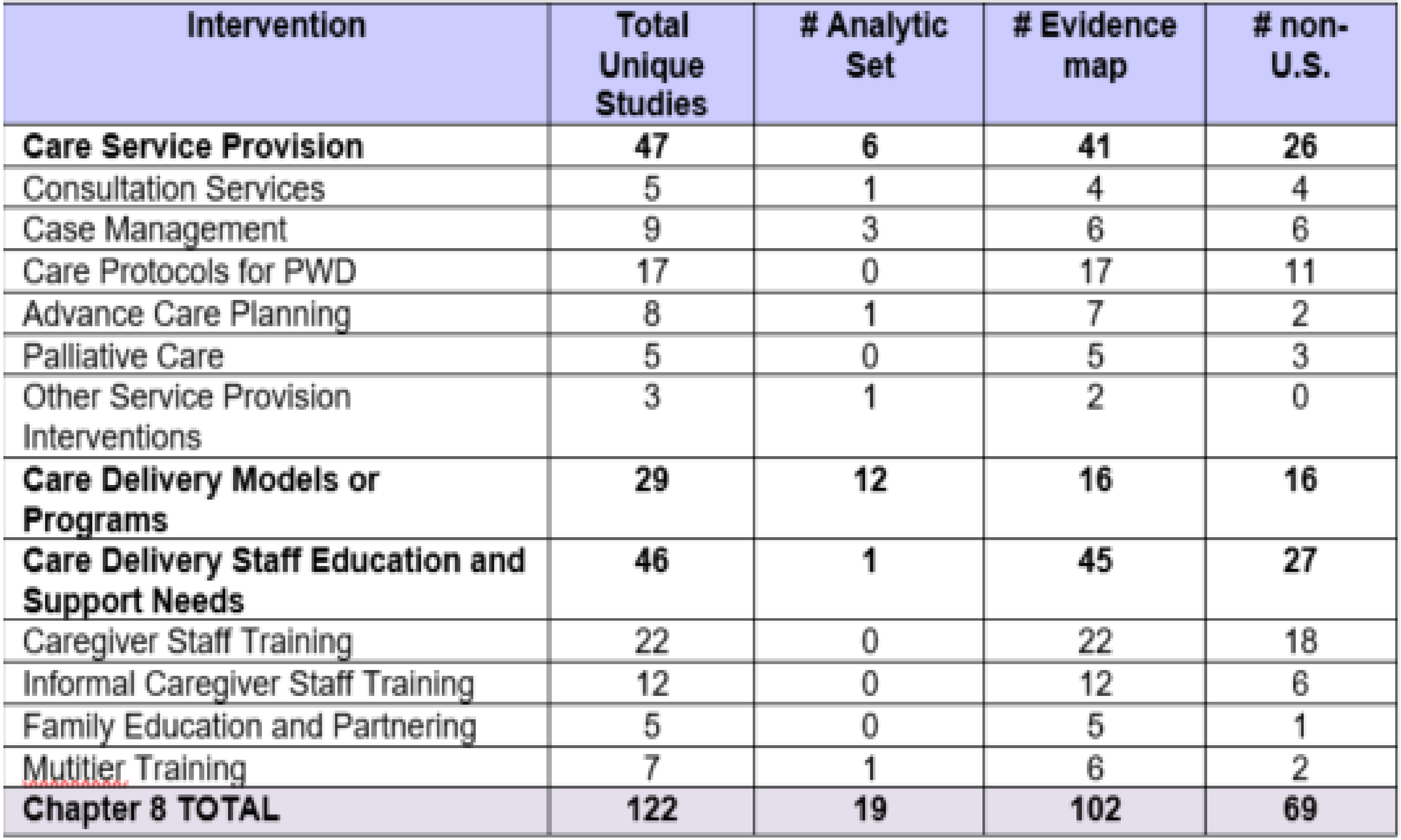
Intervention	Total Unique Studies	# Analytic Set	# Evidence map	# non-U.S.
Formal Caregiver Wellbeing	3	0	3	3
Chapter 7 TOTAL	**3**	**0**	**3**	**3**

Care Interventions for Formal Caregivers

Evidence that did not advance to analysis

- Support such as peer support, stress management, and relaxation techniques

Care Delivery (Ch 8)



Intervention	Total Unique Studies	# Analytic Set	# Evidence map	# non-U.S.
Care Service Provision	**47**	**6**	**41**	**26**
Consultation Services	5	1	4	4
Case Management	9	3	6	6
Care Protocols for PWD	17	0	17	11
Advance Care Planning	8	1	7	2
Palliative Care	5	0	5	3
Other Service Provision Interventions	3	1	2	0
Care Delivery Models or Programs	**29**	**12**	**16**	**16**
Care Delivery Staff Education and Support Needs	**46**	**1**	**45**	**27**
Caregiver Staff Training	22	0	22	18
Informal Caregiver Staff Training	12	0	12	6
Family Education and Partnering	5	0	5	1
Mutitier Training	7	1	6	2
Chapter 8 TOTAL	**122**	**19**	**102**	**69**

Care Delivery Models

Low-strength evidence

- Collaborative care models may improve PWD quality of life. This improvement may be very small to small, or it may be larger but concentrated in some not yet identified subgroup of people.

- Collaborative care models may improve system-level markers, including guideline-based quality indicators and reduction in emergency department visits.

Care Service Provision

Evidence was insufficient to draw conclusions

- Consultation services
- Case management
- Advance care planning
- Other service provision (decision aid)

Evidence that did not advance to analysis

- Care protocols for PWD
- Palliative care

Care Staff Education and Support

Evidence was insufficient to draw conclusions

- Multi-tier training

Evidence that did not advance to analysis

- Formal caregiver staff training
- Informal caregiver staff training
- Family education and partnering

Discussion

- Despite a lot of work and often compelling rationales, current available evidence cannot yet provide clear answers about which interventions (or interventions components) offer consistent benefits.
  - Low-strength evidence for collaborative care models
  - Low-strength evidence for REACH II

- On-going research funded post-2015 under stronger rigor/reporting requirements may help resolve some questions.

Methods Issues

- Applying strength of evidence (SOE) criteria to largely negative studies poses challenges.
    - The goal of rating SOE is to assess the level of confidence in the findings.
    - How comfortable can we be that results showing no effect would not be overturned with further research?
    - Some of the core elements of SOE are not as helpful for studies that show no effect.

- Not advancing pilot, small sample, and high risk of bias studies to full analysis leads to high-level assessment of the state of the science.

Thoughts for Future Research

- Weaknesses of the current evidence base can be addressed through attention to study design and conduct
  - Small studies biased toward showing larger effect sizes that are reduced or eliminated with later larger studies.
  - Risk of bias largely due to problems with
    - Selection
    - Attrition
    - Fidelity

Thoughts for Future Research

- Many populations and outcomes of interest were not represented in the literature.
- Lack of consensus on intervention taxonomies and terms hampers aggregation.
- Fidelity to interventions is a particular challenge.
- Quality of life still often lacking as outcome, as were harms

Bigger Thoughts for Future Research

- Research questions related to dissemination and implementation at the outset of intervention design may help prepare dementia care and caregiver interventions for rapid implementation in real-world settings.

- Complex interventions for complex systems are hard to do. Initiatives to creatively redesign research processes in other fields may provide opportunities to learn from and experiment with other ways of doing this science.

Thank you!

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Study selection criteria - Population

Element	PWD	PWD Caregiver
Population	**PWD**, including individuals with possible or diagnosed AD/ADRD. PWD Subgroups: Age, sex, sexual orientation/gender identity, race/ethnicity, education, socioeconomic status, prior disability, age at diagnosis, dementia type, dementia severity [e.g. stage of dementia (early stage, moderate, or severe), level of cognitive impairment rate of cognitive decline], family/household characteristics, health insurance, geographic location (e.g. urban, rural), setting type	**Informal PWD Caregivers**, such as spouses, family, friends, and volunteers Informal PWD Caregiver Subgroups, including age, sex, sexual orientation/gender identity, race/ethnicity, family history of dementia, education, socioeconomic status, employment status, relationship with PWD, living distance from PWD, dementia care training, general health status, caregiving networks, setting type **Formal PWD Caregivers**, such as certified nursing assistants (CNAs), home health aides, auxiliary workers, personal care aides, hospice aides, promotoras or promotores, and community health workers Formal PWD Caregiver Subgroups, including age, sex, race/ethnicity, education, job position, skill, training, general health status, setting type

Study selection criteria - Interventions

Element	PWD	PWD Caregiver
Intervention	KQ 1-4. Any nondrug care intervention intended to benefit PWD **except** interventions to treat conditions other than dementia, including but not limited to CPAP, and those that use supplements/natural products. (See list of example intervention types in Appendix A.) Guiding Question: Any quality improvement or implementation science study that informs the dissemination or implementation of a care intervention at least low-strength evidence for “real-world” benefits and harms (i.e., NIH Stage Model for Behavioral Intervention Development Stages 3-5)	KQ 5-6. Any care intervention intended to support informal PWD caregivers’ well-being **except** interventions to treat health conditions unrelated to providing care to PWD. KQ 7-8. Any care intervention intended to support formal PWD caregivers’ well-being except interventions to treat health conditions unrelated to providing care to PWD. KQ 9-10. Any care delivery intervention to improve how care is delivered IF the training intervention is incorporated as on-going operational procedures into the structure or processes of the organization. Interventions carried out by higher education organizations or professional organizations to provide training toward licensed professionals, and continuing education for degreed health professionals are also excluded. (See list of example intervention types in Appendix A.) Guiding Question: Any quality improvement or implementation science study that informs the dissemination or implementation of a care intervention at least low-strength evidence for “real-world” benefits and harms (i.e., NIH Stage Model for Behavioral Intervention Development 3-5)

Study selection criteria - Outcomes

Element	PWD	PWD Caregiver
Outcomes (Generally organized to correspond with Figure 1 Framework)	Quality of life and subjective well-being Burden of care Satisfaction with care Perceived Support Expenditures/financial burden (informal caregivers) Health-related outcomes: Psychological health (e.g., depression, anxiety) Neuropsychiatric symptoms (including apathy, aggression, and agitation) Function (e.g., ADL, IADL, ability to care for one's self, ability to recreate/socialize Weight loss Sleep problems Use of restraints Use of anti-psychotics Harm reduction (e.g. driving, firearms) Palliative care/hospice outcomes: Completion of advanced directives Comfort during dying process Concordance with preferred location of death Social/Community level outcomes: Engagement in community activities, Perceived inclusion Safety/perceived safety Utilization of healthcare service outcomes: Admission to nursing home Access to care and services ICU and ED usage Hospital admission and readmission Primary, Specialty, Long-term Care usage Quality of care and services (e.g., overutilization of unnecessary antibiotics, other quality care metrics.) Societal costs, including caregiving time/time spent on activities Harms, including isolation, loneliness, perceived stigma, suicidal ideation or suicide, elder abuse (e.g., physical harm, abuse, neglect, exploitation, family violence)	Quality of life and subjective well-being Burden of care Satisfaction with care for PWD (informal caregivers) Perceived Support Expenditures/financial burden (informal caregivers) Health-related outcomes: Psychological health (e.g., depression, anxiety) Immune function (e.g., inflammation or cortisol) Sleep problems Weight loss due to stress Health behaviors (e.g., exercise, substance use) Caregiving self-efficacy Confidence to manage caregiver tasks Social/Community level outcomes (informal caregivers): Engagement in community activities, Perceived inclusion Safety/perceived safety Turnover and retention (formal caregivers) Utilization of healthcare service (e.g., physician visits, antidepressant or antianxiety medication usage) Societal costs including caregiving time/time spent on activities Harms, including isolation, loneliness, perceived stigma, caregiver PTSD

Study selection criteria - Timing and Settings

Element	PWD	PWD Caregiver
Timing	No minimum duration or followup	No minimum duration or followup
Setting	Any setting; no exclusion based on geographic location or setting. Includes home, home health care, adult day care, acute care settings, social service agencies, nursing homes, assisted living, memory care units, hospice, rehabilitation centers/ skilled nursing facilities, long-distance caregiving, and nonplace-based settings	Any setting; no exclusion based on geographic locations or setting. Includes home, home health care, adult day care, acute care settings, social service agencies, nursing homes, assisted living, memory care units, hospice, rehabilitation centers/ skilled nursing facilities, long-distance caregiving, and nonplace-based settings

Study Selection Criteria - other

Category	Criteria for Inclusion
Study Enrollment	Adults with possible or diagnosed AD/ADRD. No age requirement is made, that is, early onset disease that may be experienced by people with Down syndrome or other genetic risk factors are included. Study populations may include adults with mild cognitive impairment (MCI) if 15% or less of total sample, or must report results for dementia population separately.
Study Objective	KQ 1-2: Evaluate benefits and harms of care interventions for BPSD symptoms in PWD KQ 3-4: Evaluate benefits and harms of care interventions for quality of life, function, or non-BPSD symptoms in PWD KQ 5-6: Evaluate benefits and harms of care interventions for quality of life and health outcomes of informal caregivers for PWD KQ 7-8: Evaluate benefits and harms of care interventions for quality of life and health outcomes of formal caregivers for PWD KQ 9-10: Evaluate benefits and harms of care delivery interventions that address how care is delivered KQ subquestions: Evaluate possible effect modifiers of intervention benefits and harms
Study Design	RCTs, and prospective studies with concurrent comparator arms, and at least 10 participants per arm at study analysis.* Interrupted time series with at least 3 measures both pre- and post-intervention.
Outcomes	Outcomes listed in Table 1. Actual outcome measures will be defined by study authors. Common measures are provided in Appendix A. We will only include studies with immune function, turnover, or retention of caregivers if the study also includes another PWD or quality outcomes; that is, we will not include the study if it only examines turnover or retention as an intermediate outcome in isolation.
Publication type	Published in peer-reviewed journals and grey literature with full text available (if sufficient information to assess eligibility and risk of bias are provided). Letters and abstracts are excluded due to the inability of such short publications to provide the information needed to fully describe the interventions.
Language of Publication	English only, due to resource limitations

Risk of Bias of Individual Studies

- Overall confidence that the results were believable given the study limitations – low, moderate or high
- Relevant components included:
  - Participant selection
  - Method of randomization or selection
  - Blinding/Independent outcome assessors
  - Allocation concealment
  - Attrition
  - Fidelity to intervention
- Dual, independent assessment

Strength of Evidence

- Confidence that the findings will not change with further research – insufficient, low, moderate, or high
- Domains:
  - Study limitations (overall risk of bias of the body of evidence)
  - Directness (single, direct link between intervention and outcome)
  - Consistency (similarity of effect direction and size)
  - Precision (degree of certainty around an estimate)
  - Reporting bias
- Strength of evidence assessed cautiously
  - Inability to pool due to heterogeneity in populations, interventions, outcomes, and settings
  - large number of comparisons with findings where intervention and comparison results not statistically significant.