APPENDIX A. SEARCH STRATEGIES

Database: **Ovid MEDLINE**(R)
Search Strategy:

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1 exp family/
2 couples.mp.
3 exp home nursing/
4 (grandparent: or grandmother: or grandfather:).mp.
5 exp legal guardians/
6 or/1-5
7 couples therapy/ or family therapy/ or marital therapy/ (8466)
8 6 or 7
9 exp Infertility/ or exp Infertility, Male/ or exp Infertility, Female/ or exp Fertilization in Vitro/ or exp Reproductive Techniques, Assisted/ or exp Insemination, Artificial/
10 8 not 9
11 limit 10 to (English language and yr="1980 -Current")
12 limit 11 to ("newborn infant (birth to 1 month)" or "infant (1 to 23 months)" or "preschool child (2 to 5 years)" or "child (6 to 12 years)")
13 11 not 12
14 limit 13 to meta analysis
15 (systematic adj review:).mp.
16 13 and 15
17 14 or 16
18 limit 13 to randomized controlled trial

Database: **PsycINFO**
Search Strategy:

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1 exp family/ or exp family members/ or exp spouses/ or exp couples/
2 exp caregivers/ or exp stepparents/ or exp siblings/ or caretaker:.mp.
3 exp grandparents/ or legal guardian:.mp.
4 or/1-3
5 couples therapy/ or family therapy/ or marital therapy/
6 4 or 5
7 exp Infertility/ or exp Reproductive Technology/
8 6 not 7
9 limit 8 to (English language and yr="1980 -Current")
10 limit 9 to 100 childhood <birth to age 12 yrs>
11 9 not 10
12 meta analysis/ or (systematic adj review:).mp.
13 11 and 12
14 (randomized or rct).mp.
15 11 and 14

APPENDIX B. CRITERIA USED IN QUALITY ASSESSMENT[20]

Criterion	Description
Risk of bias	Internal validity: study design and the quality of individual studies included in the review. Study design limitations may bias the estimates of treatment effect (such as lack of allocation concealment, or lack of blinding). Other areas for potential bias include stopping early for benefit and selective outcome reporting.
Consistency	The effect sizes from the included studies are similar and have the same direction of effect (positive or negative).
Directness	Interventions are directly related to health outcomes. For comparative effectiveness reviews, head-to-head comparisons are made. Indirectness is suspected if surrogate or intermediate outcomes are used instead of health outcomes. For CERs, indirectness is also suspected if more than one body of evidence is needed to link interventions, ad in the das with placebo controlled trials. Directness also includes applicability and relevance of the included studies to the VA population or to specific subpopulations within the VA. Applicability may also include settings (e.g., primary care vs. specialty care) and physician experience.
Precision	The degree of certainty surrounding an estimate of effect for each outcome of interest. Uncertainty of effect does not allow for a clinically useful conclusion, and is unable to rule out an important benefit or harm.
Risk of publication bias	Publication bias can result in an overestimate of effect. Publication bias is suspected if evidence is derived from a small number of commercially funded trials with small sample sizes and a small number of event.

APPENDIX C. PEER REVIEW COMMENTS/AUTHOR RESPONSES

REVIEWER COMMENT	RESPONSE
1. Are the objectives, scope, and methods for this review clearly described?	
Yes. This is a well-done systematic review.	Thank you.
In general, yes. Although I was confused by the term alternative family oriented intervention in KQ2 and remained so during my reading.	Our intention in Key Question #2 was to evaluate the comparative effectiveness of interventions. Typically one family–involved intervention was the primary intervention and it was compared to an alternative intervention. For example, one trial compared a skill building and problem solving intervention to an intervention where families received supportive telephone calls. The alternative family condition was the group receiving the phone calls. We have revised the wording throughout the report to better reflect this description.
Yes	No response needed
Yes	No response needed
Yes. The objectives, scope, and methods are clearly described in significant detail ensuring that the reader is aware of the implications as well as the limitations of the review.	Thank you.
Yes. I'm not quite sure why it was appropriate to exclude non-U.S. studies. A supporting citation would be useful for the strength of evidence ratings.	We have added a reference to the strength of evidence tables in Executive Summary and report.
No. 1. It is unclear how the 'quality' of studies was determined; no reference was included. I am particularly concerned about the lack of consideration given to power (studies that were adequately powered to detect differences in the primary outcome should be rated highly) and the over consideration given to blinding (most behavioral interventions cannot be blinded to the subject or the interventionalist – it's just not feasible- the only place where blinding is possible is at the level of analysis). 2. I believe that it is not appropriate to extract data on any outcomes that the study was not originally designed to affect or powered to detect. I would prefer an approach where no primary outcomes of interest were chosen by the authors of the synthesis; the synthesis team would simply judge the quality of each study and list each study's primary outcomes as they were originally published. An alternative approach would be to examine results by outcome including only RCTs that were powered to detect that outcome (e.g. Table 2 Cancer Studies – Quality of Life – Physical Functioning would only include those studies that had physical function as an outcome of interest, rather than including those who had physical function as a possible modifier or confounder). 3. Your search strategy did not include the words "caregiver" or "carer". Not sure this would make a difference, but those terms have been used successfully in other reviews.	1. We have revised the description of the method we use for assessing risk of bias and quality. We base these assessments on approaches used by the Cochrane Collaboration and AHRQ-EPC (Higgins, et al, 2001; Owens, et al 2010). Risk of bias assessments do not include power/sample size as quality measures (though this would be incorporated into the strength of evidence we have included). Power is more likely to affect the precision of the estimate rather than bias results and alter study quality (we could have a high quality small study and a poor quality large study). We agree that blinding is difficult, though the subjects and assessors could be blinded to the study objective, and outcome assessors, when used, could be blinded to the randomized condition. Risk of bias is most concerning in these situations where outcomes are subjective. Our findings did not change materially when focusing on studies of low risk of bias (good to fair quality studies). 2. We respectively disagree. While the reviewer's approach certainly would be sound for choosing an intervention for a specific patient, our approach is consistent with standard systematic review methodology and guidance statements used by AHRQ-EPC and Cochrane. 3. We used two databases for our search: PsycInfo and MEDLINE. Our search strategy for PsycInfo did include the word caregiver. For MEDLINE, however, you are correct, we did not include "caregiver" as a MeSH term in our final search. The definition (in MEDLINE) includes trained medical, nursing, and other health professionals as well as family, teachers, clergy, social workers, and fellow patients. In our work to refine the search terms, we found that many of the articles captured when searching with the term caregiver included formal, paid caregivers. Therefore, we first used the terms family and couples. We then also used the term "home nursing." Home nursing focused more on non-professional care.

REVIEWER COMMENT	RESPONSE
4. A large number of studies were excluded because "intervention is not counseling, therapy, education, or family based treatment involving a family member." How many were excluded because of the modality of the intervention and how many were excluded because they did not involve a family member? 5. I do not believe it is fair to say that "evidence does not favor family-involved interventions over …" but rather "there is insufficient evidence to say that family involved interventions improve x,y,z outcomes". If you judge that most of the studies you examined were methodologically weak, then you need to temper the strength of the conclusions you can make.	4. We did not identify how many studies were uniquely excluded for each specific reason. The exclusion typically was for the full phraseology not separated items. Therefore, studies may have met multiple exclusion criteria (e.g., conducted outside the US and included teachers, instead of family members). Each specific reason was not recorded; instead, if any of the exclusion criteria were met, the study was excluded. 5. We have reviewed and revised this statement to include that there is insufficient evidence for outcomes. However, we revised this statement because the heterogeneity of the studies makes it difficult to be unequivocal. We retain our statement that positive effects were infrequent, not consistently seen, typically small in magnitude, often based on multiple outcome reporting or subscale findings. Thus any positive effects and the clinical importance of these findings should be viewed with caution.
2. Is there any indication of bias in our synthesis of the evidence?	
No. Although there were few studies that were of "good" quality, at times I felt there was not enough attention to weighting these studies more than those of poorer quality. This concern was somewhat lessened given that only RCTs were included	Because we did not conduct a meta-analyses we could not formally weight studies. We do note, however, that only 2 of 26 cancer trials were rated good quality. For memory trials, six trials were rated good quality. Five of the 6 reported one significant intervention effect each. However, these effects were across 3 different outcomes. Limiting our evaluation to just good quality studies did not change the strength of evidence.
No	No response needed
No	No response needed
No	No response needed
No. There is no evidence of bias in the review.	No response needed
No. I do wonder about the precision of the comparisons, in the sense that it's pretty hard to know the quality of the family-oriented interventions reflected in these studies. They also are likely to vary quite a bit in the degree to which they *include* family members vs. *involve* family members, etc. In other words, systemic interventions vary a lot and that makes this review challenging. The general vs. specific focus the authors identify is helpful and should be pursued. Perhaps the authors could give some specific examples when they make this point so readers have even greater clarity	Thank you. We have incorporated this suggestion into the discussion.
Yes. 1) By extracting data on outcomes that the studies were not powered to detect, the synthesis is systematically biasing towards finding no effect. I believe your conclusions would be very different if you examined only the outcomes originally chosen as the primary outcomes for each study. 2) Also, if the authors of the synthesis examined only data that was unadjusted, this would also bias the results of the synthesis towards finding no effect. One major challenge in caregiver interventions is sample size – recruitment of dyads is difficult and, thus, studies typically have small samples. With a smaller sample size, the chances are higher that the intervention and control groups have differences at baseline that need adjusting in the final analysis. Thus, unadjusted data is often not reported in caregiving studies (as you saw) – and, when it is reported, should NOT be used to base conclusions upon.	We agree that recruitment to these studies is difficult and that future, large and methodologically rigorous randomized trials are needed. We do, however, respectfully disagree about our decisions on data extraction and study inclusion. We conducted the systematic review based on standard and validated methodology established by the AHRQ Evidence-based practice centers. We commented on the size, quality, applicability of studies and consistency of findings. Not including smaller studies or studies not powered for certain outcomes would systematically eliminate findings from many studies and result in a small study publication bias that would artificially increase effect size. We have commented on findings where adjusted results were provided throughout the report. Small studies, while potentially resulting in "imbalance," are unlikely to result in systematic bias-the purpose that randomization is intended to avoid.

REVIEWER COMMENT	RESPONSE
3. Are there any published or unpublished studies that we may have overlooked?	
Yes. The effect of telephone support groups on costs of care for veterans with dementia. Wray LO, Shulan MD, Toseland RW, Freeman KE, Vásquez BE, Gao J. Gerontologist. 2010 Oct;50(5):623-31. Epub 2010 May 27.	Thank you for the reference information. We have added this study to the review
Maybe. I wondered why you didn't include the REACH II study, which used RMBPC as one of its outcome measures – it is included as part of the multicomponent outcome. 1. Coon, David, W., et al. (2004). Ethnicity and time to institutionalization of dementia patients: A comparison of latina and caucasian female family caregivers. Journal of American Geriatrics Society, 52, 1077-1084. 2. REACH II Investigators (alphabetical order: Belle, S.H., Burgio, L., Burns, R., Coon, D., Czaja, S., Gallagher-Thompson, D., Gitlin, L., Klinger, J., Koepke, K. M., Lee, C. C., Martindale-Adams, J., Nichols, L., Schulz, R., Stahl, S., Stevens, A., Winter, L. & Zhang, S.) (2006). Enhancing the quality of life of dementia caregivers from different ethnic or racial groups: A randomized, controlled trial. Annals of Internal Medicine, 145, 727-738.	Thank you for the suggested references. We have reviewed the two papers. Coon (Mausbach 2004) reported results by ethnicity but not by intervention group so the study did not address our key questions. Belle et al. 2006 has been added to the review.
No	No response needed
Yes Good selection of articles. Other potential articles: 1. Belle, SH et al. (2006). Ann Intern Med 2006, Nov 21;145(10): 727-38 (includes institutionalization of dementia patients as an outcome of a caregiver RCT 2. Linda Nichols' research with the REACH program (although I could not easily find articles in PubMed related to her intervention with dementia caregivers – I think she has unpublished results) 3. 2012 articles: a. Failho, PP et al. (2012) Arq Neuropsiquiatr. October 70(10) 786-790 b. Liddle, J et al Int Psychogeriatr Dec 24 (12) 1927-42	Thank you for the suggested references. We have reviewed the three suggested papers: We have added Belle 2006 to the review. We identified another reference from the REACH study (Burns 2003) and have added that paper to the review. Failho did not meet our criteria; it was conducted in Brazil. Liddle did not meet our criteria; it was conducted in Australia.
No. I am not aware of any published or unpublished studies that were overlooked.	No response needed
I'm not aware of any.	No response needed
No	No response needed
4. Please write any additional suggestions or comments below. If applicable, please indicate the page and line numbers from the draft report.	
1. Executive Summary – Terms are not defined before they are mentioned in the ES – is that function assumed to be managed by the glossary of terms at the end of the ES? 2. I remained confused about the definition of alternative family oriented interventions. 3. The criteria for good, fair and poor quality of studies are not explicitly defined until (the first place I could find) page 72 (but I did not read the Cancer section). 4. page 4, - paragraph 1 under KQ1, last sentence is confusing	1. We have corrected this-terms are now defined. 2. Please see explanation in first comment. 3. We have clarified the definitions of good, fair, and poor quality studies in the Methods and Results sections of the Executive Summary and full report. 4. Thank you. We have revised this sentence.

REVIEWER COMMENT	RESPONSE
5. page 7, paragraph 3, bullet 2, are weekly nurse telephone calls counseling? 6. Tables. Several comments about tables. I could not find definitions for risk of bias, directness, precision, consistency or evidence rating in the text. Some of them are later, after the tables have been presented for example strength of evidence rating is on page 32; others I could not find it all. Also table information is not consistent, for example, sometimes there is in and between entries under risk of bias sometimes a semicolon, sometimes commas are used sometimes not. This type of sentence is often under precision: Three trials reported (one good, one far, one poor)… I believe that the parenthetical expression should modify trials and not reported as in: Three trials (one good, one far, one poor) reported 7. the word veteran is not always capitalized. 8. Figure 1 is presented before it is referenced in the text/ 9. Page 30, paragraph 1. Text says articles were conducted in the US. this sentence needs to be clarified. 10. Page 30/31, last paragraph area in general psychological function does not correspond with mental health conditions in the DSM; where does this leave depression and anxiety which are secondary outcomes. 11. I know you will fix all this later on-multiple references within parentheses are not organized. some references are not found or are mislabeled-Gitlin has a 2010 a and a2010 ACT; Mittleman is sometimes done as 2004/2006. 12. Page 66, paragraphs 3 and 5. I am not exactly sure how these two paragraphs are different. Also, paragraph 2 talks about family focused CBT interventions while talks about multicomponent intervention targeted at family members. In the first instance the CBT appears to be the most important, in the second instance the multicomponent. This is also the case on page 76 where the heading is family focused CBT interventions, not multicomponent. 13. page 67, paragraph 2. Support groups for patients with early-stage memory loss does not indicate that there is a family component 14. The formatting changes somewhere in the text and the headings are smaller. 15. Page 82. Paragraph 4, first sentence is confusing. 16. Page 88 – paragraph 3. None were superior to alternative interventions (such as? – ones that they have listed in their studies?) Also, last sentence is unclear – where were there no data? 17. Page 93, paragraph 1 (and in conclusion of Executive Summary). Needs to read: In this review we assess the evidence of family-involved interventions for improving *outcomes of* adult patients with cancer and memory-related conditions. Next sentence is a bit unclear. Does individually-focused mean patient focused? And interventions that provide only health or psychoeducation? Not sure what the health means in this – health education?	5. We have clarified this statement by clarifying that nurse phone calls were to manage uncertainty and patient concerns. 6. We have added these definitions to the text and corrected the inconsistency in reporting; we agree with your comment about placement of the parenthetical expressions. 7. We have corrected this throughout. 8. We have corrected the reference to Figure 1. 9. We have clarified this sentence. 10. General psychological functioning is grouped under quality of life and corresponds to psychological functioning. This is in contrast to more specific mental health conditions, such as depression and anxiety, which are in the DSM. In order to avoid any confusion about this, we have removed the classification of primary and secondary outcomes. 11. We have changed the references to superscripts and clarified the multiple reference citations. 12. We agree this was not clear and have made changes to clarify the differences across the types of interventions. 13. We have clarified this statement. 14. We have reviewed the formatting and font size and made changes as needed. 15. We have revised this sentence. 16. We have revised these sentences. 17. We have revised these sentences to indicate patient-focused instead of individually-focused and health education and psychoeducation, instead of health and psychoeducation.

REVIEWER COMMENT	RESPONSE
While we understand the rationale for limiting results to patient outcomes, we question the wisdom of this with regard to dementia and memory impairment. We think that preventing caregiver burnout is a critical issue that has major implications for the well-being of the person with the disease. The data on caregiver interventions thus far do not indicate they reduce out-of-home placements, but these are likely overdetermined by many other factors—number of available caregivers, finances, health of the caregiver, kinds of care facilities available, etc. However, it is certainly plausible that caregivers who feel more supported and educated can adhere better to patient treatment plans, provide better care, etc. With regard to aging related memory disorders, having a psychosocial intervention goal of improving patient behavior seems unlikely at this point.	The topic nominated for this review was to examine the effect of caregiver interventions on patient outcomes. We agree that caregiver burnout is a critical issue and that by limiting the review to only patient outcomes, we are not able to present evidence on the potential pathways by which caregiver experiences affect patient outcomes. We do acknowledge this as a limitation in the discussion and recommend this as a potential area for further research. We should note that there have been recent VA reviews on caregiver interventions to improve caregiver outcomes, such as managing problem behavior (Goy, et al, 2010; Kansagara, 2012), but, as we describe in the background section for the report, few reviews have extended beyond the caregivers to examine the effects of these interventions on the patient.
Well written and comprehensive	Thank you.
The review is very thorough and certainly thought provoking in light of VA's focus on supporting family members and Caregivers. Most studies focus on family/caregiver outcomes and not patient outcomes. It will be essential to establish a balance of these two outcomes in order to provide the best programming.	Thank you. We agree with the need to consider family/caregiver and patient outcomes in making program decisions.
I don't know what style guide is being used – text citations don't appear to be listed by author or year. p. 83 – Font size shifts p. 94 – I find the second sentence in the paragraph beginning 'based on our findings' hard to follow. p. 96 – is an author name missing for the first citation in the reference list?	Thank you. We have addressed these concerns.
Personally, I prefer using the term "informal caregiver" rather than "family" (especially if you are including friends as possible subjects).	We agree that in many cases, caregiver is the appropriate term. However, in others, where more emphasis is on psychosocial adjustment to the disease or treatment, it may be less appropriate.
5. Are there any clinical performance measures, programs, quality improvement measures, patient care services, or conferences that will be directly affected by this report? If so, please provide detail.	
Caregiver Support Services and GEC would be interested. There is a caregiver conference call led by John Piette, PhD that would be interested. There have been a couple of VHA Caregiver conferences largely organized by Caregiver support Services.	Thank you for this suggestion.
Not that I know	No response needed
Conferences for geriatric clinicians, such as AGS and GSA would be appropriate	Thank you for this suggestion.
The Caregiver Support Program Office as well as the Office of Mental Health will be impacted by this review as they continue to roll out legislatively mandated programs to support families and Caregivers. In addition, there is much interest in Congress, Veteran Service Organizations, Non Governmental Organizations, Veterans and their families and Caregivers as well as other stakeholders to provide support and assistance to families, especially of those ill and injured. VA will need to evaluate the impact that such programs have, both on family members or Caregivers, as well as the impact on Veterans in order to proceed with such programming.	Thank you for this suggestion.
I'm sorry, but I'm not sufficiently familiar with the VA to be able to say	No response needed

REVIEWER COMMENT	RESPONSE
The VA's national caregiver program may be affected by this report; funding for expanding programs to help caregivers provide better care for cancer and dementia patients may be affected if there is a sense that research shows no benefit to such interventions. Similarly, VA HSRD may choose to reduce the funding it provides to caregiving research if the impression is given that studies show no benefit.	We thank the reviewer for these comments and appreciate that our report has implications for health care practice, policy and research. Our goal is to objectively identify and synthesize the existing evidence and provide an assessment of the effectiveness and harms of interventions. We do not set policy, make practice implementation or research funding decisions. These may be made by factors beyond the available evidence, though we hope our report provides evidence based guidance in these decisions. We have reviewed our discussion and summary recommendations to make these issues clear. We believe that this report provides strong support that future research is needed particularly assessing the effect of currently rolled out VA programs and any future design and implementation of caregiver programs. We also believe that this report may help reduce implementation of ineffective and costly programs and target interventions of established effectiveness.
6. Please provide any recommendations on how this report can be revised to more directly address or assist implementation needs.	
It would be useful to draft 1-2 RFPs for VA R&D to address gaps in literature that are nicely outlined in review.	Thank you for this suggestion.
Do you have any recommendations on what we should be doing clinically?	We have added to the discussion how clinicians might use this report. Because the evidence does not strongly favor one intervention over another, it is difficult to make recommendations on how our findings can directly affect practice.
We think these negative results, especially regarding aging related memory disorders, may have implications for the VA Social Work and Care Management Program Office as they consider their program goals	No response needed
The authors conclude that the previous interventions have had no or modest effects on patient outcomes, thus implementation most of the interventions would not be helpful. However, it is commendable that the authors provide recommendations for improving research in this area and emphasize that interventions, which target specific areas (sleep, etc.) are most effective.	Thank you.
No additional comments	No response needed
My main uncertainty is whether sufficient attention was paid to the quality of the family interventions in the studies examined. I notice fairly frequently that the sophistication of measurement about families is low – could the same be true of the quality of the family-focused intervention strategy?	Throughout this revised report, we call attention to the quality of the family interventions, and we agree that not all studies are methodologically rigorous. We have also added our criteria for assessing quality to the executive summary. One recommendation in the discussion is for more methodologically sound research to be developed, using measures that are validated, comparable, and reporting findings at consistent intervals.
For the reasons stated in #5, I would strongly recommend that the summary and discussion state that the science is limited and, while there is insufficient evidence to say that caregiver interventions improve patient outcomes, there have been some promising findings in the areas of x, y, z…	As noted above, our goal was to identify, synthesize and communicate the evidence on the key questions. We have, however, reviewed and revised our discussion section. While we conclude that there is low to moderate strength of evidence that family directed caregiver interventions are not more effective than usual care or other patient- or family- directed interventions for improving patient outcomes, we have revised the conclusions to point to areas that have insufficient evidence and where additional, methodologically rigorous research is needed.

APPENDIX D. EVIDENCE TABLES

Table 1. Cancer Studies – Study Characteristics

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Badger 2007[9] Funding Source: Government Condition: Breast cancer, Stage I-III, receiving adjuvant treatment **KQ1 ☐ KQ2 ☒** **Intervention Type:** 1) Multicomponent (education, support, management of depression and anxiety symptoms) 2) Exercise	N=96 (of 97 randomized) Age (years): 54.1 Gender (% male): 0 Race/ethnicity (%): *White* 85; *African-American* 0; *other* 15 Marital Status (%): *Married* 73 Education (%): *HS or less 21; Post HS 79* Veterans (%): NR Recruitment Method: local cancer center, oncologists' offices, support groups, and self-referral Family Characteristics: Relationship to patient: *Any person patient viewed as significant in coping and recovery* Age (years): 51.7 Gender (% female): 26 Race/ethnicity (%): *White* 87; *African-American* 2; *other* 12 Education (%): *HS or less 16; Post HS 84* Veterans (%): NR	Inclusion: diagnosis of Stage I-III breast cancer; currently receiving adjuvant treatment for breast cancer; ability to speak English and talk on the telephone; no physical or psychological disabilities that would prevent participating in the interventions; availability of a partner who was willing to participate in the investigation Exclusion: NR	1st Intervention: Telephone interpersonal counseling (TIP-C) (n=38): 6 weekly calls from psychiatric nurse counselor; average call duration = 34 min; call to partners every other week to discuss emotional well-being and relationship with patient 2nd Intervention: Self-managed exercise (n= 23): 6 weekly calls; focus on regular, low-impact exercise; calls to partner every other week; encouraged exercise and tracked progress; average call duration = 11 min Comparator: Attention control (n=37): Information about breast cancer; 6 weekly calls; biweekly calls to partner; average call duration = 7 min; no counseling or exercise encouragement; questions or problems referred to primary physician Length of Follow-up: 4 weeks (post tx)	***Depression/ anxiety:*** a. Depression (CES-D) b. Anxiety (composite of PANAS, SF-12, and Index of Clinical Stress) Self-reported outcomes assessed at baseline, post-treatment (6 weeks after baseline), and 1 month post-treatment ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: unclear Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: *treatment dropouts* – TIP-C = 0 Exercise = 2/23 (8.7%) Control = 3/37 (8.1%) Treatment integrity: interventions delivered by counselors trained in the intervention for which they were responsible; interventions taped and reviewed for quality control **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Badger, 2011[21] Funding Source: Government Condition: Prostate cancer, undergoing or completed tx (Stage I = 16%, II=9%, III = 11%, IV=11%, unknown = 53%) **KQ1 ☐ KQ2 ☒** **Intervention Type:** Multicomponent (education, support, management of depression and anxiety symptoms)	N=70 (of 71 randomized) Age (years): 67 Gender (% male): 100 Race/ethnicity (%): *White* 84; *African-American* 9; *other* 7 Marital Status (%): *Married* 79 Education (%): *HS or less* 14; *Post HS* 86 Veterans (%): NR Recruitment Method: regional cancer centers; VA centers; cancer support groups; oncologists' offices; research study websites Family Characteristics: Relationship to patient: *Spouse 83%; Sibling 4%; Adult Child 2%; other 11%* Age (years): 61 Gender (% female): 93 Race/ethnicity (%): *White* 81; *African-American* 9; *other* 10 Marital Status (%): *Married* 81 Education (%): *HS or less* 18; *Post HS* 82 Veterans (%): NR	Inclusion: diagnosis of prostate cancer, currently undergoing or had completed treatment within the past 6 months, ability to speak English, no physical or psychological disabilities that would prevent participation; availability of a "social network member" (i.e., anyone patient felt was significant to his recovery – most were spouses) willing to participate Exclusion: NR	Intervention: Telephone interpersonal counseling (TIP-C) (n=36): targets social support behaviors of cancer pts & partners; 8 weekly calls to pts (first call average 56 min, then 31 min) from master's prepared nurse or social worker; calls to partners every other week (discussed emotional well-being; 4 calls, average 31 min), individualized, but followed structured protocol Comparator: Health education attention condition (HEAC) (n=35): written materials (cancer and other health topics) from National Cancer Institute for 8 weeks; weekly calls to review materials; delivered by research assistants (RA) – most from non-health disciplines; no counseling; calls to partners every other week (4 sessions); average of 28 min for all calls Length of Follow-up: 8 weeks post-tx	***Physical functioning:*** a. UCLA Prostate Cancer Index (prostate specific health related QOL) ***General psychological functioning:*** a. Spiritual well-being (QoL Breast Cancer subscale) b. Positive & negative affect schedule (PANAS) c. Perceived stress scale (PSS) ***Depression/ anxiety:*** a. Depression (CES-D) ***Symptom control/ management:*** a. Multidimensional Fatigue Inventory (MFI) Outcomes assessed at baseline, post-tx, 8 weeks post-tx ☐ **Negative caregiver outcomes reported**	Allocation concealment: adequate Blinding: unclear Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes T2 (end of treatment) – 5 total dyad withdrawals T3 (end of follow-up) – 2 additional dyads lost to follow-up *Treatment adherence*: # of sessions completed: TIP-C survivor = 85% HEAC survivor = 89% TIP-C partner = 85% HEAC partner = 93% *Outcomes assessed*: Baseline 100% Post-tx: 93% 8 weeks post-tx: 90% Treatment integrity: both interventions manualized; Interventions recorded and investigators reviewed recordings, giving feedback to maintain fidelity and prevent drift; had to maintain >90% on protocol implementation at all times **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Baucom, 2009[31] Funding source: Government, Foundation Condition: Stage I or II breast cancer **KQ1 ☒ KQ2 ☐** **Intervention Type:** Multicomponent (educational, skill-based, emotional, conflict resolution)	N=14 couples (demographic data for patients and partners combined) Age (years): 50 (median) Gender (% male): 0 Race/ethnicity (%): *White 86; African-American NR; other NR* Marital Status (%): *Married/cohabitating* 100 Education (years): 16 (median) Veterans (%): NR Recruitment Method: medical records of one hospital Family Characteristics: Relationship to patient: *Male romantic partner* Age (years): See above Gender (% female): 0 Race/ethnicity (%): See above Education (%): See above Veterans (%): See above	Inclusion: recently diagnosed with Stage I or II breast cancer; no history of other breast cancer; no history of cancer within the last 5 years; currently married or living together with a male romantic partner for at least 12 months; both partners willing to participate and able to speak English Exclusion: NR	Intervention: Relationship enhancement (RE) (n=8): 6 bi-weekly, face-to-face, 75 min. sessions; each couple seen individually by therapist in outpatient setting, teaching how to communicate effectively and reach important decisions jointly; manualized Comparator: Usual care (n=6): Couples received list of community resources for additional support; no cancer education or psychosocial intervention from the project therapists or as part of their routine hospital-based treatment for cancer Length of Follow-up: Assessments were conducted before treatment, post treatment, and 12 months later	***Physical functioning:*** a. Functional Assessment of Cancer Therapy (FACT-B) ***General psychological functioning:*** a. Brief Symptom Inventory (BSI-18) ***Symptom control/ management:*** a. Brief Fatigue Inventory (BFI) b. Brief Pain Inventory (BPI) c. Rotterdam Symptom Checklist (RSC) ***Relationship adjustment:*** a. Quality of Marriage Index *All assessed by self-report at pretreatment, post treatment, and 12 months after treatment (e.g., Depression, BDI, SR, post tx, 6 moss, 12 mos)* **☐ Negative caregiver outcomes reported**	Allocation concealment: adequate Blinding: unclear (at initial assessment, couples and assessor blinded to subsequent treatment assignment; unclear if all assessments were blinded) Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: no Treatment adherence: outcomes given for 8 patients only, and the N for each arm is not reported; text reports on only 2 dropouts (1 per group) Treatment integrity: supervisor reviewed videotapes of treatment sessions; group discussion of completed sessions **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Blanchard, 1996[37] Funding Source: Foundation Condition: Cancer (any, 51% breast) diagnosed more than 3 months before recruitment but patient not eligible for hospice **KQ1 ☒ KQ2 ☐** **Intervention Type:** Problem solving	N=57 (of 86 randomized) Age (years): 52 Gender (% male): NR Race/ethnicity (%): *White 98; African-American 2; other 0* Marital Status (%): *Married/cohabiting 100* Education (%): *HS or less 28; Post HS 72* Veterans (%): NR Recruitment Method: convenience sample - regional medical oncology clinic Family Characteristics: Relationship to patient: *Spouse* Age (years): 52.5 Gender (% female): 48 Race/ethnicity (%): *White 97; African-American1.5; other 1.5* Education (%): *HS or less 65; Post HS 35* Veterans (%): NR	Inclusion: cancer diagnosed >3 months before recruitment; not eligible for hospice; married Exclusion: NR	Intervention (n=25): Standardized intervention protocol to teach spouses how to reduce or manage specific problems; 6 1-hr one-on-one training sessions with social worker (how to identify a problem, generate alternate solution; examine benefits; discuss, rehearse action plan; carry out and evaluate the plan) Comparator (n=32): Usual care; did not receive any part of the intervention but were allowed to receive usual services offered by clinical practice Length of Follow-up: 6 months	***Physical functioning:*** a. Medical Outcomes Study (MOS) SF20 ***General psychological functioning:*** ***a.*** Medical Outcomes Study (MOS) SF20 ***Social functioning:*** a. Medical Outcomes Study (MOS) SF20 ***Global quality of life:*** a. Functional Living Index-Cancer (FLIC) ***Depression/anxiety*** a. Depression (CES-D) ***Symptom control/ management:*** a. Medical Outcomes Study (MOS) SF20 (pain subscale) ***Relationship adjustment:*** a. Dyadic Adjustment Scale (DAS) Outcomes assessed at baseline, post-treatment (within 2 wks), and at 6 months post-baseline **☐ Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: yes - single (interviewer blinded to condition) Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: partial, dropouts mentioned, but not explained Treatment adherence: NR Treatment integrity: sessions were audiotaped; authors reviewed 20% of tapes **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Budin, 2008[30] Funding Source: Government Condition: Breast lesion – confirmed or strongly suspected diagnosis of cancer **KQ1 ☒ KQ2 ☒** **Intervention Type:** Multicomponent (psychoeducation, support, coping, communication)	N=249 Age (years): 53.8 Gender (% male): 0 Race/ethnicity (%): *White* 69; *African-American* 16;*other* 15 Marital Status (%): *Married/cohabiting* 56 Education (%): *HS or less* 23; *Post HS* 74 Veterans (%): NR Recruitment Method: participating surgeons from four medical centers Family Characteristics: Relationship to patient: *Person most intimately involved in cancer experience* Age (years): 51.6 Gender (% female): 42 Race/ethnicity (%): *White* 70; *African-American* 13; *other* 17 Education (%): *HS or less* 15; *Post HS* 74 Veterans (%): NR	Inclusion: breast lesion with confirmed or strongly suspected diagnosis of cancer; enrolled in 1 of 4 oncology services that were part of study; no previous history of cancer; identified person intimately involved in breast cancer experience; willing to participate in 1 of 4 groups; able to read and understand English; no concurrent, uncontrolled, chronic medical illness; neither patient nor partner had history of psychiatric hospitalization or drug abuse Exclusion: no additional exclusion criteria	1st Intervention: Psychoeducation (SE) (n=66): 4 videos, viewed separately by patients and partners 2nd Intervention: Telephone Counseling (TC) (n=66): 4 sessions, separate scripts for patient and partner, conducted by nurse interventionist; manualized 3rd Intervention SE + TC (n=58) Comparator (n=59): Disease Management (DM), evidence-based national treatment protocols **NOTE: Groups 1, 2, & 3 also received DM** Length of Follow-up: Interventions were administered at 4 phases: 1) T0/T1 – baseline/diagnostic (diagnosis determined) 3) T2 – post surgical (within 2 days) 4) T3 – adjuvant therapy (making decisions about therapy) 5) T5 – ongoing recovery (2 wks after chemotherapy or radiation or 6 months after surgery)	***Physical functioning:*** a. Overall Health Status (subscale of SRHS) (SR) ***General psychological functioning:*** a. Psychological Well-being (subscale of PAL-C) (SR) ***Social functioning:*** a. Psychosocial Adjustment to Illness Scale (social adjustment) – Domestic, Vocational and Social Environments (SR) ***Symptom control/ management:*** a. Side Effects Severity (subscale of BCTRI) (SR) b. Side Effect Distress (subscale of BCTRI) (SR) All outcomes at baseline/ diagnostic phase, post-surgery phase, adjuvant therapy phase, ongoing recovery phase ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: no Intention-to-treat analysis (ITT): modified Withdrawals/dropouts adequately described: partial (specific numbers of withdrawals/dropouts for each reason not provided) Treatment adherence: data received from 79% at T0/T1, 80% at T2, 78% at T3, and 71% at T4 Treatment integrity: nurse interventionist for TC was trained and supervised in individualized TC approaches **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Campbell, 2004,[25] 2007[26] Funding Source: Government Condition: Prostate cancer with Karnofsky Performance Status scores >= 60 **KQ1 ☒ KQ2 ☐** **Intervention Type:** Multicomponent (education, problem solving, coping skills)	N=40 Age (years): 61 Gender (% female): 0 Race/ethnicity (%): *African-American 100* Marital Status (%): *Married/cohabiting 85* Education (%): *HS or less 53; Post HS 48* Veterans (%): NR Recruitment Method: urology clinic, regional tumor registry, community Family Characteristics: Relationship to patient: *Intimate partner* Age (years): 58 Gender (% female): NR Race/ethnicity (%): NR Education (%): *HS or less 60; Post HS 38* Veterans (%): NR	Inclusion: African-American men; beyond the acute diagnosis and treatment phase for prostate cancer; Karnofsky Performance Status scores 60 or higher (only occasional assistance needed in caring for self) Exclusion: NR	Intervention (n=12): Coping Skills Training (CST); 6 weekly 1-hour telephone sessions; followed detailed written outline Comparator (n=18): Usual care though patient's outpatient program Length of Follow-up: None after 6 week treatment phase	***Physical functioning:*** a. Short Form-36 Health Survey (SF-36) ***General psychological functioning:*** a. Short Form-36 Health Survey (SF-36) ***Symptom control/ management:*** a. Expanded Prostate Cancer Index Composite (EPIC) (urinary, bowel, sexual functioning symptoms) Self-reported outcomes assessed pre-treatment and post-treatment (6 weeks) **☐ Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: unclear Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: 77.5% (31/40) completed intervention; one additional couple not included in data analysis Treatment integrity: sessions audiotaped and reviewed for adherence to protocol **Study quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Canada, 2005[43] Funding Source: Government/ foundation Condition: Localized prostate cancer; Stages A-C **KQ1 ☐ KQ2 ☒** **Intervention Type:** Multi-component; Education; skill-based training; emotional support	N=84 Age (years): 64.3 Gender (male): 100 Race/ethnicity (%): *White* 83; *African-American* 11; *Hispanic* 6 Marital Status (%): *Married/cohabiting* 100 Education (%): *HS or less* 12; *Post HS* 88 Veterans (%): NR Recruitment Method: letters to clinic registry members; flyers posted in clinics; physicians encouraged during visits to ED clinics; outreach to cancer ministries at African-American churches Family Characteristics: *Spouses or cohabiting female partners* Age (years): 59.6 Gender (% female): 100 Race/ethnicity: NR Education (%): NR Veterans (%): NR	Inclusion: undergone treatment for localized prostate cancer; Stage A-C, with either surgery or radiation 3-60 months previously; married or living with female partner ≥1 year who was willing to participate; speak English; reside with reasonable distance of clinic. Exclusion: currently receiving hormonal therapy for prostate cancer; currently using a successful or satisfactory medical treatment for ED; or able to achieve erection without medical or mechanical assistance on ≥ 50% attempts during last 3 months	Couples Counseling (n=25); manualized and standardized; 4 sessions of 1 hour each; education provided concerning sexual impact of surgery/therapy, coping strategies, communication skill training; cognitive-behavioral techniques, homework assignments. Patient Counseling alone (n=26); Same intervention as Couples Counseling (described above) but information presented to patient alone over 4 sessions. Length of Follow-up: 6 months	***General psychological functioning:*** a. Brief Symptom Inventory, Global Symptom Inventory (BSI/ GSI) [SR] ***Symptom control/ management:*** a. IIEF International Index of Erectile Functioning [SR] ***Relationship adjustment:*** a. Abbreviated Dyadic Adjustment Scale (A-DAS) [SR] Outcomes assessed at baseline, post-tx, 3 and 6 months post-tx. Scores by group not provided. **☒ Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: no Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: Session adherence: Session 1: 100% (84/84) Session 2: 90% (76/84) Session 3: 67% (56/84) Session 4: 61% (51/84) Dropouts (no outcomes assessed): 39% (33/84) Treatment integrity: manualized treatment, weekly supervision of counselors **Study quality: Poor**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Giesler, 2005[22] Funding Source: NR Condition: Prostate cancer (localized); Stage T1a-T2c **KQ1 ☒ KQ2 ☐** **Intervention Type:** Multicomponent (psychoeducational, symptom management	N=99 Age (years): 64 Gender (% male): 100 Race/ethnicity (%) *White 90; African-American 8; other 2* Marital Status (%) *Married/cohabiting 96* Education (%): *HS or less 32; Post HS 68* Veterans (%): some recruited from a VA hospital Recruitment Method: NR Family Characteristics: Relationship to patient: *Spouse or relationship partner* Age (years): NR Gender (% female): NR Race/ethnicity (%): NR Education (%): NR Veterans (%): NR	Inclusion: Diagnosis of Stage T1a-T2c prostate carcinoma; scheduled to undergo or to have undergone surgery, external beam radiation, or brachytherapy; spouse or relationship partner willing to participate and who enrolled within 2 weeks after conclusion of therapy; age ≥ 18 years, fluent English Exclusion: NR	Intervention (n=48): Cancer Care Intervention; 6 monthly sessions (2 in-person, 4 telephone); facilitated by computer program (standardized questions and strategies for solving problems); goal was to eliminate or reduce the impact of identified problems related to sexual, urinary, & bowel dysfunction, cancer worry, dyadic adjustment, depression, and other sequelae of cancer (e.g., fatigue and pain) Comparator (n=51): Standard care (no description) Length of Follow-up: 12 months post treatment	***Physical functioning:*** a. SF-36 Short Form Health Survey (physical health subscale) ***General psychological functioning:*** a. SF-36 Short Form Health Survey (mental functioning subscale) ***Social functioning:*** a. SF-36 Short Form Health Survey (social functioning subscale) ***Depression/anxiety:*** a. Center for Epidemiologic Studies-Depression (CES-D) ***Symptom control/ management:*** a. SF=36 Short Form Health Survey (pain subscale) b. Prostate Cancer Quality of Life Instrument, urinary function, limitation, and bother scales ***Relationship adjustment:*** a. Dyadic Adjustment Scale (DAS) [SR] Outcomes assessed at baseline and 4, 7, and 12 months post-tx **☐ Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: yes (outcome assessment) Intention-to-treat analysis (ITT): unclear Withdrawals/dropouts adequately described: partial (primary reason for dropping out was inconvenience; no other reasons provided) Treatment adherence: 85.9% (85/99) completed all assessments Treatment integrity: NR (computer program documented intervention process) **Study quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Gustafson, 2013[44] Funding Source: Government Condition: Lung cancer (nonsmall cell) **KQ1 ☐ KQ2 ☒** **Intervention Type:** Psychosocial (information, communication, coaching)	N=varies by parameter (of 285 dyads randomized) Age (years): 62 (n=224) Gender (% male): 51 (n=121) Race/ethnicity (%): NR Marital Status (%): *Cohabiting 78 (n=190)* Education (%): *HS or less 34 (n=82)* Veterans (%): NR Recruitment Method: 4 cancer center hospitals in east, midwest, and southwest US; identified by oncologists Family Characteristics: Relationship to patient: NR Age (years): 56 (n=234) Gender (% female): 68 (n=168) Race/ethnicity (%): NR Education (%): *HS or less 21 (n=51)* Veterans (%): NR	Inclusion: English speaking; adults *Care recipient* - nonsmall cell lung cancer stage IIIA, IIIB, or IV; caregiver (identified by patient) willing to participate in study; clinician-perceived life expectancy of at least 4 months; brain metastasis stable (if present) *Caregiver* – providing instrumental, emotional, and/or financial support Exclusion: NR	Intervention (n=144): Standard care plus CHESS (Comprehensive Health Enhancement Support System); CHESS Website provided information, channel for communication with and support from peers, experts, clinicians, & social networks, coaching, and tools to improve caregiving experience; could receive intervention for 25 months or 13 months after patient death (whichever was less) Comparator (n=141): Standard care plus the Internet (training and list of sites about lung cancer) Both groups received computers and Internet service if needed plus reimbursement for cost of Internet service Length of Follow-up: None (study period of 25 months or up to 13 months after patient death)	***Physical functioning:*** a. Mortality ***Symptom control/ management:*** a. Patient symptom distress using modified Edmonton Symptom Assessment Scale (ESAS) [PR] Assessed at pretest and 2, 4, 6, and 8 months after start of intervention ☐ **Negative caregiver outcomes reported**	Allocation concealment: adequate Blinding: no Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: CHESS used at least once: 73% of caregivers, 50% of patients CHESS used 5 or more times: 52% of caregivers, 35% of patients Median minutes of CHESS use: 103 for caregivers, 146 for patients Median logins: 8 for caregivers, 12 for patients Treatment integrity: not applicable **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Kayser, 2010[32] Funding Source: Government Condition: Breast cancer (early-stage) **KQ1 ☒ KQ2 ☐** **Intervention Type:** Multicomponent (mainly emotional, with some skill-based training and education)	N=47 (of 63 randomized) Age (years): 46 Gender (% male): 0 Race/ethnicity (%): NR Marital Status (%) *Married/cohabiting 100* Education (%): NR Veterans (%): NR Recruitment Method: 2 breast oncology centers; protocol to identify and refer potential patients; met with or sent invitation letter Family Characteristics: Relationship to patient: *Spouse or intimate partner* Age (years): 49 Gender (% female): Unclear if all male (87% married to female patient) Race/ethnicity (%): NR Education (%): *Post HS 89* Veterans (%): NR	Inclusion: diagnosis of primary, non-metastatic breast cancer within the last three months; currently receiving treatment such as chemotherapy, radiation, or a combination of treatments; married or in an intimate relationship Exclusion: NR	Intervention (n=36): Partners in Coping Program (PICP) - couples with clinical social worker; protocol of specific psycho-social interventions (cognitive–behavioral framework); 9 biweekly, 1-hour sessions; average 5-month intervention Comparator (n=27): Standard social work services (SSWS) available at the hospital (individual & family counseling, crisis intervention, community referrals, tangible assistance, discharge planning) Length of Follow-up: 6 months and 1 year after enrollment	***Global quality of life:*** a. Functional Assessment of Cancer Therapy–Breast (FACT-B) Self-report, at 6 months and 1 year after enrollment (1 and 7 months post-treatment) ☐ **Negative caregiver outcomes reported**	Allocation concealment: adequate Blinding: no Intention-to-treat analysis (ITT): no, 25% excluded from analyses Withdrawals/dropouts adequately described: yes Treatment adherence: *Study dropouts* *PICP*=2/36 (33%); 9 did not receive intervention, 1 withdrew, 2 did not return questionnaires *Usual care*=4/27 (15%); 1 withdrew, 3 did not return questionnaires Treatment integrity: manualized, 8 item adherence checklist for each session; competencies rated; biweekly meetings to provide feedback to therapists **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Keefe, 2005[34] Funding Source: Government Condition: Advanced cancer with disease-related pain, life-expectancy < 6 months **KQ1 ☒ KQ2 ☐** **Intervention Type:** Multicomponent (pain management, education, coping)	N=78 Age (years): 60 Gender (% male): 56 Race/ethnicity (%) *White* 78; *African-American* 21 Marital Status (%): NR Education (%): NR Veterans (%): NR Recruitment Method: collaborating hospices, cancer center, and medical center Family Characteristics: Relationship to patient: *Spouses 49%; daughters 9%; NR 42%* Age (years): 58 Gender (% female): 62 Race/ethnicity (%) *White* 79; *African-American* 20 Education (%): NR Veterans (%): NR	Inclusion: advanced cancer diagnosis (metastatic or disseminated disease) with disease related pain; worst pain rating > 3 on the Brief Pain Inventory (BPI); life expectancy <6 mo; no change in disease treatment planned; >18 years of age (Note: all patients met Medicare hospice benefit definition for hospice eligibility) Exclusion: NR	Intervention (n=41): Partner-guided pain management training; 3 in person sessions of 45-60 minutes in patient's home; conducted over 1-2 weeks by RN-level nurse educator; manualized, (detailed written outline for each session); educate patient and partner about cancer pain and management; teach coping strategies; teach partner to help patient acquire coping skills Comparator (n=37): Usual care; routine care provided through patient's medical outpatient or hospice program Length of Follow-up: post-tx only	***Physical functioning:*** a. Functional Assessment of Cancer Therapy-General (FACT-G) ***Social functioning:*** a. Functional Assessment of Cancer Therapy-General (FACT-G) ***Symptom control/ management:*** a. Brief Pain Inventory (BPI) Self-report; assessments made pre- and post-treatment, mean follow-up = 7.6 days (range 0-31 days) **☐ Negative caregiver outcomes reported**	Allocation concealment: adequate Blinding: yes (outcome assessment); no (patients & caregivers) Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: *Intervention* – 13/41 (32%) no post-treatment evaluation (8 died, 3 could not be reached, 2 too ill to complete evaluation) *Usual care* - 9/37(24%) no post-treatment evaluation (4 died, 1 could not be reached, 2 too ill to complete evaluation, 1 dropped out) Treatment integrity: manualized treatment; sessions audiotaped; 58% reviewed & rated for therapist competence (scale 0-5) & treatment fidelity; mean therapist competence rating 4.7; treatment fidelity 81.7% **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Kozachik, 2001[35] Funding Source: Unclear Condition: recent cancer diagnosis (48% Stage I or II; 52% Stage III or IV) **KQ1 ☒ KQ2 ☐** **Intervention Type:** Multi-component; educational and skill based	N=120 Age (years): 56 Gender (% male): 24 Race/ethnicity (%): NR Marital Status (%): NR Education (%): NR Veterans (%): NR Recruitment Method: convenience sampling; 2 cancer treatment sites Family Characteristics: Relationship to patient: *"Primary person assisting the patient with care needs at home"* Age (years): 52 Gender (% female): 51 Race/ethnicity (%): NR Education (%): NR Veterans (%): NR	Inclusion: newly diagnosed lung, breast, colorectal, pancreatic or other solid tumor cancer or non-Hodgkin's lymphoma; undergoing or eligible to receive chemotherapy; within 56 days of initiating chemo for active treatment; could identify a caregiver Exclusion: NR	Cancer Care Intervention (CCI) (n=61): instructions to patients & caregivers on symptom management and surveillance; training on disease and treatment; how to coordinate and mobilize support; 9 standardized sessions with each dyad over 16 weeks; 5 in-person sessions (60 min each) and 4 telephone sessions (20 min each); in person meetings took place together; phone encounters patient and family member separate Comparator (n=59): Usual care (UC) Length of Follow-up: post-tx only (8 weeks)	***Depression/anxiety:*** a. Depression CES-D [SR] Outcomes assessed at baseline, mid-tx (week 9 of 16 week tx) and post-tx (24 weeks post baseline), **☒ Negative caregiver outcomes reported** *NOTE: post-tx control group CG's slightly less depressed than intervention CG's. Noted in discussion though that high attrition in intervention group, and among CG's who were more depressed at baseline may have made it difficult to accurately test the intervention.*	Allocation concealment: unclear Blinding: no Intention-to-treat analysis (ITT): unclear Withdrawals/dropouts adequately described: yes Treatment adherence: *Study dropouts* 31/120=26% did not complete post-tx assessment CCI: 5 died, 15 withdrew UC: 6 died, 5 withdrew p=0.04 attrition between groups Treatment integrity: nurse interventionists trained to standard using both paper and mock patient cases. **Study Quality: Poor**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Kurtz, 2005[39] Funding Source: Government Condition: Recent diagnosis of a solid tumor (breast, lung and other); early stage, 33.0%; late stage, 67.0% **KQ1 ☒ KQ2 ☐** **Intervention Type:** Multi-component; Skill building; educational; emotional	N=237 Age (years): 60 Gender (% male): 27 Race/ethnicity (%): NR Marital Status (%): NR Education (%): NR Veterans (%): NR Recruitment Method: nurse recruiters from 2 comprehensive cancer centers and 4 community oncology settings approached patients undergoing a first course of chemotherapy Family Characteristics: Relationship to patient: *Spouse 66%* Age (years): 55 Gender (% female): 54 Race/ethnicity (%) *White 92%; African-American 5; other 3* Education (%): NR Veterans (%): NR	Inclusion: ≥21 years of age, recently diagnosed with a solid tumor, undergoing a first course of chemotherapy, and have completed no more than the first two cycles prior to their baseline interview; identify a family caregiver; both patient and caregiver able to speak and read English; both patient and caregiver cognitively intact (as screened by recruiters) Exclusion: patients with previous chemotherapy treatment not eligible, nor were patients receiving radiation therapy at time of entry into study	Intervention (n=118): Clinical nursing intervention; alternating in person and telephone sessions – 10 sessions up to 20 weeks; intervention used cognitive behavioral model for both patient and caregiver in managing patient symptoms and reducing emotional distress Comparator (n=119): Usual care for each setting (not described further) Length of Follow-up: post -tx only	***Physical functioning:*** a. SF-36 Short Form Health Survey (physical health subscale) [SR] ***Social functioning:*** a. SF-36 Short Form Health Survey (social functioning subscale) [SR] ***Depression/anxiety:*** a. Depression CES-D All scales were self-report and assessed at baseline, mid-tx (10 weeks) and post-tx (20 weeks) **☐ Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: unclear Intention-to-treat analysis (ITT): unclear Withdrawals/dropouts adequately described: yes Treatment adherence: *Study dropouts* 59/237=25% lost to attrition before 10 weeks 39/237=16% lost to attrition between 10-20 weeks 139/237=59% of dyads remained for assessment for all 3 time points (ns dropouts between groups) Treatment integrity: monthly quality assurance for all nurse interventionists, audiotaped sessions, review of encounters, feedback sessions. **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Manne, 2005,[8] 2007[33] Funding Source: Government Condition: Breast cancer (early-stage) **KQ1 ☒ KQ2 ☐** **Intervention Type:** Emotional and skill-based	N=238 Age (years): NR Gender (% male): 0 Race/ethnicity (%): NR Marital Status (%): *Married/cohabiting 100* Education (%): NR Veterans (%): NR Recruitment Method: 3 comprehensive cancer centers; approached by research assistant either after outpatient visit or by telephone Family Characteristics: Relationship to patient: *Married or living with* Age (years): 50 Gender (% female): NR Race/ethnicity (%): *White 89; African-American 5; other 6* Marital Status (%): *Married/cohabiting 100* Education (%): *HS or less: 34; Post HS: 66* Veterans (%): NR	Inclusion: primary diagnosis of ductal carcinoma in situ or Stage 1, 2, or 3a breast cancer; Eastern Cooperative Oncology Group performance status of 0 (*fully active, able to carry on all pre-disease performance without restriction*) or 1 (*restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature*); had undergone breast cancer surgery; married or living with significant other of either gender; both partners 18 years of age or older; competent to give informed consent; English speakers Exclusion: NR	Intervention (n=120): Couple focused group; 6 weekly 90-min sessions; Session 1 - group rapport & connections; Session 2 - couple-level stress management; Session 3 - couple-focused coping; Session 4 - basic communication concepts and skills; Session 5 - constructive ways to communicate support needs; Session 6 - anticipating post-treatment transition phase (esp. changes relationship before, during, & after cancer); 20 therapists provided intervention; 6 hrs training in manual based protocol Comparator (n=118): Usual care Length of Follow-up: post-treatment, 6 months post-treatment	***General psychological functioning:*** a. Impact of Event Scale (IES); 15-item self-report measure focusing on intrusive and avoidant ideation associated with a stressor (breast cancer and its treatment) b. Mental Health Inventory - (MHI–18); 3 distress subscales, and Loss of Behavioral and Emotional Control (BEC) (4 items) Well-Being subscale (6 items). ***Depression/anxiety:*** a. Mental Health Inventory - (MHI–18); Anxiety (4 items), Depression (4 items) subscales Both self-report and assessed at 1 week and 6 months post treatment **☐ Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: no Intention-to-treat analysis (ITT): yes Withdrawals/dropouts adequately described: yes Treatment adherence: 42 (35%) in intervention group attended no sessions; 93 (78%) and 84 (70%) completed Time 2 and 3 surveys 94 (80%) and 79 (66%) controls completed Time 2 and 3 surveys Treatment integrity: yes manual with suggested text for leaders and co-leaders; in-session handouts; ongoing supervision provided; sessions audiotaped and treatment fidelity rated **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Manne, 2011[27] Funding Source: Government, Foundation Condition: Prostate cancer (localized, diagnosed within last year; 15% stage 1, 85% stage 2) **KQ1 ☒ KQ2 ☐** **Intervention Type:** Multi-component; skill-based and emotional; therapy for couples based on cognitive and marital behavioral therapy.	N=71 Age (years): 60 Gender (% male): 100 Race/ethnicity (%): *White* 88; *other* 11 Marital Status (%): *Married/cohabiting: 100* Education (%): *HS or less 11; Post HS 89* Veterans (%): NR Recruitment Method: 2 cancer centers; approached after outpatient visit or by telephone Family Characteristics: Relationship to patient: *Married or living with* Age (years): 56 Gender (% female): 97 Race/ethnicity (%): *White 83; other 11; Missing 6* Marital Status (%): *Married/cohabiting* 99; *Missing* 1 Education (%): *HS or less* 21; *Post HS* 78; *Missing* 1 Veterans (%): NR	Inclusion: localized prostate cancer diagnosed within last year; Eastern Cooperative Oncology Group (ECOG) 0 or 1; married or living with significant other of either gender; age ≥18 years;, living within 2 hours of cancer center; English speaking; no hearing impairment Exclusion: NR	Intervention (n=37): Intimacy-enhancing therapy (IET) – 5 90-min couples sessions; based on cognitive-behavioral and behavioral marital therapy; in session skills & practice + homework; manualized treatment Comparator (n=34): Usual care – standard psychosocial care provided by social workers with referral to psychiatrist or psychologist if indicated (provided to both groups) Length of Follow-up: 8 weeks (end of intervention)	***General psychological functioning:*** a. Mental Health Inventory (MHI) - Psychological Well-Being scale b. MHI Psychological Distress scale c. Impact of Events Scale – Cancer Specific Distress ***Relationship adjustment:*** a. DAS (Relationship Functioning) All outcomes self-report and assessed at baseline and at 8 wks post-baseline (end of 5 session intervention) **☒ Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: unclear (outcomes assessed by survey) Intention-to-treat analysis (ITT): yes Withdrawals/dropouts adequately described: yes Treatment Adherence: 8/37 = 22% in IET group did not attend any sessions 27/37 = 73% attended 4 or 5 sessions Treatment integrity: therapists trained in manualized IET, sessions audiotaped for fidelity, monthly group supervision **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
McCorkle, 2007[28] Funding Source: Foundation Condition: Prostate cancer **KQ1 ☒ KQ2 ☐** **Intervention Type:** Emotional; problem solving; educational	N=107 (of 126 randomized) Age (years): 60 Gender (% male):100 Race/ethnicity (%): *White 87; Non-White 12; missing 1* Marital Status (%): *Married/cohabiting: 94* Education (%): *HS or less 21.5; Post HS 78.5* Veterans (%): NR Recruitment Method: men or spouses from 1-hour pre-op preparation class provided by nurses in urology department Family Characteristics: Relationship to patient: *Spouse/partner* Age (years): 56.0 Gender (% female): 100 Race/ethnicity (%): *White 85; Non-White 12; Missing 3* Education (%): *HS or less 36.4; Post HS 63.6* Veterans (%): NR	Inclusion: newly diagnosed men with prostate cancer; married or in committed relationship; elected radical prostatectomy as primary tx; lived within 50 miles of study center where recruited Exclusion: NR	Intervention (n=62): Standardized intervention: SNIP (Standardized Nursing Intervention Protocol) (symptom control; education; and exploiting resources) Comparator (n=64): Usual Care Length of Follow-up: 6 months	***Depression/anxiety:*** a. CES-D (Center for Epidemiologic Studies-Depression) ***Symptom control/ management:*** a. Cancer Rehabilitation Evaluation System (CARES)-Sexual function subscale ***Relationship adjustment:*** a. CARES-Marital interaction All self-reported at 6 months **☒ Negative caregiver outcomes reported** NOTE: Spouses in intervention group reported greater distress, worse sexual functioning and reduced marital interaction after the intervention	Allocation concealment: unclear Blinding: no Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: N=19 study dropout (8 intervention/11 control) No report of treatment dropout Treatment adherence: NR Treatment integrity: NR **Study quality: Poor**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
McMillan, 2007[40] Funding Source: Government Condition: Late stage cancer (patients in hospice) **KQ1 ☒ KQ2 ☒** **Intervention Type:** Problem-solving (COPE – creativity, optimism, planning, expert information)	N=329 Age (years): 70.6 Gender (% male): 60 Race/ethnicity (%): NR Marital Status (%): NR Education (mean): 12.2 years Veterans (%): NR Recruitment Method: identified by study staff at large nonprofit hospice Family Characteristics: Relationship to patient: *Family member (not specified)* Age (years): NR Gender (% female): NR Race/ethnicity (%): NR Education (%): NR Veterans (%): NR	Inclusion: Adults with diagnosis of cancer; identified family caregiver; patient and caregiver with a) at least 6th grade education, b) able to read and understand English, and c) score of 7 or higher on Short Portable Mental Status Questionnaire (SPMSQ); patient with score of 40 or higher on Palliative Performance Scale Exclusion: excluded if patient did not have at least 2 of the following symptoms: pain, dyspnea, or constipation	1st Intervention (n=109): Standard care from hospice staff plus friendly visits on same schedule as 2nd intervention; focus on support, feelings, fears, relationships 2nd Intervention (n=111): **manualized** COPE intervention – caregiver problem solving; 3 visits during 9 day intervention plus telephone call between visits; caregiver given *Home Care Guide for Advanced Cancer* Comparator (n=109): Standard care from hospice staff; included some caregiver education and support Length of Follow-up: 9 day intervention with follow-up to 30 days after hospice admission	***Global quality of life:*** a. Hospice Quality of Life Index (HQLI) [SR] ***Symptom control/ management:*** a. Memorial Symptom Assessment Scale (MSAS) [SR] b. Numeric rating scale (NRS) for PAIN [SR] c. Dyspnea intensity scale [SR] d. Constipation assessment scale (CAS) [SR] Data collected at baseline (within 24-48 hours of hospice admission), 2 weeks after entry (day 16), and 2 weeks later (day 30) ☐ **Negative caregiver outcomes reported**	Allocation concealment: adequate Blinding: no Intention-to-treat analysis (ITT): yes Withdrawals/dropouts adequately described: no (numbers provided but no details) Reported post-intervention data: Control: 37% Intervention 1: 29% Intervention 2: 28% Treatment adherence: both interventions received by 100% of caregivers in those groups Treatment integrity: caregivers given guide on home care; study staff trained on COPE intervention and home care guide; all intervention visits audio recorded; investigators reviewed 10% of tapes **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Meyers, 2011[38] Funding Source: Government Condition: relapsed, refractory or recurrent solid tumors or lymphoma (gastrointestinal, genito-urinary, thoracic, breast, gynecologic, sarcoma, melanoma or other cancer) **KQ1 ☒ KQ2 ☐** **Intervention Type:** Standardized, cognitive behavioral educational, emphasizing problem solving	N=441 (of 476 randomized) Age (years): 62 Gender (% male): 44 Race/ethnicity (%): *White 88; African-American 5; other 7* Marital Status (%): NR Education (%): *HS or less 35; Post HS 63; NR 2* Veterans (%): NR Recruitment Method: patients in qualifying phase 1, 2 or 3 clinical treatment trials at 4 participating cancer centers Family Characteristics: "Adult regularly involved with patient and their care" Relationship to patient: *Spouse 70; Adult child 16; other 12; NR 2* Age (years): 61 Gender (% female): 31 Race/ethnicity (%): *White 85; African-American 6; other 9* Education (%): *HS or less 32; Post HS 66; NR 2* Veterans (%): NR	Inclusion: Adults with "relapsed, refractory, or recurrent solid tumors or lymphoma enrolled onto phase 1 or 2, or phase 3 trials that compared therapy for advanced cancer." (Patients among the sickest and most distressed, as clinical trial participation usually follows depleting conventional therapies, or because few therapies available for that diagnosis.) Exclusion: Patients receiving concomitant chemotherapy and radiation; on adjuvant phase III studies; those with hematopoietic malignancies; with primary brain tumors; not fluent in English; < 18 years of age or lacking a willing caregiver.	Intervention (n=348): COPE: (Creativity, Optimism, Planning and Expert Information) Dyads received a copy of "The Home Care Guide for Cancer," then had three conjoint educational sessions (pt, caregiver, educator). Standardized, cognitive behavioral intervention. First session conducted up to 7 days prior to day the pt started their investigational clinical trial and focused on familiarity with the guide and COPE problem-solving model, to solve a pt and caregiver identified problem. Two other sessions conducted within 30 days, reinforcing learning using COPE model on two additional pt/caregiver identified problems. Comparator (n=128): Usual care Length of Follow-up: 6 months	***Global quality of life:*** a. City of Hope Quality of Life instrument (COH QOL) Self-reported outcome assessed at baseline and 30, 60, 90, 120, 180 days after randomization ☐ **Negative caregiver outcomes reported**	Allocation concealment: adequate Blinding: no Intention-to-treat analysis (ITT): yes Withdrawals/dropouts adequately described: yes Treatment adherence: *SCEI* -Withdrew a) before intervention = 5% (27/348); b) before end of study = 65% (227/348) (Of this 53 deaths = 15%) *Usual care* -Withdrew a) before intervention = 8% (10/128); b) before end of study = 67% (86/128) (Of this 27 deaths = 21%) *Outcomes assessed:* 444/476=94% completed at least one assessment; 156/376=33% completed through six month follow up Treatment integrity: educators trained in "COPE" model; sessions reviewed to increase consistency; educators documented sessions **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Mishel, 2002[24] Funding Source: Government Condition: localized prostate cancer **KQ1 ☒ KQ2 ☒** **Intervention Type:** Psychoeducational	N=239 (of 252 enrolled) Age (years): 64 Gender (% male): 100 Race/ethnicity (%): *White 56; African-American 44* Marital Status (%): *Married/cohabiting 84* Education (%): *HS or less* 43; *Post HS* 57* Veterans (%): NR *Noted that may not be accurate - time lost while harvesting Recruitment Method: approached at clinic visits (9 facilities); potential African-American participants personally visited by "two African-American men well known in the community" Family Characteristics: Patient selected family member helping with cancer care ("mostly spouses" but exact numbers not reported) Demographics: NR	Inclusion: African-American and Caucasian men; localized prostate carcinoma within 2 wks post catheter removal after surgical treatment and/or within 3 wks into current radiation therapy; access to telephone; identifiable family member willing to participate; and planned to reside in current community for 12 months Exclusion: major cognitive impairment or concurrent treatment for another form of malignancy.	1st Intervention: Uncertainty Management Direct (UMD) (n=NR): 8 weekly calls from male nurse matched to ethnicity; semi-structured interview format; assess patients' concerns and uncertainty; standardized lists of problems to discuss + discussion of specific concerns 2nd Intervention: Uncertainty Management Supplemented (UMS) (n=NR): same as UMD group; family support person received a matching concurrent intervention from a female nurse (matched to ethnicity) Comparator: Usual care (n=NR): printed general health info. (not related to prostate cancer or side effects of treatment) Length of Follow-up: 8 weeks post-treatment (considered post-treatment) and 5 months post-treatment	***Symptom control/ management:*** a. Symptom Distress Scale (# of symptoms) b. Symptom Distress Scale (average intensity of symptoms) c. Urine flow d. Ability to have an erection e. Satisfaction with sexual function All outcomes self-reported and assessed at baseline, baseline + 8 weeks post-treatment and 5 months post-treatment ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: unclear Intention-to-treat analysis (ITT): unclear Withdrawals/dropouts adequately described: yes Treatment adherence: study dropouts = 95% of 252 enrolled completed measurements at all 3 time points Treatment integrity: none reported **Study quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Mokuau, 2008[47] Funding Source: Government Condition: Cancer **KQ1 ☐ KQ2 ☒** **Intervention Type:** Educational, skill-based, problem solving or conflict resolution	N=10 (of 12 randomized) Age (years): 55 Gender (% male): 0 Race/ethnicity (%): *other 100 (Hawaiian)* Recruitment Method: through physicians, providers, print and electronic media Family Characteristics: Age (years): 54 Gender (% female): 50	Inclusion: Native Hawaiian; female; diagnosis of cancer in last 12 months Exclusion: none reported	Intervention (n=6): Two health educators provided a culturally-specific (Hawaiian) intervention to increase knowledge, behavioral capabilities and support for women cancer survivor and one or 2 family members. Six visits/sessions over 3 months conducted in various places (homes, offices and libraries). Comparator (n=4): Two health educators introduced a culturally non-specific intervention, mostly consisting of educational brochures. Two sessions (Baseline and one additional session at the end of intervention) over 3 months. Length of Follow-up*:* none (3 month intervention only)	***General psychological functioning:*** a. Global severity index of the Brief Symptom Inventory (BSI) for distress ☐ **Negative caregiver outcomes reported**	Allocation concealment: adequate Blinding: no Intention-to-treat analysis (ITT): unclear Withdrawals/dropouts adequately described: unclear Treatment adherence: treatment dropouts and study dropouts not assessed Treatment integrity: unclear **Study Quality: Poor**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Nezu, 2003[36] Funding Source: Government Condition: Cancer, diagnosed in the past 6 months, 28% Stage I, 56% Stage II, 16% Stage III **KQ1 ☒ KQ2 ☒** **Intervention Type:** Problem solving	N=132 (of 150 randomized) Age (years): 47 Gender (% male): 33 Race/ethnicity (%): *White 77; African-American 17; other 6* Marital Status (%): *Married/cohabiting 61* Education (years): 14.6 Veterans (%): NR Recruitment Method: receiving oncology-related services at 2 sites; neighboring hospitals; cancer centers; local cancer referral agencies Family Characteristics: Relationship to patient: *Spouses 95%, Adult son/ daughter 5% (except 1 friend)* Age (years): NR Gender (% female): NR Race/ethnicity (%): NR Education (%): NR Veterans (%): NR	Inclusion: ages 18-65; meet screening criteria for psychological distress; able to read English (6th gr. level+); person to participate in study; prognosis of 5-yr survival rate of ≥50%; Karnofsky Performance Status Scale score of 70+ Exclusion: known psychiatric disturbance prior to diagnosis of cancer; diagnosis of mental retardation; acute suicidal behavior; current treatment for emotional or psychological problem	Intervention 1 - PST (n=45): Problem-solving training, manualized; provided on individual basis during 10 1.5 hr/wk session Intervention 2 – PST-SO (n=43): Problem-solving training (as above) with significant other included as problem-solving coach (social support, encouragement, feedback) Comparator (n=44): wait list controls; contacted twice to assess need for crisis mgmt or referral; no direct counseling Length of Follow-up: Mean of 13 weeks treatment	***General psychological functioning:*** a. Emotional distress, Omega (clinician report) b. Mood, POMS (SR) c. Psychological distress, BSI (SR) ***Global quality of life:*** a. QL Index (clinician report) ***Depression/anxiety:*** a. Depression, HRSD (clinician report) ***Symptom control/ management:*** a. Day-to-day problems and rehab needs, CARES (SR) All assessments at post tx, 6 months, 12 month ☐ **Negative caregiver outcomes reported**	Allocation concealment: inadequate Blinding: yes (outcome assessment) Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: PST group completed mean of 9.7 sessions in 12.8 weeks; PST-SO group completed mean of 9.6 sessions in 13.1 weeks Treatment integrity: weekly supervision of therapists to foster adherence to therapy manuals; sessions audiotaped and reviewed for adherence **Study Quality: Poor**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Northouse, 2005[29] Funding Source: Foundation Condition: Recurrent or progressing breast cancer; analysis included only patients with Stage 3 or 4 cancer **KQ1 ☒ KQ2 ☐** **Intervention Type:** Multicomponent (FOCUS - Family involvement, Optimistic attitude, Coping effectiveness, Uncertainty reduction, Symptom management)	N=134 (of 200 randomized) Age (years): 54 Gender (% male): 0 Race/ethnicity (%): *White 77; African-American 19; other 4* Marital Status (%): NR Education (mean): 14 years Veterans (%): NR Recruitment Method: staff in medical oncology clinics Family Characteristics: Relationship to patient: *Primary source of support - husband 62%, sibling 9%, adult daughter 13%, adult son 3%, other relatives or friends 13%* Age (years): 52 Gender (% female): NR Race/ethnicity (%): *White 77; African-American 19; other 4* Education (mean): 14 years Veterans (%): NR	Inclusion: *Patient* - Confirmed diagnosis of recurrent breast cancer within previous month (reappearance after any disease-free interval) OR confirmation that breast cancer had progressed in past month (laboratory test, radiologic test, or clinical exam that required a change in treatment); life expectancy ≥ 6 months; able to identify family caregiver willing to participate *Patient and caregiver* – age 21 or older; mentally and physically able to participate; able to speak and understand English *Caregiver* – confirmed as primary support for patient Exclusion: NR	Intervention (n=69): FOCUS Program + usual care; manualized; initial phase of 3 home visits with patient and caregiver (one month apart, 90 min/visit); booster phase of 2 phone calls to patient and caregiver (30 min/call) Comparator (n=65): Usual care Length of Follow-up: 6 months post-baseline (initial treatment + booster phase)	***Physical functioning:*** a. Combined measure using FACT-B (SR) and SF-36 (SR) to create overall QOL (physical functioning) ***Mental functioning:*** a. Combined measure using FACT-B (SR) and SF-36 (SR) to create overall QOL (mental health functioning) ***Depression/anxiety:*** a. Beck Hopelessness (depression) Outcomes assessed at baseline, 3 mo (after initial phase of FOCUS) and 6 mo (after booster phase of FOCUS) ☐ ***Negative caregiver out comes reported***	Allocation concealment: unclear Blinding: unclear Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: attendance not reported; 74% (134/182) completed 3 and 6 month assessments Treatment integrity: intervention staff met regularly to review caseload of dyads **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Northouse, 2007[23] Funding Source: Government Condition: Prostate cancer; newly diagnosed (65%); biochemical recurrence (14%); or advanced (21%) **KQ1 ☒ KQ2 ☐** **Intervention Type:** educational, skill-based, emotional problem solving or conflict resolution, decision support	N=263 dyads Age (years): 63 Gender (% male): 0 Race/ethnicity (%): *White 84; African-American 14; Multiracial 2* Marital Status (%): *Married/cohabiting 100* Education (mean): 16 years Veterans (%): NR Recruitment Method: three large cancer centers in Midwest; patients identified by clinical staff, recruited by research staff Family Characteristics: Relationship to patient: *Spouse/partner* Age (years): 59 Gender (% female): 100 Race/ethnicity (%): *White 84; African-American 15; Multiracial 1.5* Education (mean): 15 years Veterans (%): NR	Inclusion: Either newly diagnosed, biochemical recurrence, or advanced metastases; ≥30 yrs old; ≥12 months of life expectancy; lived within 75 miles of cancer center; married or with a partner Exclusion: *patients* - a second, primary cancer; *dyads* - spouse ≤21 yrs or diagnosed with cancer within the prior year or was receiving cancer treatment	Intervention (n=129): Manualized; family Intervention; 3 90-min home visits and 2 30-min telephone sessions; spaced 2 weeks apart for 4 months Comparator (n=134): Usual care Length of Follow-up: 8 months post-treatment	***Physical functioning:*** a. SF-12 ***General psychological functioning:*** a. SF-12 b. OSQ (Omega Screening Questionnaire) (77-item) ***Global quality of life:*** a. FACT-G (Functional Assessment of Cancer Therapy; 27 items, ***Depression/anxiety:*** a. Beck Hopelessness (depression) ***Symptom management/ control:*** a. EPIC (Expanded Prostate Cancer Index Composite) (50-item) All outcomes self-report and assessed at 4, 8, 12 months post-baseline); or post, 4, and 8 months post-treatment. **☒ Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: yes, data collectors blinded to dyad condition Intention-to-treat analysis (ITT): unclear Withdrawals/dropouts adequately described: yes Study dropouts: Refused assignment (inter=9; control=1) Incomplete 4-mo assessment (inter=17; control=11) Incomplete 8-mo assessment (inter=5; control=2) Incomplete 12-mo assessment (inter=3; control=7) Treatment adherence: 82.9% (218/263) Treatment integrity: yes **Study quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Porter, 2009[46] Funding Source: Government Condition: Gastrointestinal (GI) cancer; stage II through IV **KQ1 ☐ KQ2 ☒** **Intervention Type:** a. Partner-Assisted Emotional Disclosure: Multicomponent (skill-based, emotional, problem solving or conflict resolution) b. Cancer Education/ Support: Multicomponent (educational, skill-based)	N=130 Age (years): 59.4 Gender (% male): 71 Race/ethnicity (%): *White 85; African-American 12; other 4* Marital Status (%): NR Education (%): *HS or less 45; Post HS 55* Veterans (%): NR Recruitment Method: GI oncology clinics at 2 university affiliated hospitals Family Characteristics: Relationship to patient: *Spouse or intimate partner* Age (years): 59 Gender (% female): 71 Race/ethnicity (%): *White 82; African-American 11; other 6* Education (%): *HS or less 41; Post HS 60* Veterans (%): NR	Inclusion: stage II through IV GI cancer; life expectancy of 6 months or longer; spouse or intimate partner Exclusion: NR	Intervention (n=65): Partner-Assisted Emotional Disclosure; 4 face-to-face sessions (45-75 min each) completed in up to 8 weeks; focus on patient disclosure of feelings and concerns about cancer experience Comparator (n=65): Couple Cancer Education/ Support; 4 face-to-face sessions for presenting information about cancer, available resources, communicating with health care providers, and maintaining quality of life Length of Follow-up: 8 week intervention only	***General psychological functioning:*** a. Profile of Moods States-Short Form (POMS-SF) ***Relationship adjustment:*** a. Quality of Marriage Index (QMI) Outcomes self-report and assessed at baseline and post-treatment ☐ ***Negative caregiver outcomes reported***	Allocation concealment: unclear Blinding: yes (outcome assessment) Intention-to-treat analysis (ITT): yes (and analysis with completers only) Withdrawals/dropouts adequately described: yes Treatment adherence: 112/130 (86%) attended at least 1 treatment session; 108/130 (83%) completed post-treatment assessments Treatment integrity: Therapists were trained, detailed treatment outlines were used, sessions were audiotaped; assessments of adherence and competence **Study Quality: Good**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Porter, 2011[45] Funding Source: Government Condition: Lung cancer, stages 1-3 **KQ1 ☐ KQ2 ☒** **Intervention Type:** a. Caregiver Assisted Coping Skills Training: Education; skill-based; emotional; problem solving or conflict resolution b. Education and Support (including caregiver): Educational	N=233 Age (years): 65 Gender (% male): 53 Race/ethnicity (%): *White 85; African-American 12; other 4* Marital Status (%): NR Education (%): *HS or less 45; Post HS 55* Veterans (%): NR Recruitment Method: oncology programs and clinics Family Characteristics: Relationship to patient: *Spouses 76%, sons/ daughters 14%, sibling/ friend 8%; 73% resided together* Age (years): 59 Gender (% female): 69 Race/ethnicity (%): *White 82; African-American11; other 6* Education (%): *HS or less 41%* *Post HS 60%* Veterans (%): NR	Inclusion: diagnosis of early stage lung cancer (stages I-III) or limited stage small-cell lung cancer; no other cancers in the past 5 years; ability to read and write English; caregiver willing to participate Exclusion: NR	Intervention (n=117): Caregiver assisted coping skills training (CST); Patients & caregivers received training in conjoint sessions by speaker phone; delivered by registered nurses; Caregivers trained to be "coaches" (help patients learn coping skills and apply them); 8 month intervention; 14 standardized sessions, 45-min each; Sessions 1-3 weekly; sessions 4-10 biweekly; sessions 11-14 monthly Comparator (n=116): *Education/Support,*; Patients & caregivers received training in conjoint sessions by speaker phone; information about lung cancer and treatment; discussions guided by specific topics; same schedule as above Length of Follow-up: Post-treatment and four month follow up	***Physical functioning:*** a. Functional Assessment of Cancer Therapy-Lung Cancer (FACT-L) (Physical functioning subscale) ***Social functioning:*** a. Functional Assessment of Cancer Therapy-Lung Cancer (FACT-L)(social functioning subscale) ***Depression/ anxiety:*** a. Beck Depression Inventory (BDI) b. State trait anxiety inventory (STAI) ***Symptom control/ management:*** a. Brief Pain Inventory (BPI) b. Functional Assessment of Cancer Therapy-Lung Cancer (FACT-L) (cancer symptoms subscale) All self-report, post-treatment and follow-up ☐ **Negative caregiver outcomes reported**	Allocation concealment: yes Blinding: yes (assessors) Intention-to-treat analysis (ITT): yes Withdrawals/dropouts adequately described: yes Treatment adherence: **CST**: 24.3% (26 of 107 surviving at post-treatment) dropped out and were not assessed at post-treatment; at follow-up, 36.3% dropped out of those who survived to follow-up (37 of 102) **Education/Support**: 14.4% (15 of 104 surviving at post-treatment) dropped out and were not assessed at post-treatment; At follow-up, 23.5% dropped out of those who survived to follow-up (23 of 98) Treatment integrity: yes **Study Quality: Good**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Schover, 2012[41] Funding Source: Foundation Condition: Localized prostate cancer ($T_{1-3}N_0M_0$) **KQ1 ☐ KQ2 ☒** NOTE: Study included a wait list control group but provided no results; findings are reported for KQ2 only **Intervention Type:** Educational, emotional	N=81 (of 115 randomized) Age (years): 64 Gender (% male): 100 Race/ethnicity (%): *White 85; African-American 8; other 7* Marital Status (%): *Married/cohabiting* 98 Education (%): *HS or less* 6; *Post HS* 94 Veterans (%): NR Recruitment Method: invitations to men in center tumor registry; physician referral; fliers in outpatient clinics; public service announcements (local media, web sites); active effort to recruit African Americans Family Characteristics: Relationship to patient: *Spouse: 98; other: 2%* Age (years): NR Gender (% female): NR Race/ethnicity (%): NR Education (%): NR Veterans (%): NR	Inclusion: heterosexual males; age ≥18 yrs; treated for localized prostate cancer ($T_{1-3}N_0M_0$) with definitive surgery or radiotherapy in previous 3 mos to 7 yrs; couples married or living together for ≥1 yr; both partners agreed to participate; reasonable English fluency; men either unable to achieve and maintain erection sufficient for sexual intercourse on ≥50% of attempts or had not attempted intercourse for past 3 months; no noted firm erections on waking from sleep; willing to come to cancer center 3 times during 12-wk tx Exclusion: using hormone therapy for prostate cancer; using a satisfactory medical treatment for erectile dysfunction	Intervention: Face-to-face counseling [FF] (n=60): 3 face-to-face sessions; 50-90 min; 12 weeks; printed handouts & homework exercises (expression of affection, sexual communication, comfort in initiating sexual activity, & resuming sex without performance anxiety); decision aid for choosing ED treatment; relapse prevention exercise; booster phone calls to discuss progress Comparator: Internet-based counseling (WEB1) (n=55): internet-based format of face-to-face counseling (e-mail contact with therapist, web-based instructions); same relapse prevention & booster calls; participants could e-mail therapists any time; loaner laptops provided, if needed Length of Follow-up: 12 months	***General psychological functioning:*** a. Brief Symptom Inventory-18 (BSI-18) ***Symptom management/ control*** a. International Index of Erectile Function (IIEF) b. % men achieving near normal erectile function over time (IIEF Erectile Function subscale ≥22) ***Relationship adjustment:*** a. Abbreviated Dyadic Adjustment Scale (DAS) All self-reported outcomes assessed at baseline, post-tx, 3, 6, and 12 months post tx. ☐ **Negative caregiver outcomes reported** NOTE: study also included 1) wait list control group – no changes over 3 months; patients then randomized into the intervention groups and 2) WEB2 group – too far away geographically to participate in randomized trial	Allocation concealment: adequate Blinding: unclear Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: partial – only report number of drop-outs during intervention and number lost to follow-up, no reasons reported Treatment adherence: treatment dropouts: FF [n=60] *During intervention = 28% (17/60)* *Lost to f/u = 5% (3/60)* WEB1 [n=55] *During intervention = 13% (7/55)* *Lost to f/u = 13% (7/55)* Treatment integrity: manual used to train therapists; biweekly group supervision **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Stephenson, 2007[48] Funding Source: *Government* Condition: Metastatic cancer **KQ1 ☐ KQ2 ☒** **Intervention Type:** Skill-based	N=86 (of 90 randomized) Age (years): 58 Gender (% male): 51 Race/ethnicity (%): *White 59; African-American 40; other 1* Education (%): *HS or less 66.3 Post HS NR* Veterans (%): NR Recruitment Method: selected from patients from four hospitals Family Characteristics: None reported	Inclusion: any kind of metastatic cancer; pain score ≥2 (0-10); dyad had to be 21 yrs old; living together as spouse/partners, family, or friends; English speaking; live within100 miles of hospital; partner available from 2-10pm Exclusion: any surgery in previous 6 weeks; any open skin wounds to feet, foot tumors or foot metastases; radiation to feet or site of pain; >50% loss of feeling due to peripheral neuropathy	Intervention (n=42): a. *One 30-minute session of reflexology using Ingham method* b. *Partners were trained in basic techniques of reflexology and received materials about conducting reflexology and signs and symptoms of deep vein thrombosis* Comparator (n=44): *Usual care plus "special attention." Special attention included partners reading a selection of patient's choice to the patient.* Length of Follow-up: Baseline and post-intervention	***Depression/anxiety:*** a. Visual Analog Scale for Anxiety (SR) ***Symptom control/ management:*** a. Brief Pain Inventory (BPI; SR) b. Short-Form McGill Pain Questionnaire (SF-MPQ; SR) *All measures assessed at pre and post-intervention. Data collected for 21 months.* ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: unclear Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: treatment adherence not reported; One control group patient did not complete post treatment assessments (2.3% did not complete); Post-treatment data available on all who received the intervention Treatment integrity: unclear **Study Quality: Fair**

Table 2. Cancer Studies – Quality of Life – Physical Functioning

Study, Year Interventions	Physical Condition	Baseline Functional Level	Quality of Life Assessment Scale	Baseline	Post-Treatment	Follow-up* (time assessed)
Badger, 2011[21] 1) TIP-C (n=36) 2) HEAC (n=35)	Prostate cancer	Currently undergoing or completed treatment w/in 6 months (Stage I=16%, II=9%, III=11%, IV=11%, unknown=53%)	UCLA Prostate Cancer Index – Prostate specific health-related QOL	1) 63.2 (25.8) (n=36) 2) 62.0 (21.3) (n=35) p=ns (NR)	1) 63.2 (19.4) (n=34) 2) 60.5 (20.6) (n=32) Change over time: 1) ns 2) ns Group 1) vs 2): p=ns (NR)	
Baucom, 2009[31] 1) Couple-based relationship enhancement (n=8 couples) 2) Treatment-as-usual (n=6 couples)	Breast cancer	Stage I or II (recently diagnosed); no history of other breast cancer; no history of cancer within last 5 years	Functional Assessment of Cancer Therapy (FACT-B) (higher score = greater daily functioning)	1) 2.48 (0.58) 2) 2.86 (0.56)	1) 3.08 (0.27) 2) 2.76 (1.15) (n=NR) d=0.97 (pre tx to post tx)	1) 3.22 (0.34) 2) 2.89 (0.91) (12 months) (n=NR) d=1.14 (pre tx to follow up)
Blanchard, 1996[37] 1) Spouse directed problem-solving intervention (n=25 couples) 2) Treatment-as-usual (TAU) (n=32 couples)	Any cancer	Diagnosed more than 3 months before recruitment but patient not eligible for hospice	Physical Functioning subscale of Medical Outcomes Scale (SF-20)	1) 38.7 (21.7) 2) 38.1 (21.2) p=ns (NR)	1) 38.3 (22.0) 2) 37.1 (22.2) p=ns (NR)	NR
Budin, 2008[30] 1) Psychoeducation (SE) +DM, n=66 2) Telephone counseling (TC) + DM, n=66 3) SE+TC+DM, n=58 4) Disease Management (DM), n=59	Breast cancer	Lesion with confirmed or strongly suspected diagnosis of cancer	Overall Health Status (subscale of SRHS); scores from 4 to 13 with higher score = better overall perceived health status	1) 8.9 (1.9) 2) 9.2 (1.6) 3) 9.6 (1.6) 4) 9.3 (1.8)	Values not reported **Main effect for time (p<0.0001)** Main effect for group (ns) Group x time interaction (ns)	

Study, Year Interventions	Physical Condition	Baseline Functional Level	Quality of Life Assessment Scale	Baseline	Post-Treatment	Follow-up* (time assessed)
Campbell, 2007[26] 1) Coping Skills Training (CST) (n=20) 2) Usual Care (UC) (n=20)	Prostate cancer	Karnofsky Performance Status score >= 60	SF-36 (Short Form Health Survey) (higher score = better functioning)	NR	Physical Function 1) 27.5 (SE=0.8) (n=12) 2) 26.1 (SE=0.7) (n=18) d=0.34, p=0.19	6 weeks
Giesler, 2005[22] 1) Cancer care intervention (n=48) 2) Standard care (n=51)	Prostate cancer (post-treatment)	T1a-T2c	SF-36 Short Form Health Survey (higher score = better functioning)	NR	Physical Functioning d=0.00, p=0.99 1 month post-intervention (n=NR)	Physical Functioning d=0.05, p=0.83 6 months post-intervention (n=85)
Gustafson, 2013[44] 1) Standard care plus CHESS (n=144) 2) Standard care plus Internet (n=141)	Nonsmall Cell Lung Cancer	16% Stage IIIA, 18% Stage IIIB, 66% Stage IV 71% ECOG 0 or 1 30% ECOG 2, 3, or 4	Mortality/Survival	NA	NR	**Deaths at 24 months** 1) 77/124 (62%) 2) 89/122 (73%) **Median Survival** 1) 14.8 months (SE=1.2) 2) 10.1 months (SE=1.5) Adjusted p=0.08
Keefe, 2005[34] 1) Partner guided (n=41) 2) Usual care (n=37)	Cancer (any)	Eligible for hospice care; life expectancy ≤ 6 months	Functional Assessment of Cancer Therapy-General (FACT-G, v4) physical functioning sub scale (scale 0-4; higher score = problem with function)	Physical well-being NR; but reported p=ns between groups (n=78)	Physical well-being 1) 2.0 (0.8) (n=28) 2) 2.1 (0.8) (n=28) p=NR	NR
Kurtz, 2005[39] 1) Clinical nursing intervention (n=118) 2) Usual care (n=119)	Cancer (any)	Recent diagnosis of a solid tumor (breast, lung, other); early stage, 3%; late stage, 67.0%	MOS SF-36 physical functioning subscale (scale 0-100, higher score = fewer limitations on activity)	Physical Functioning 1) 65.8 (28.6) 2) 63.2 (30.0) n=NR	Physical Functioning 1) 77.2 (22.9) 2) 67.0 (30.2) n=NR p=NR	NR
Northouse, 2005[29] 1) FOCUS (n=69) 2) Usual care (n=65)	Breast cancer	Recurrent or progressing, Stage 3 or 4	Composite of FACT-B and SF-36-physical health (converted to T scores with mean of 50 and SD of 10)	1) 51.7 (9.6) (n=NR) 2) 49.6 (9.3) (n=NR)	1) 49.7 (9.2) (n=NR) 2) 49.8 (9.7) (n=NR) 6 months (after booster phase of FOCUS) Group x time (p=0.19)	NR

Study, Year Interventions	Physical Condition	Baseline Functional Level	Quality of Life Assessment Scale	Baseline	Post-Treatment	Follow-up* (time assessed)
Northouse, 2007[23] 1) Couples intervention (FOCUS) (n=129) 2) Usual care (UC) (n=134)	Prostate cancer	Newly diagnosed (65%); biochemical recurrence (14%); advanced (21%)	SF12-Physical (post-tx and follow up control for baseline scores)	1) NR 2) NR	1) 48.6 (6.7) (n=113) 2) 48.7 (6.5) (n=133) ES=-0.02 (F=0.01, p=0.96)	8 months post-tx 1) 42.7 (6.5) (n=104) 2) 42.5 (6.4) (n=114) ES=0.03 (F=0.02, p=0.88)
Porter, 2011[45] 1) Coping skills training (CST) (n=117) 2) Education (EDU) (n=116)	Lung cancer	Stage I-III	FACT-L: Physical Well-Being	1) NR 2) NR	1) NR 2) NR Time x Treatment interaction: p=ns Time x Treatment x Cancer Stage interaction: p=ns	NR

*Last follow-up reported only if > 6 months post-treatment
[1]Scale of -3 to +3; higher score indicates better well-being
d or ES=effect size, NR=not reported, ns=not statistically significant

Table 3. Cancer Studies – Quality of Life – General Psychological Functioning

Study, Year Interventions	Physical Condition	Baseline Functional Level	Quality of Life Assessment Scale	Baseline	Post-Treatment	Follow-up* (time assessed)
Badger, 2011[21] 1) TIP-C (n=36) 2) HEAC (n=35)	Prostate cancer	Currently undergoing or completed treatment w/in 6 months (Stage I=16%, II=9%, III=11%, IV=11%, unknown=53%)	Spiritual well-being (QoL Breast Cancer subscale) (higher score = greater influence of cancer on pt's spirituality)	1) 43.6 (14.8) (n=36) 2) 44.2 (11.6) (n=35) p=ns (NR)	1) 42.8(14.0) (n=34) 2) 46.5 (11.9) (n=32) Change over time: 1) ns **2) p<0.05** **Group 1) vs 2): p<0.01 (favoring group 2)**	
			Positive affect (PANAS) (score range 20-50; higher score = more positive affect)	1) 35.1 (6.6) (n=36) 2) 36.7 (7.4) (n=35) p=ns (NR)	1) 36.7 (7.7) (n=34) 2) 37.9 (6.1) (n=32) Change over time: 1) ns 2) ns Group 1) vs 2): p=ns (NR)	
			Negative affect (PANAS) (score range 20-50; higher score = more negative affect)	1) 16.0 (6.3) (n=36) 2) 17.0 (7.4) (n=35) p=ns (NR)	1) 16.8 (7.1) (n=34) 2) 14.8 (6.2) (n=32) Change over time: 1) ns **2) p<0.05** **Group 1) vs 2): p<0.001 (favoring group 2 – less negative affect)**	
			Perceived stress (PSS) (score 0-40; higher score = more perceived stress)	1) 12.7 (6.5) (n=36) 2) 13.2 (7.1) (n=35) p=ns (NR)	1) 12.5 (6.5) (n=34) 2) 11.2 (7.3) (n=32) Change over time: 1) ns **2) p<0.05** **Group 1) vs 2): p<0.001 (favoring group 2)**	
Baucom, 2009[31] 1) Couple-based relationship enhancement (n=8 couples) 2) Treatment-as-usual (n=6 couples)	Breast cancer	Stage I or II (recently diagnosed); no history of other breast cancer; no history of cancer within last 5 years	Brief Symptom Inventory (BSI-18)	1) 11.9 (10.8) 2) 16.3 (9.5)	1) 8.0 (5.9) 2) 12.5 (14.7) n=NR d=0.07 (pre tx to post tx)	1) 6.7 (5.8) 2) 15.8 (20.9) (12 months) n=NR d=0.45 pre tx to follow-up)
Blanchard, 1996[37] 1) Spouse directed problem-solving intervention (n=25 couples) 2) Treatment-as-usual (TAU) (n=32 couples)	Any cancer	Diagnosed more than 3 months before recruitment but patient not eligible for hospice	Mental Health Functioning subscale of Medical Outcomes Scale (SF-20)	1) 66.3 (22.1) 2) 70.4 (15.1) p=ns (NR)	1) 70.0 (17.6) 2) 74.1 (15.0) p=ns (NR)	NR

Study, Year Interventions	Physical Condition	Baseline Functional Level	Quality of Life Assessment Scale	Baseline	Post-Treatment	Follow-up* (time assessed)
Budin, 2008[30] 1) Psychoeducation (SE) +DM, n=66 2) Telephone counseling (TC) + DM, n=66 3) SE+TC+DM, n=58 4) Disease Management (DM), n=59	Breast cancer	Lesion with confirmed or strongly suspected diagnosis of cancer	Psychological Well-Being (subscale of PAL-C) (scores of 5 to 20; higher score = higher level of well-being)	1) 14.9 (3.2) 2) 14.5 (2.6) 3) 15.7 (2.9) 4) 15.5 (2.6)	Values NR Main effect for patients (ns) Main effect for time (p=0.03) **Group x time interaction (p=0.01)**	NR
Campbell, 2007[26] 1) Coping Skills Training (CST) (n=20) 2) Usual Care (UC) (n=20)	Prostate cancer	Karnofsky Performance Status score >= 60	SF-36 (Short Form Health Survey) (higher score = better functioning)	NR	Mental Health 1) 24.9 (SE=0.7) (n=12) 2) 25.2 (SE=0.5) (n=18) d=0.01, p=0.70	
Canada, 2005[43] 1) Couples Counseling (n=25) 2) Patient Counseling (n=26)			Brief Symptom Inventory/Global Symptom Inventory (BSI/GSI) (lower score = better functioning)	1) NR 2) NR Groups 1 and 2 combined: 0.38 (0.29) (n=51)	1) NR 2) NR Groups 1 and 2 combined: 0.29 (0.26) (n=44)	6 months post-tx: 1) NR 2) NR Groups 1 and 2 combined: 0.29 (0.22) (n=39) Group 1 vs 2: p=NR, ns
Giesler, 2005[22] 1) Cancer care intervention (n=48) 2) Standard care (n=51)	Prostate cancer (post-treatment)	T1a-T2c	SF-36 Short Form Health Survey (higher score = better functioning)	NR	Mental Health d=0.17, p=0.46 1 month post-intervention, n=NR	Mental Health d=-0.06, p=0.78 6 months post-intervention (n=85)
Manne, 2005[8] 1) Couple focused group (n=120) 2) Usual care (n=118)	Breast cancer	Early-stage, Eastern Cooperative Oncology Group performance status of 0 (*fully active*) or 1 (*restricted but ambulatory; able to carry out light or sedentary work*)	Mental Health Inventory (MHI) – Loss of Behavioral and Emotional Control scale (4 items)	1) 8.8 (3.0) (n=120) *1a) Attenders only 8.9 (2.8) (n=78)* 2) 8.9 (2.8) (n=118) p=NR	1) 8.1 (2.8) (n=120) *1a) Attenders only 7.6 (2.4) (n=78)* 2) 8.0 (2.8) (n=118) p=NR	6 months 1) 7.7 (2.9) (n=120) *1a) Attenders only 7.2 (2.4) (n=78)* 2) 8.5 (4.3) (n=118) p=NR
			Impact of Events Scale (15-items)	1) 24.2 (14.8) (n=120) *1a) Attenders only 23.3 (15.0) (n=78)* 2) 23.3 (15.0) (n=118) p=NR	1) 19.3 (13.7) (n=120) *1a) Attenders only 19.4 (13.9) (n=78)* 2) 20.9 (14.7) (n=118) p=NR	6 months 1) 16.8 (13.9) (n=120) *1a) Attenders only 15.7 (13.9) (n=78)* 2) 17.6 (15.5) (n=118) p=NR
			Mental Health Inventory (MHI) - Well-Being subscale (6 items)	1) 24.1 (5.1) (n=120) *1a) Attenders only 24.5 (5.0) (n=78)* 2) 24.5 (5.0) (n=118) p=NR	1) 26.0 (5.0) (n=120) *1a) Attenders only 26.7(4.7) (n=78)* 2) 25.6 (4.90) (n=118) p=NR	6 months 1) 26.5 (5.2) (n=120) *1a) Attenders only 27.3 (4.5) (n=78)* 2) 25.6 (6.2) (n=118) p=NR

Study, Year Interventions	Physical Condition	Baseline Functional Level	Quality of Life Assessment Scale	Baseline	Post-Treatment	Follow-up* (time assessed)
Manne, 2011[27] 1) IET (n=37) 2) Usual Care (n=34)	Prostate cancer	Diagnosed within past year; 15% stage 1, 85% stage 2	Mental Health Inventory (MHI) Psychological Distress scale	NR	NR p=ns treatment effects	NR
			Impact of Events Scale – Cancer Specific Distress	NR	NR p=ns treatment effects.	NR
			Mental Health Inventory (MHI) - Psychological Well-Being scale; 15 items (higher score = greater well-being)	NR	Controlling for co-variates: 1) 67.5 (n=37) 2) 65.0 (n=34) p=0.08	NR
Mokuau, 2008[47] 1) Cultural Intervention with SO (n=6) 2) Education with SO (n=4)	Cancer (any)	Cancer diagnosed in the last 12 months, any stage	Brief Symptom Inventory (BSI) Global Severity Index (53 items)	1) 26.67 2) 36.75 p<0.01	1) 17.00 2) 36.25 p<0.01 (group 1 over time)	NR
Nezu, 2003[36] 1) Problem solving (individual) (n=45) 2) Problem solving with SO (n=43) 3) Wait list (n=44)	Cancer (any)	Diagnosed in past 6 months, currently receiving treatment, experiencing significant psychological distress	Omega Vulnerability Rating Scale (Omega) (higher score = more distress)	1) 25.2 (4.2) 2) 25.6 (4.3) 3) 25.4 (4.5)	**1) 14.9 (3.8)** **2) 15.8 (2.9)** 3) 24.3 (5.3) Groups 1 & 2 decreased over time and different than group 3 post tx	1) 17.0 (6.0) (n=41) 2) 15.0 (4.3) (n=38) 3) not assessed (12 months)
			Profile of Mood States (POMS); 65 adjectives; rated 0 (not at all) to 4 (extremely)	1) 73.0 (21.3) 2) 70.4 (23.7) 3) 75.7 (25.7)	**1) 33.3 (21.6)** **2) 37.0 (21.0)** 3) 83.3 (24.5) Groups 1 & 2 decreased over time and different than group 3 post tx	1) 37.0 (25.6) (n=41) 2) 25.0 (28.2) (n=38) 3) not assessed (12 months)
			Brief Symptom Inventory/Global Severity Index (BSI/GSI) (higher score = greater distress)	1) 1.3 (0.4) 2) 1.3 (0.4) 3) 1.4 (0.3)	**1) 0.4 (0.3)** **2) 0.3 (0.2)** 3) 1.5 (0.3) Groups 1 & 2 decreased over time and different than group 3 post tx	1) 0.4 (0.3) (n=41) 2) 0.2 (0.2) (n=38) 3) not assessed (12 months)
Northouse, 2005[29] 1) FOCUS (n=69) 2) Usual care (n=65)	Breast cancer	Recurrent or progressing, Stage 3 or 4	Composite of FACT-B and SF-36-mental health (converted to T scores with mean of 50 and SD of 10)	1) 51.9 (10.4) (n=NR) 2) 49.2 (9.4) (n=NR)	1) 51.1 (10.8) (n=NR) 2) 48.8 (10.7) (n=NR) 6 months (after booster phase of FOCUS) Group x time (p=0.79)	NR

Study, Year Interventions	Physical Condition	Baseline Functional Level	Quality of Life Assessment Scale	Baseline	Post-Treatment	Follow-up* (time assessed)
Northouse, 2007[23] 1) Couples intervention (FOCUS) (n=129) 2) Usual care (UC) (n=134)	Prostate cancer	Newly diagnosed (65%); biochemical recurrence (14%); advanced (21%)	SF12-Mental (post-tx and follow up control for baseline scores)	1) NR 2) NR	1) 52.4 (6.5) (n=113) 2) 51.9 (6.6) (n=133) Effect size=0.08 (F=0.41, p=0.53)	8 months post-tx 1) 53.1 (7.1) (n=104) 2) 53.6 (7.1) (n=114) ES=-0.07 (F=0.01, p=0.96)
Porter, 2009[46] 1) Partner-assisted Emotional Disclosure, n=65 2) Education/ Support, n=65	Gastro-intestinal cancer	Stage II through IV	Profile of Moods States-Short Form (POMS-SF); score 0 to 90 with higher scores = "very much like this"	1) NR 2) NR	1) NR 2) NR No significant main effects or interaction ITT or completers (n=112)	
Schover, 2012[41] 1) Face-to-face counseling (FF) (n=60) 2) Internet-based counseling (WEB1) (n=55)	Prostate cancer	Localized prostate cancer ($T_{1-3}N_0M_0$)	Brief Symptom Inventory/General Severity Index (BSI/ GSI-18)	1) NR 2) NR Groups 1 and 2 combined: 4.6 (6.2)	NR	1) NR 2) NR Groups 1 and 2 combined: 4.6 (5.6) (12 months) p=NR, ns

*Last follow-up reported only if > 6 months post-treatment.
[1]Scale of -3 to +3; higher score indicates better well-being
d or ES=effect size, NR=not reported, ns=not statistically significant, SO=significant other

Table 4. Cancer Studies – Quality of Life – Social Functioning

Study, Year Interventions	Physical Condition	Baseline Functional Level	Quality of Life Assessment Scale	Baseline	Post-Treatment	Follow-up* (time assessed)
Blanchard, 1996[37] 1) Spouse directed problem-solving intervention (n=25 couples) 2) Treatment-as-usual (TAU) (n=32 couples)	Any cancer	Diagnosed more than 3 months before recruitment but patient not eligible for hospice	Social functioning subscale of the Medical Outcomes Scales SF-20	1) 75.2 (31.6) 2) 81.1 (22.1) p=ns (NR)	1) 74.8 (32.6) 2) 78.9 (27.4) p=ns (NR)	NR
Budin, 2008[30] 1) Psychoeducation (SE) +DM, n=66 2) Telephone counseling (TC) + DM, n=66 3) SE+TC+DM, n=58 4) Disease Management (DM), n=59	Breast cancer	Lesion with confirmed or strongly suspected diagnosis of cancer	Psychosocial Adjustment to Illness Scale (PAIS) – Domestic, Social, Vocational Environments (social adjustment) – higher score = poorer adjustment	Domestic Environment 1) 3.1 (3.3) 2) 3.6 (3.1) 3) 2.6 (3.0) 4) 3.1 (2.5)	Values NR Main group effect for patients (p=NR, ns) Main effect for time (p=NR, ns) Group x time interaction (p=NR, ns)	NR
				Social Environment 1) 4.0 (3.5) 2) 3.7 (3.6) 3) 2.7 (3.9) 4) 3.6 (4.0)	Values NR Main group effect for patients (p=0.92) **Main effect for time (p<0.0001)** Group x time interaction (p=0.63)	NR
				Vocational Environment 1) 3.4 (2.3) 2) 3.8 (3.5) 3) 3.3 (2.9) 4) 3.5 (3.6)	Values NR Main group effect for patients (p=0.52) Main effect for time (p=0.08) Group x time interaction (p=0.37)	NR
Giesler, 2005[22] 1) Cancer care intervention (n=48) 2) Standard care (n=51)	Prostate cancer (post-treatment)	T1a-T2c	SF-36 Short Form Health Survey (higher score = better functioning)	NR	Social Functioning d=0.00, p=0.99 1 month post-intervention, n=NR	Social Functioning d=0.21, p=0.35 6 months post-intervention (n=85)
Keefe, 2005[34] 1) Partner guided (n=41) 2) Usual care (n=37)	Cancer (any)	Eligible for hospice care; life expectancy ≤ 6 months	Functional Assessment of Cancer Therapy-General (FACT-G, v4) (scale 0-4, higher score = problem with function)	Social/family well-being NR; but reported p=ns between groups (n=78)	Social/family well- being 1) 3.6 (0.5) (n=28) 2) 3.3 (0.5) (n=28) p=0.13	NR

Study, Year Interventions	Physical Condition	Baseline Functional Level	Quality of Life Assessment Scale	Baseline	Post-Treatment	Follow-up* (time assessed)
Kurtz, 2005[39] 1) Clinical nursing intervention (n=118) 2) Usual care (UC) (n=119)	Cancer (any)	Recent diagnosis of a solid tumor (breast, lung, other); early stage, 3%; late stage, 67.0%	MOS SF-36 (scale 0-100, higher score = fewer limitations on social activity)	Social Functioning 1) 57.0 (28.3) 2) 57.2 (30.0) n=NR	Social Functioning 1) 80.0 (26.8) 2) 69.8 (30.4) n=NR p=NR	
Porter, 2011[45] 1) Coping skills training (CST) (n=117) 2) Education (EDU) (n=116)	Lung cancer	Stage I-III	FACT-L: Social Well-Being	1) NR 2) NR	1) NR 2) NR Time x Treatment interaction: p=ns Time x Treatment x Cancer Stage interaction: p=ns	NR

*Last follow-up reported only if > 6 months post-treatment
[1]Scale of -3 to +3; higher score indicates better well-being
d or ES=effect size, NR=not reported, ns=not statistically significant

Table 5. Cancer Studies – Quality of Life – Global Quality of Life

Study, Year Interventions	Physical Condition	Baseline Functional Level	Quality of Life Assessment Scale	Baseline	Post-Treatment	Follow-up* (time assessed)
Blanchard, 1996[37] 1) Spouse directed problem-solving intervention (n=25 couples) 2) Treatment-as-usual (TAU) (n=32 couples)	Any cancer	Diagnosed more than 3 months before recruitment but patient not eligible for hospice	Functional Living Index-Cancer (FLIC)	1) 112.8 (17.8) 2) 118.0 (15.6) p=ns	1) 114.6 (20.6) 2) 120.8 (16.5) p=ns	NR
Kayser, 2010[32] 1) Partners in Coping Program (PICP) (n=24) 2) Standard social work services (SWSS) (n=23)	Cancer, breast	Early-stage, non-metastatic (diagnosed within past three months)	Functional Assessment of Cancer Therapy–Breast (FACT-B) (27 generic items (4 well-being subscales) + 9 items specific to breast cancer; scale 0-4; higher score = better quality of life)	Total well-being 1) 105.6 (13.4) (n=24) 2) 101.2 (20.7) (n=23)	Total well-being 1) 112.0 (12.2) (n=24) 2) 105.7 (19.7) (n=23) p=NR, ns ES=0.38	At 12 months (7 months post-tx) Total well-being 1) 119.0 (14.0) (n=24) 2) 111.3 (20.3) (n=23) p=NR, ns ES= 0.44
McMillan, 2007[40] 1) Standard care + friendly visits, n=109 2) COPE, n=111 3) Standard care, n=109	Cancer	Hospice care	Hospice Quality of Life Index (HQLI); scores from 0 to 280	NR	Values not reported Time, group, and group x time interaction (all ns) (30 day)	NR
Meyers, 2011[38] 1) SCEI (Simultaneous Care Educational Intervention) (n=348) 2) Usual care (n=128)	Cancer (any)	Relapsed, refractory or recurrent solid tumors or lymphoma enrolled onto phase 1 or 2, or phase 3 trials that compared therapy for advanced cancer	City of Hope QOL (higher score indicates better outcome; rescaled by authors 0-100 for comparison between pts and caregivers)	1) 61.7 (15.2) (n=331) 2) 64.4 (15.6) (n=118) p=0.11	NR	NR
Nezu, 2003[36] 1) Problem solving (individual) (n=45) 2) Problem solving with SO (n=43) 3) Wait list (n=44)	Cancer (any)	Diagnosed in past 6 months, currently receiving treatment, experiencing significant psychological distress	QL Index (higher score=better QOL)	1) 8.1 (2.3) 2) 8.7 (1.1) 3) 7.9 (1.8)	1) 8.3 (1.7) 2) 8.6 (1.0) 4) 8.3 (1.8) No changes over time and no difference between groups	1) 8.7 (2.0) (n=41) 2) 8.4 (1.8) (n=38) 3) not assessed (12 months)
Northouse, 2007[23] 1) Couples intervention (FOCUS) (n=129) 2) Usual care (UC) (n=134)	Prostate cancer	Newly diagnosed (65%); biochemical recurrence (14%); advanced (21%)	FACT-G (post-tx and follow up control for baseline scores)	1) NR 2) NR	1) 87.2 (10.6) (n=113) 2) 85.5 (10.3) (n=133) ES=0.16 (F=2.67, p=0.10)	8 months post-tx 1) 86.1 (10.9) (n=104) 2) 85.8 (10.7) (n=114) ES=0.03 (F=0.09, p=0.77)

*Last follow-up reported only if > 6 months post-treatment
[1]Scale of -3 to +3; higher score indicates better well-being
d or ES=effect size, NR=not reported, ns=not statistically significant, SO=significant other

Table 6. Cancer Studies – Depression and Anxiety

Study, Year Interventions	Physical Condition	Baseline Functional Level	Assessment Tool	Baseline	Post-Treatment	Follow-up* (time assessed)
Badger, 2007[9] 1) Telephone interpersonal counseling (TIP-C) (n=38) 2) Exercise (n=23) 3) Attention Control (n=36)	Breast cancer	Stage I-III currently receiving adjuvant treatment	Depression: CES-D (score ≥16 positive for depression)	1) 16.4 (1.7) 2) 13.3 (2.4) 3) 9.9 (1.8)	1) 14.1 (1.5) (n=38) 2) 11.3 (2.1) (n=21) 3) 9.4 (1.6) (n=33)	
			Anxiety: 8-item composite index using PANAS (4 items), SF-12 (1 item), and Index of Clinical Stress (3 items) (scale 1-10, higher score = more anxiety)	1) 4.4 (0.3) 2) 4.1 (0.5) 3) 3.1 (0.3)	1) 3.2 (0.3) (n=38) 2) 2.6 (0.4) (n=21) 3) 2.9 (0.3) (n=33)	
Badger, 2011[21] 1) Telephone Interpersonal Counseling (TIP-C) (n=36) 2) Health Education Attention Condition (HEAC) (n=35)	Prostate cancer	Currently undergoing or completed treatment w/in 6 months (Stage I=16%, II=9%, III=11%, IV=11%, unknown=53%)	Depression: CES-D	1) 11.4 (9.0) (n=36) 2) 12.4 (9.7) (n=35) p=ns (NR)	1) 11.3 (9.2) (n=34) 2) 9.1 (9.7) (n=32) Group change over time: 1) ns **2) p<0.05** **Group 1) vs 2): p<0.001 (favoring group 2)**	
Blanchard, 1996[37] 1) Spouse directed problem-solving intervention (n=25 couples) 2) Treatment-as-usual (TAU) (n=32 couples)	Any cancer	Diagnosed more than 3 months before recruitment but patient not eligible for hospice	Depression: CES-D	1) 18.9 (8.3) 2) 15.7 (6.9)	1) 16.3 (6.9) 2) 18.9 (8.3)	
Giesler, 2005[22] 1) Cancer care intervention (n=48) 2) Standard care (n=51)	Prostate cancer (post-treatment)	T1a-T2c	Depression: CES-D NOTE: CES-D score was also a moderator	1) 6.9 2) 8.8	d=0.36, p=0.12 (7 months or post intervention; n=NR)	d=0.24, p=0.29 (n=85) (12 months)
Kozachik, 2001[35] 1) Cancer Care intervention (CCI) (n=61) 2) Usual care (UC) (n=59)	Cancer (46% breast, 24% lung, 21% colon, 9% other)	Newly diagnosed solid tumor (48% Stage I or II; 52% Stage III or IV)	Depression: CES-D (higher score = greater depression)	1) 12.6 (7.8) (n=61) 2) 10.8 (7.6) (n=59) p=NR	1) 8.8 (6.7) (n=40) 2) 8.0 (7.4) (n=49) p=NR	
Kurtz, 2005[39] 1) Clinical nursing intervention (n=118) 2) Usual care (n=119)	Cancer (any)	Recent diagnosis of a solid tumor (breast, lung, other); early stage, 33%; late stage, 67.0%	Depression: CES-D (20 items scored on a scale of 0-60; higher score = greater depressive symptoms)	1) 12.2 (9.0) 2) 13.6 (9.0) n=NR	1) 6.6 (7.7) 2) 9.9 (9.2) n=NR p=NR	NR

Study, Year Interventions	Physical Condition	Baseline Functional Level	Assessment Tool	Baseline	Post-Treatment	Follow-up* (time assessed)
Manne, 2005[8], 2007[33] 1) Couple focused group (n=120) 2) Usual care (n=118)	Breast cancer	Early-stage, Eastern Cooperative Oncology Group performance status of 0 (*fully active*) or 1 (*restricted but ambulatory; able to carry out light or sedentary work*)	Depression: Mental Health Inventory (MHI–18) subscale (4 items)	1) 9.4 (2.9) (n=120) *1a) Attenders only* 9.1 (2.5) (n=78) 2) 9.1 (2.5) (n=118) p=NR	1) 8.6 (2.7) (n=120) *1a) Attenders only* 8.1 (2.3) (n=78) 2) 8.9 (2.8) (n=118) p=NR	6 months 1) 8.1 (3.0) (n=120) *1a) Attenders only* 7.7 (2.3) (n=78) 2) 9.0 (3.9) (n=118) p=NR
			Anxiety: Mental Health Inventory (MHI–18); subscale (4 items)	1) 10.3 (3.5) (n=120) *1a) Attenders only* 10.1 (3.6) (n=78) 2) 10.1 (3.6) (n=118) p=NR	1) 9.9 (3.4) (n=120) *1a) Attenders only* 9.5 (3.2) (n=78) 2) 9.8 (3.6) (n=118) p=NR	6 months 1) 9.2 (3.2) (n=120) *1a) Attenders only* 8.8 (3.0) (n=78) 2) 10.3 (4.97) (n=118) p=NR
McCorkle, 2007[28] 1) Standardized Nursing Intervention Protocol (SNIP) (n=62) 2) Usual care (UC) (n=64)	Prostate cancer	Newly diagnosed, undergoing radical prostatectomy	Depression: CES-D (higher score = greater depression)	1) 11.30 (6.84) (n=54) 2) 11.40 (7.40) (n=53) p=ns	3 months post-surgery 1) 7.74 (6.81) (n=54) 2) 6.35 (5.34) (n=53) p=ns	NR
Nezu, 2003[36] 1) Problem solving (individual) (n=45) 2) Problem solving with SO (n=43) 3) Wait list (n=44)	Cancer (any)	Diagnosed in past 6 months, currently receiving treatment, experiencing significant psychological distress	HRSD	1) 20.4 (4.2) 2) 21.3 (3.7) 3) 21.2 (3.3)	**1) 6.4 (3.8)** **2) 6.0 (2.7)** 3) 22.1 (4.5) Groups 1 & 2 decreased over time and different than group 3 post tx	1) 7.1 (4.2) (n=41) 2) 6.2 (3.0) (n=38) 3) not assessed (12 months)
Northouse, 2005[29] 1) FOCUS, n=69 2) Usual care, n=65	Breast cancer	Recurrent or progressing, Stage 3 or 4	Depression: Beck Hopelessness Scale (higher score indicates more hopelessness)	1) 4.5 (4.8) (n=NR) 2) 3.0 (4.0) (n=NR) p<0.05 (controlled for in subsequent analyses)	1) 4.2(4.9) (n=NR) 2) 3.5 (4.0) (n=NR) 6 months (after booster phase of FOCUS) Group x time F=1.72, p=0.19	
Northouse, 2007[23] 1) Couples intervention (FOCUS) (n=129) 2) Usual care (UC) (n=134)	Prostate cancer	Newly diagnosed (65%); biochemical recurrence (14%); advanced (21%)	Depression: Beck Hopelessness Scale (higher score indicates more hopelessness) (post-tx and follow up controlled for baseline scores)	1) NR 2) NR	1) 2.2 (2.4) (n=113) 2) 2.7 (3.1) (n=133) ES=0.17 (F=3.22, p=0.07)	8 months post-tx 1) 2.7 (2.7) (n=104) 2) 2.6 (3.1) (n=114) ES=0.01 (F=0.19, p=0.67)

Study, Year Interventions	Physical Condition	Baseline Functional Level	Assessment Tool	Baseline	Post-Treatment	Follow-up* (time assessed)
Porter, 2011[45] 1) Coping skills training (CST) (n=117) 2) Education (EDU) (n=116)	Lung cancer	Stage I-III	Depression: Beck Depression Inventory (scores from 0-63)	1) NR 2) NR	1) NR 2) NR Time x Treatment Interaction: p=ns Time x Treatment x Cancer Stage interaction: *B*=-2.38; SE=0.86; p=0.006	NR
			Anxiety: State-Trait Anxiety Scale (STAI) (scores from 20-80)	1) NR 2) NR	1) NR 2) NR Time x Treatment Interaction: p= ns Time x Treatment x Cancer stage Interaction: *B*=-8.28; SE=2.85; p=0.006	
Stephenson, 2007[48] 1) Reflexology that included education for partner 2) Usual care plus special attention (reading a chosen selection to patient)	Cancer	Metastatic cancer	Anxiety: Visual Analog Scale for Anxiety	Anxiety 1) 5.0 2) 5.6	Anxiety 1) 1.9 2) 4.3 *F*=12.27, *p*<0.01, eta squared=0.13, moderate effect, adjusted for baseline anxiety	Subgroup: *patients with severe to moderate anxiety* (Pain ≥5) *Baseline:* 1) 7.9 (n=12) 2) 8.0 (n=20) *Post-treatment:* 1) 2.9 (n=12) 2) 5.5 (n=20) *F*=8.16, *p*=0.01, eta squared=0.15, moderate effect, adjusted for baseline anxiety

*Last follow-up reported only if > 6 months post-treatment
[1]higher score indicates higher level of emotion
[2]higher score indicates poorer adjustment
SO=significant other, d or ES=effect size, NR=not reported, ns=not statistically significant

Table 7. Cancer Studies – Symptom Control/Management

Study, Year Interventions	Physical Condition	Baseline Functional Level	Symptom Assessment	Baseline	Post-Treatment	Follow-up* (time assessed)
Badger, 2011[21] 1) TIP-C (n=36) 2) HEAC (n=35)	Prostate cancer	Currently undergoing or completed treatment w/in 6 months (Stage I=16%, II=9%, III=11%, IV=11%, unknown=53%)	Multidimensional Fatigue Inventory (MFI) (Higher scores indicate more fatigue)	1) 26.8 (15.8) (n=36) 2) 28.2 (18.1) (n=35) p=ns (NR)	1) 27.1 (17.5) (n=34) 2) 24.5 (19.2) (n=32) Group change over time: 1) ns **2) p<0.05** **Group 1) vs 2): p<0.01 (favoring group 2)**	
Baucom, 2009[31] 1) Couple-based relationship enhancement (RE) (n=8 couples) 2) Treatment-as-usual (TAU) (n=6 couples)	Breast cancer	Stage I or II (recently diagnosed); no history of other breast cancer; no history of cancer within last 5 years	Brief Fatigue Inventory (BFI) (higher score = greater fatigue)	1) 4.9 (1.4) 2) 3.6 (2.1)	1) 2.9 (1.4) 2) 4.4 (1.9) n=NR d=1.67 (pre tx to post tx)	1) 3.0 (1.0) 2) 3.2 (2.3) (12 months) n=NR d=0.90 (pre tx to follow-up)
			Brief Pain Inventory (BPI) (higher score = greater pain)	1) 2.8 (2.0) 2) 2.0 (1.3)	1) 2.3 (1.4) 2) 2.7 (2.7) n=NR d=0.59 (pre tx to post tx)	1) 2.3 (1.5) 2) 2.4 (1.7) (12 months) n=NR d=0.53 (pre tx to follow-up)
			Rotterdam Symptom Checklist (RSC) (higher score = more symptoms)	1) 23.1 (4.5) 2) 24.5 (5.6)	1) 20.7 (3.8) 2) 27.2 (8.7) n=NR d=0.86 (pre tx to post tx)	1) 18.7 (2.4) 2) 23.8 (9.8) d=0.61 (pre tx to follow-up)
Blanchard, 1996[37] 1) Spouse directed problem-solving intervention (n=25 couples) 2) Treatment-as-usual (TAU) (n=32 couples)	Any cancer	Diagnosed more than 3 months before recruitment but patient not eligible for hospice	Pain subscale of Medical Outcomes Scale (SF-20)	1) 57.0 (19.6) 2) 59.0 (18.2) p=ns (NR)	1) 56.5 (21.0) 2) 56.2 (18.1) p=ns (NR)	1) 54.0 (19.4) 2) 57.3 (16.4) p=ns (NR)
Budin, 2008[30] 1) Psychoeducation (SE) +DM, n=66 2) Telephone counseling (TC) + DM, n=66 3) SE+TC+DM, n=58 4) Disease Management (DM), n=59	Breast cancer	Lesion with confirmed or strongly suspected diagnosis of cancer	Side Effects Severity (subscale of BCTRI); scores from 1 to 60 with higher score = greater severity	1) NR 2) NR 3) 28.0 (1.4) 4) 27.7 (1.3) Post-surgery values	1) NR 2) NR 3) 25.7 (1.5) 4) 31.8 (1.4) **Main effect for time (p=0.002) but only SE+TC group had decrease** Differences ns (group or group x time)	
			Side Effect Distress (subscale of BCTRI) (scores of 0 to 60; higher score = more side effect distress)	1) NR 2) NR 3) 20.4 (2.0) 4) 19.5 (1.8) Post-surgery values	1) NR 2) NR 3) 18.7 (2.1) 4) 26.9 (2.0) Differences ns (group, time, or group x time)	NR

Study, Year Interventions	Physical Condition	Baseline Functional Level	Symptom Assessment	Baseline	Post-Treatment	Follow-up* (time assessed)
Campbell, 2007[26] 1) Coping Skills Training (CST) (n=20) 2) Usual Care (UC) (n=20)	Prostate cancer	Karnofsky Performance Status score >= 60	EPIC (0 to 100 scale; higher score = better QOL)	NR	Urinary total 1) 78.0 (SE=3.5) 2) 74.8 (SE=2.8) d=0.14, p=0.49 Bowel total 1) 86.3 (SE=2.5) 2) 82.4 (SE=2.0) d=0.31, p=0.24 Sexual total 1) 34.4 (SE=5.2) 2) 25.0 (SE=4.3) d=0.34, p=0.18 Hormonal total 1) 88.8 (SE=2.3) 2) 84.2 (SE=1.8) d=0.30, p=0.12	
Canada, 2005[43] 1) Couples Counseling (n=25) 2) Patient Counseling alone (n=26)	Prostate cancer	Localized prostate cancer; Stage A-C	International Index of Erectile Functioning (IIEF) Total score (higher score indicates better functioning)	1) NR 2) NR Groups 1 and 2 combined: 24.8 (18.7) (n=51)	1) NR 2) NR Groups 1 and 2 combined: 36.3 (17.3) (n=44)	6 months post-tx: 1) NR 2) NR Groups 1 and 2 combined: 31.1 (20.1) (n=39) Group 1 vs 2: p=NR, ns
Giesler, 2005[22] 1) Cancer care intervention (n=48) 2) Standard care (n=51)	Prostate cancer (post-treatment	T1a-T2c	SF-36 Short Form Health Survey-pain subscale (higher score = better functioning)	NR	Pain Index d=0.25, p=0.27 At 7 months (post-intervention, n=NR)	Pain Index d=0.23, p=0.30 At 12 months (n=85)
			Urinary function; Prostate Cancer Quality of Life Instrument (range 0-100, higher score = better outcome)	NR	Difference scores from baseline (1 month post-intervention) 1) 18.86 (19.71) 2) 22.35 (19.32) d=-0.18, p=0.44	Difference scores from baseline (6 mos post-intervention) 1) 19.55 (23.57) 2) 23.09 (22.34) d=-0.15, p=0.49
			Urinary bother; Prostate Cancer Quality of Life Instrument (range 0-100, higher score – better outcome)	NR	Difference scores from baseline (1 month post-intervention) 1) 27.55 (21.91) 2) 20.51 (21.72) d=0.32, p=0.19	Difference scores from baseline (6 mos post-intervention 1) 21.76 (30.93) 2) 25.84 (24.48) d=0.15, p=0.53

Study, Year Interventions	Physical Condition	Baseline Functional Level	Symptom Assessment	Baseline	Post-Treatment	Follow-up* (time assessed)
Giesler, 2005[22] (continued)			Urinary limitation; Prostate Cancer Quality of Life Instrument (range 0-100^)	NR	Difference scores from baseline (1 month post-intervention) 1) 23.05 (23.26) 2) 17.58 (24.17) d=0.23, p=0.34	Difference scores from baseline (6 mos post-intervention) 1) 23.40 (24.14) 2) 17.19 (26.72) d=0.24, p=0.28
			Bowel bother; Prostate Cancer Quality of Life Instrument (range 0-100)^	NR	Difference scores from baseline^ (1 month post-intervention 1) 15.56 (24.51) 2) 12.18 (23.96) d=0.14, p=0.58	Difference scores from baseline (6 mos post-intervention) 1) 14.00 (23.67) 2) 10.22 (25.49) d=0.15, p=0.53
			Bowel function; Prostate Cancer Quality of Life Instrument (range 0-100)^	NR	Difference scores from baseline^ (1 month post-intervention 1) 6.79 (13.97) 2) 11.42 (19.26) d=-0.27, p=0.25	Difference scores from baseline (6 mos post-intervention) 1) 4.80 (16.91) 2) 8.35 (15.71) d=10.22, p=0.34
			Bowel limitation; Prostate Cancer Quality of Life Instrument (range 0-100)^	NR	Difference scores from baseline^ (1 month post-intervention 1) 6.01 (11.62) 2) 5.04 (13.88) d=0.08, p=0.76	Difference scores from baseline (6 mos post-intervention) 1) 2.80 (10.99) 2) 3.27 (10.60) d=0.04, p=0.86
			Sexual function; Prostate Cancer Quality of Life Instrument (range 0-100)^	NR	Difference scores from baseline^ (1 month post-intervention) 1) 21.90 (22.72) 2) 12.60 (26.33) d=0.38, p=0.10	Difference scores from baseline (6 mos post-intervention) 1) 25.26 (26.60) 2) 15.32 (27.77) d=0.37, p=0.10
			Sexual bother; Prostate Cancer Quality of Life Instrument (range 0-100)^	NR	Difference scores from baseline^ (1 month post-intervention) 1) 5.54 (23.74) 2) -0.20 (19.67) d=0.26, p=0.25	Difference scores from baseline (6 mos post-intervention) 1) 9.21 (29.63) 2) 3.3 (25.35) d=0.21, p=0.34
			Sexual limitation; Prostate Cancer Quality of Life Instrument (range 0-100^)	NR	Difference scores from baseline^ (1 month post-intervention) 1) 10.68 (15.93) 2) 3.80 (15.05) d=0.45, p=0.05	Difference scores from baseline (6 mos post-intervention) 1) 12.35 (17.28) 2) 3.11 (19.61) d=0.50, p=0.02

Study, Year Interventions	Physical Condition	Baseline Functional Level	Symptom Assessment	Baseline	Post-Treatment	Follow-up* (time assessed)
Gustafson, 2013[44] 1) Standard care plus CHESS (n=144) 2) Standard care plus Internet (n=141)	Nonsmall Cell Lung Cancer	16% Stage IIIA, 18% Stage IIIB, 66% Stage IV 71% ECOG 0 or 1 30% ECOG 2, 3, or 4	Caregiver-reported patient symptom distress (7 physical symptoms, rated 0 (absence) to 10 (worst possible); range=0-70)	NR	**1) 17.0 (SE=1.8) (n=NR)** **2) 22.3 (SE=1.9) (n=NR)** **d=0.46, p=0.005** scores adjusted for pretest ESAS score, study site, caregiver-patient relationship, and caregiver race	NR
Keefe, 2005[34] 1) Partner guided (n=41) 2) Usual care (n=37)	Cancer (any)	Eligible for hospice care; life expectancy ≤ 6 months	Pain intensity – Brief Pain Inventory (BPI); scale 0-10 with higher score indicating greater pain intensity	Week's usual pain (BPI): values NR; reported p=ns between groups (n=78) Week's worst pain (BPI): values NR; reported p=ns between groups (n=78)	Week's usual pain (BPI): 1) 4.6 (2.0) (n=28) 2) 5.2 (2.0) (n=28) p=0.28 Week's worst pain (BPI): 1) 6.5 (2.2) (n=28) 2) 6.9 (2.2) (n=28) p=0.37 BOTH adj for pre-tx scores	NR
McCorkle, 2007[28] 1) Standardized Nursing Intervention Protocol (SNIP) (n=62) 2) Usual Care (UC) (n=64)	Prostate cancer	NR	CARES (Sexual Function); 8 items (scale 0 – 4; higher score = poorer function)	1) 9.82 (5.48) (n=54) 2) 12.67 (7.03) (n=53) p=ns This outcome first assessed at 1 month post-surgery (or 1 month into the intervention period)	1) 12.96 (6.20) (n=54) 2) 10.86 (6.30) (n=53) p=ns 1 month post intervention	NR
McMillan, 2007[40] 1) Standard care + friendly visits, n=109 2) COPE, n=111 3) Standard care, n=109	Cancer	Hospice care	Memorial Symptom Assessment Scale (MSAS); scores from 0 (no distress) to 90 (very much distress)	NR	Values NR (30 day) Time and group main effects (ns) **Group x time interaction (p=0.009); Group 2 vs. 3; p=0.013**	
			Numeric rating scale (NRS) for pain	NR	Values NR (30 day) Time, group, and group x time interaction (all ns)	NR
			Dyspnea intensity scale	NR	Values NR (30 day) Time, group, and group x time interaction (all ns)	NR
			Constipation assessment scale (CAS)	NR	Values not reported Time, group, and group x time interaction (all ns) (30 day)	NR

Study, Year Interventions	Physical Condition	Baseline Functional Level	Symptom Assessment	Baseline	Post-Treatment	Follow-up* (time assessed)
Mishel, 2002 [24] 1) Uncertainty management direct (n=NR) 2) Uncertainty management supplemented (n=NR) 3) Usual care (n=NR)	Prostate cancer	TNM staging classification 8% T1 61% T2 27% T3 4% unknown	# of symptoms reported	1) 7.7 (2.8) (n=NR) 2) 7.4 (3.0) (n=NR) 3) 7.6 (2.7) (n=NR)	1) 6.2 (2.8) (n=NR) 2) 5.7 (2.9) (n=NR) 3) 6.5 (2.7) (n=NR) (assessed at baseline + post-intervention - 8 weeks after intervention) p=NR Sub group analyses: White men in intervention grps had sign decrease in symptoms compared to white men in control group from baseline to post-intervention. AA men in tx direct group compared to AAs in control grp from post-inter. to follow up had sign decrease in symptoms	NR
			Control over urine flow (scale 1-5; higher score = more improvement in the symptom)	1) 3.6 (1.2) (n=NR) 2) 3.6 (1.2) (n=NR) 3) 3.9 (1.2) (n=NR)	1) 4.5 (0.7) (n=NR) 2) 4.6 (0.8) (n=NR) 3) 4.4 (0.7) (n=NR) (8 weeks post- intervention) p=NR NOTE: Interv. grps vs. control showed more control over urine flow ($F_{2, 212}$=3.7, p=.03)	NR
			Ability to have an erection (scale 1-5; higher score = more improvement)	1) 1.9 (1.2) (n=NR) 2) 1.7 (1.3) (n=NR) 3) 1.9 (1.2) (n=NR)	1) 2.4 (1.0) (n=NR) 2) 2.4 (1.2) (n=NR) 3) 2.4 (1.1) (n=NR) (8 weeks post- intervention) p=NR	NR
			Overall Symptom intensity (scale 1-5; higher score = more improvement in the symptom)	1) 1.9 (0.4) (n=NR) 2) 1.8 (0.4) (n=NR) 3) 1.8 (0.4) (n=NR)	1) 1.7 (0.3) (n=NR) 2) 1.5 (0.3) (n=NR) 3) 1.7 (0.3) (n=NR) (8 weeks post- intervention) p=NR	NR

Study, Year Interventions	Physical Condition	Baseline Functional Level	Symptom Assessment	Baseline	Post-Treatment	Follow-up* (time assessed)
Mishel, 2002[24] (continued)			Satisfaction with sexual function (scale 1-5; higher score = more improvement)	1) 2.2 (1.4) (n=NR) 2) 1.6 (1.5) (n=NR) 3) 2.2 (1.4) (n=NR)	1) 2.2 (1.3) (n=NR) 2) 2.4 (1.4) (n=NR) 3) 2.2 (1.3) (n=NR) (8 weeks post- intervention) p=NR AA men in tx supplemented group compared to AAs in control grp from baseline to post-inter. had higher satisfaction with sexual functioning ($F_{1,186}$=6.57, p=0.01)	NR
Nezu, 2003[36] 1) Problem solving (individual) (n=45) 2) Problem solving with SO (n=43) 3) Wait list (n=44)	Cancer (any)	Diagnosed in past 6 months, currently receiving treatment, experiencing significant psychological distress	CARES (Total Score, higher=more severe)	1) 2.4 (0.4) 2) 2.4 (0.4) 3) 2.4 (0.4)	**1) 0.8 (0.3)** **2) 0.7 (0.4)** 3) 2.4 (0.3) Groups 1 & 2 decreased over time and different than group 3 post tx	1) 0.8 (0.4) (n=41) 2) 0.6 (0.4) (n=38) 3) not assessed (12 months)
Northouse, 2007[23] 1) Couples intervention (FOCUS) (n=129) 2) Usual care (UC) (n=134)	Prostate cancer	Newly diagnosed (65%); biochemical recurrence (14%); advanced (21%)	Expanded Prostate Cancer Index Composite (EPIC) Urinary Symptoms (higher score = better prostate-specific symptom outcome) *Post-tx and follow up controlling for baseline scores*	1) NR 2) NR	1) 86.9 (12.7) (n=113) 2) 81.6 (13.8) (n=133) d=0.19 (F=2.86, p=0.09)	8 months post-tx 1) 84.5 (12.5) (n=104) 2) 83.9 (13.6) (n=114) d=0.05 (F=0.19, p=0.67)
			EPIC Bowel Symptoms	1) NR 2) NR	1) 89.5 (7.0) (n=113) 2) 90.3 (8.4) (n=133) d=-0.10 (F=0.33, p=0.57)	8 months post-tx 1) 89.6 (7.4) (n=104) 2) 90.5 (8.0) (n=114) d=0.12 (F=0.59, p=0.44)
			EPIC Sexual Symptoms	1) NR 2) NR	1) 28.5 (21.4) (n=113) 2) 29.3 (20.9) (n=133) d=-0.04 (F=0.13, p=0.72)	8 months post-tx 1) 30.4 (21.7) (n=104) 2) 31.3 (21.1) (n=114) d=-0.04 (F=0.14, p=0.71)
			EPIC Hormonal Symptoms	1) NR 2) NR	1) 83.7 (9.9) (n=113) 2) 83.8 (10.4) (n=133) d=0.01 (F=0.01, p=0.95)	8 months post-tx 1) 83.9 (10.0) (n=104) 2) 85.2 (10.3) (n=114) d=-0.13 (F=0.85, p=0.36)

Study, Year Interventions	Physical Condition	Baseline Functional Level	Symptom Assessment	Baseline	Post-Treatment	Follow-up* (time assessed)
Porter, 2011[45] 1) Coping skills training (CST) (n=117) 2) Education (EDU) (n=116)	Lung cancer	Stage I-III	BPI (higher score=greater pain intensity)	1) NR 2) NR	1) NR 2) NR Time x Treatment Interaction: p=ns Time x Treatment x Cancer Stage interaction: p=ns	NR
			FACT-L: Lung Cancer Symptoms (shortness of breath, coughing, weight loss, loss of appetite)	1) NR 2) NR	1) NR 2) NR Time x Treatment Interaction: p=ns Time x Treatment x Cancer Stage interaction: p=ns	NR
Schover, 2012[41] 1) Face-to-face counseling (FF) (n=60) 2) Internet-based counseling (WEB1) (n=55)	Prostate cancer	Localized prostate cancer ($T_{1-3}N_0M_0$)	International Index of Erectile Function (IIEF) (higher score indicates better function)	1) 26.4 (18.2) (n=39) 2) 27.4 (17.3) (n=33)	1) 34.4 (22.2) (n=30) 2) 31.3 (20.4) (n=27)	1) 33.6 (23.1) (n=26) 2) 34.5 (22.5) (n=25) (12 months) **Group 1) improvement over time: p<0.0001, d=0.35** **Group 2) improvement over time: p=0.04, d=0.35** Group 1) vs 2) p=NR
			% men achieving near normal erectile function over time (IIEF Erectile Function subscale ≥22)	1) 12% 2) 15%	NR	1) 32% 2) 31% **Group 1 and 2 over time: p<0.005** Group 1) vs 2) p=NR, ns

Study, Year Interventions	Physical Condition	Baseline Functional Level	Symptom Assessment	Baseline	Post-Treatment	Follow-up* (time assessed)
Stephenson, 2007[48] 1) Reflexology that included education for partner (n=42) 2) Usual care plus special attention (reading a chosen selection to patient) (n=44)	Cancer	Metastatic cancer	Pain (reported using BPI or SF-MPQ)	1) 3.2 (n=42) 2) 4.5 (n=44)	1) 2.1 (n=42) 2) 4.4 (n=44) *Decrease in pain from pre to post* 1) 1.1 2) 0.1 F=11.74, p<0.01, eta squared=0.12, moderate effect, adjusted for baseline pain Subgroup: *patients with severe to moderate pain* (Pain ≥5) *Baseline:* 1) 7.3 (n=12) 2) 7.7 (n=20) *Post treatment:* 1) 4.6 (n=12) 2) 7.2 (n=20) *Decrease in pain from pre to post* 1) 2.7 (n=12) 2) 0.5 (n=20) *F*=8.41, *p*<0.01, eta squared=0.23, large effect, adjusted for baseline pain	

*Last follow-up reported only if > 6 months post-treatment

[1]Univariate analyses of covariance, with baseline measures of HbA1c, FBP and diabetes knowledge as covariates (no significant differences between groups at baseline)

^Larger difference = better outcome

d or ES=effect size; NR=not reported; ns=not statistically significant, SO=significant other

Table 8. Cancer Studies – Relationship Adjustment

Study, Year Interventions	Physical Condition	Baseline Functional Level	Assessment Tool	Baseline	Post-Treatment	Follow-up* (time assessed)
Baucom, 2009[31] 1) Couple-based relationship enhancement (RE) (n=8 couples) 2) Treatment-as-usual (TAU) (n=6 couples)	Breast cancer	Stage I or II (recently diagnosed); no history of other breast cancer; no history of cancer within last 5 years.	Quality of Marriage Index (QMI) (higher score = greater quality)	1) 34.0 (13.6) 2) 40.8 (6.0)	1) 39.3 (4.7) 2) 42.2 (4.1) (n=NR) d=0.48 (pre tx to post tx)	1) 39.7 (3.5) 2) 40.2 (5.1) (12 months) (n=NR) d=0.77 (pre tx to follow-up)
Blanchard, 1996[37] 1) Spouse directed problem-solving intervention (n=25 couples) 2) Treatment-as-usual (TAU) (n=32 couples)	Any cancer	Diagnosed more than 3 months before recruitment but patient not eligible for hospice	Dyadic Adjustment Scale (DAS)	1) 35.2 (3.5) 2) 34.6 (3.6) p=ns (NR)	1) 34.8 (3.8) 2) 34.3 (3.9) p=ns (NR)	
Canada, 2005[43] 1) Couples Counseling (n=25) 2) Patient Counseling alone (n=26)	Prostate cancer	Localized prostate cancer; Stage A-C	Abbreviated Dyadic Adjustment Scale (A-DAS)	1) NR 2) NR Groups 1 and 2 combined: 25.3 (4.8) (n=51)	1) NR 2) NR Groups 1 and 2 combined: 25.3 (4.7) (n=44)	6 months post-tx: 1) NR 2) NR Groups 1 and 2 combined: 24.8 (4.9) (n=39) Group 1 vs 2: p=NR, ns
Giesler, 2005[22] 1) Cancer care intervention (n=48) 2) Standard care (n=51)	Prostate cancer (post-treatment)	T1a-T2c	DAS - Dyadic Cohesion	NR	d=0.19, p=0.43 (7 months or post intervention; n=NR)	d=0.07, p=0.75 (12 months; n=85)
			DAS - Dyadic Satisfaction	NR	d=0.24, p=0.31 (7 months or post intervention; n=NR)	d=0.37, p=0.10 (12 months; n=85)
Manne, 2011[27] 1) IET (n=37) 2) Usual Care (n=34)	Prostate Cancer	Diagnosed within past year; 15% stage 1, 85% stage 2	DAS (Relationship Functioning)	NR	NR; ns treatment effects	NR
McCorkle, 2007[28] 1) Standardized Nursing Intervention Protocol (SNIP) (n=62) 2) Usual care (UC) (n=64)	Prostate cancer	Newly diagnosed, undergoing radical prostatectomy	CARES (Marital Interaction) (higher score=poorer function)	1 month post-surgery 1) 2.69 (4.21) (n=54) 2) 3.58 (4.56) (n=53) p=ns (between groups)	3 months post-surgery 1) 5.92 (7.55) (n=54) (p=0.002 from initial value) 2) 5.23 (6.69) (n=53) Group effect: p=ns	NR

Study, Year Interventions	Physical Condition	Baseline Functional Level	Assessment Tool	Baseline	Post-Treatment	Follow-up* (time assessed)
Porter, 2009[46] 1) Partner-assisted Emotional Disclosure, n=65 2) Education/ Support, n=65	Gastro-intestinal Cancer	Stage II through IV	Quality of Marriage Index (QMI)	1) NR 2) NR	1) NR 2) NR ITT: Group x time interaction (*B* = -.07, p=0.02); increase in relationship quality for Group 1, decrease for Group 2 Completers (n=112): Group x time interaction (*B* = -.08, p=0.02)	
Schover, 2012[41] 1) Face-to-face counseling (FF) (n=60) 2) Internet-based counseling (WEB1) (n=55)	Prostate cancer	Localized prostate cancer ($T_{1-3}N_0M_0$)	Dyadic Adjustment Scale (A-DAS)	1) NR 2) NR Groups 1 and 2 combined: 24.4 (4.7)	NR	1) NR 2) NR Groups 1 and 2 combined: 24.6 (4.5) (12 months) p=NR, ns

*Last follow-up reported only if > 6 months post-treatment; d or ES=effect size; NR=not reported; ns=not statistically significant

Table 9. Memory-Related Disorders – Study Characteristics

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Bass, 2003[56] Funding Source: Foundation, Government Condition: Dementia, Alzheimer's disease, memory loss **KQ1 ☒ KQ2 ☐** **Intervention Type:** Multicomponent (education, and coaching/care consultation to enhance competence and self-efficacy)	N=157 (of 182 randomized) Age (years): NR Gender (% male): NR Race/ethnicity (%): NR Marital Status (%): NR Education (%): NR Veterans (%): NR Recruitment Method: medical records of health plan members Family Characteristics: Relationship to patient: *"Primary family caregiver"* Age (years): NR Gender (% female): NR Race/ethnicity (%): NR Education (%): NR Veterans (%): NR	Inclusion: diagnosis of dementia or symptom code indicating memory loss; age 55 or older; non-nursing home resident; living in area served by Cleveland Area Alzheimer's Association Exclusion: NR	Intervention (n=109): Integration of services from managed care system & Alzheimer's Association care consultation service; standardized protocol; worked with families to create individualized plan of care; plan then completed by patients, family members, Association staff/volunteers; care consultants followed-up biweekly then at 1- and 3-month intervals or as needed (i.e., in difficult periods may have daily contact); average, care consultants have 12 direct contacts with patients and caregivers per year Comparator (n=73): Usual care within managed care medical system; families able to contact Alzheimer's Association and use any individual services offered other than care consultation Length of Follow-up: 1 year intervention only	***Utilization:*** a. # hospital admissions past 12 months (MR) b. # ER visits past 12 months (MR) c. # physician visits past 12 months (MR) MR=Medical Record report Outcomes assessed at baseline and post-treatment ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: providers not told of treatment group Intention-to-treat analysis (ITT): no (only analyzed data from those who allowed medical record access – see below) Withdrawals/dropouts adequately described: yes Treatment adherence: treatment dropouts (from sessions) - NR 157/182 (86%) completed follow-up assessment 120/182 (66%) allowed medical record access Treatment integrity: NR **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Belle, 2006[55] REACH II Funding Source: Government Condition: Alzheimer's disease or related disorders **KQ1 ☐ KQ2 ☒** **Intervention Type:** Education, role-playing, skills training, stress management, support	N=518 (of 642 randomized) Age (years): 79 Gender (% male): 35 Race/ethnicity (%): *Hispanic/Latino 32; white 35; black/African American 32 (used stratified randomization)* Marital Status (%): *married 59* Education (%): *<HS 16; HS 20; >HS 50* Veterans (%): NR Recruitment Method: memory disorder and primary care clinics, social service agencies, churches, community centers, brochures, media, targeted newsletters, presentations Family Characteristics: Relationship to patient (%): *Spouse 38; child 41; sibling 2* Age (years): 61 Gender (% female): 85 Race/ethnicity (%): see above Education (%): <HS 16; HS 20; >HS 50 Veterans (%): NR	Inclusion: *Care Recipient* – diagnosed Alzheimer's disease or related disorder *Caregiver* - Hispanic or Latino, white/ Caucasian, or black or African-American race or ethnicity; 21 years or older; living with or sharing cooking facilities with care recipient; providing care for relative with diagnosed Alzheimer's disease or related disorders at least 4 hrs/day for past 6 months; reported distress associated with caregiving (at least 2 of 6 items); have telephone; will remain in area for at least 6 months; competent in English or Spanish Exclusion: *Care Recipient* – bedbound, MMSE score of 0 *Caregiver* – involved in another caregiver intervention study; participated in REACH I; illness preventing 6 months participation	Intervention (n=261): education, skills training, problem solving, support directed at 5 target areas – depression, burden, self-care and healthy behaviors, social support, problem behaviors; 12 session (9 1.5-hr in-home + 3 0.5-hr telephone) plus 5 telephone support group sessions over 6 months; study provided resource notebooks and telephones with display screens; delivered by certified interventionists; unclear if manualized; tailored to meet individual needs Control (n=257): mailed educational materials; 2 <15-min telephone "check-in" calls at 3 and 5 months after randomization; invited to workshop on dementia & caregiving after 6 month assessment Length of Follow-up: 6 month intervention only	***Quality of life:*** a. Single question about whether participation in study helped improve the care recipient's life ("not at all," "some," or "a great deal") ***Symptom control/ management:*** a. Change in problem behaviors (3 items from Revised Memory and Behavior Problem Checklist – memory, depression, & disruption; scored from1 [substantial improvement] to 5 [substantial decline] (PR) ***Utilization:*** a. Institutional placement (permanent institutionalization) (PR) Outcomes assessed at baseline and 6 months (post tx) **☐ Negative caregiver outcomes reported**	Allocation concealment: adequate Blinding: unclear Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: 60% of intervention group completed all 12 sessions; 5% did not complete any session; 90% of control group received both telephone contacts; 3% did not receive any Treatment integrity: Certified interventionists; intensive training (reading materials, role-playing, practice); first session audiotaped and feedback provided (plus additional audiotaping during study); delivery assessment form for each contact **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Bourgeois, 2002[72] Funding Source: Government Condition: Alzheimer's disease **KQ1 ☐ KQ2 ☒** **Intervention Type:** a. Patient change group: skill-based; educational, problem solving (to change patient behavior) b. Self-change group: skill-based, educational, problem solving (to change caregiver coping behavior)	N=63 (of 93 caregivers randomized) Age (years): 75 Gender (% male): 54 Race/ethnicity (%): *white 87; African-America 13; other 0* Marital Status (%): *Married/cohabiting: 100* Education (%): NR Veterans (%): NR Recruitment Method: professional referral from geriatric and Alzheimer's centers and self-referral (via media notices) Family Characteristics: Relationship to patient: *Spouse (primary caregiver)* Age (years): 73 (primary), 48 (secondary) Gender (% female): 54 (primary), 63 (secondary) Race/ethnicity (%): *white 87 (primary and secondary); African-American 13 (primary and secondary); other 0* Education (%): NR Veterans (%): NR	Inclusion: 45 years or older; met ADRDA-NINCDS criteria for probable Alzheimer's disease; score of 20 or less on MMSE within 4 weeks of enrollment; average score of at least 1.0 (mild behavioral disturbance) on Global Rating Item of Behave-AD; stable medical condition; reside with spousal caregiver who had no major debilitating health problems, who agreed to random assignment, and who spent at least 8 daytime hours/day in home with patient; had secondary caregiver (adult relative, neighbor, or friend) who spent at least 4 hours/ week in direct contact and who would complete subsample of assessment battery Exclusion: Documented history of alcoholism, schizophrenia, Parkinson's disease, or head trauma with cognitive sequelae; MRI or CAT scan evidence of focal stroke	Intervention #1 (n=22): Patient-change – behavior management plan for frequent and stressful problem behaviors Intervention #2 (n=21): Self-change – strategies for caregiver coping Comparator (n=20) Visitation control – general information about caregiver's concerns; no skills training content All caregivers had 2 1-hour home visits in 1st week, attended a 3-hour workshop (different workshops for each group) in 2nd week, and had a 1-hour home visit each week during weeks 3-12; procedures manual for all groups Length of Follow-up: 12 week intervention	***Symptom control/ management:*** a. Behave-AD Scale (PR) -Total Score -Aggressivity/Activity Disturbance Subscale -Psychosis/Delusion Subscale b. Frequency of patient problem behaviors (PR) Outcomes assessed post tx, and at 3 months and 6 month follow-up ☐ **Negative caregiver outcomes reported**	Allocation concealment: adequate Blinding: yes (outcomes assessment) Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: 100% attended workshop 96-99% of intervention visits were conducted 68% (63/93) completed study Treatment integrity: notes written at end of each visit reviewed by investigator and at staff meetings **Study Quality: Good**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Brodaty, 2009[59] Funding Source: Industry Condition: Alzheimer's disease **KQ1 ☒ KQ2 ☐** **Intervention Type:** Emotional	N=52 (US study group only) Age (years): 73 Gender (% male): 65 Race/ethnicity (%): NR Marital Status (%): *married/cohabiting* 100 Education (%): *HS or less NR; Post HS NR* Veterans (%): NR Recruitment Method: recruited from the Silberstein Aging & Dementia Research Center at the New York University School of Medicine Family Characteristics: Relationship to patient: *Spouse* Age (years): 70 Gender (% female): 64 Race/ethnicity (%): NR Education (%): NR Veterans (%): NR	Inclusion: stable physical health for previous year; meet National Institute of Neurological and Communicative Diseases and Stroke-Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) and the Diagnostic and Statistical Manual of Mental Disorders 4th Edition criteria for probable Alzheimer's disease (AD); Global Deterioration Scale score of 4-5 at time of enrollment; no contraindication to taking donepezil; stable with other medications; able to give informed consent (or not object to participating); be community dwelling with spouse; be the spouse & primary caregiver of the patient [caregiver] Exclusion: previously received formal caregiver counseling [caregiver]	Intervention (n=26): donepezil + standard services + psychological caregiver intervention; caregivers received 5 counseling sessions w/ in 3 months of enrollment (1 individual session with spouse, 3 counseling sessions with family members invited by caregiver, & 1 more individual session with spouse); content of sessions individualized & could include education about AD, information about community resources, family issues (helping caregiver & patient), and management of difficult behavior; manualized; based on NYU intervention Comparator (n=26): donepezil + standard services (resource information, emergency help, & routine service); no formal structured counseling sessions Length of Follow-up: 5.4 yr (range: 5 mo – 8.5 yr)	***Physical functioning:*** a. Death (PR); follow-up = 8.5 years ***Utilization:*** a .Nursing home placement (PR); follow-up = 8.5 years ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear – "dyads were randomly assigned by lottery", no other details Blinding: yes – "caregivers and patients were assessed by independent raters… Strenuous efforts were made to keep rates blind to group assignment" Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: no – only withdrawals from the UK group are reported Treatment adherence: NR Treatment integrity: unclear – "Principal investigators at each site were involved in regular meetings with counselors as well" **Study Quality: Poor**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Burgener, 1998[65] Funding Source: NR Condition: Alzheimer's or multi-infarct dementia; moderate to severe **KQ1 ☒ KQ2 ☒** **Intervention Type**: Educational, behavioral	N=47 (of 54 randomized) Age (years): 78 Gender (% male): 47 Race/ethnicity (%): NR Marital Status (%): NR Education (mean): 12 years Veterans (%): NR Recruitment Method: NR Family Characteristics: Relationship to patient: *"Primary caregiver"* Age (years): 67 Gender (% female): 74 Race/ethnicity (%): NR Education (mean): 13 years Veterans (%): NR	Inclusion: Alzheimer's/ multi-infarct dementia Exclusion: NR	Intervention (n=11): Caregiver Education/ Behavioral Intervention; script and videotape for education information and booklet for behavioral information; one 90 min session Comparator (n =12): Education component only; one session Comparator (n=12): Behavioral component only; one session Comparator (n =12): Comparison group (not described) Length of Follow-up: 6 months after study entry	***Physical functioning:*** a. Instrumental Activities of Daily Living b. Social Competence scale (SCS) c. Older Americans Resources and Services (OARS) ***Symptom control/ management:*** a. Dementia Behavior Disturbance Scale (DBDS) All outcomes assessed at baseline and 6 months ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: unclear Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: no Treatment adherence: NR Treatment integrity: NR **Study quality: Poor**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Burns, 2003[51] REACH Funding Source: Government Condition: Alzheimer's and related dementias **KQ1 ☐ KQ2 ☒** **Intervention Type:** a. Behavior Care (management of care recipient's behavioral problems) b. Enhanced Care (Behavior Care plus skills training for caregiver's well-being)	N=76 (of 167 randomized) Age (years): 80 Gender (% male): 55 Race/ethnicity (%): black 42 Marital Status (%): NR Education (mean): 11 years Veterans (%): NR (included VA patients) Recruitment Method: recruited from physicians' offices (14 sites, 19 physicians) in Memphis Family Characteristics: Relationship to patient: *Spouse 50%, child 38%, other 12%* Age (years): 65 Gender (% female): 82 Race/ethnicity (%): black 42 Education (mean): 13 years Veterans (%): NR	Inclusion: *Care recipients* – medical diagnosis of probable Alzheimer's disease or related disorders or score <24 on MMSE; at least 1 limitation in basic ADLs or 2 dependencies in IADLs as reported by caregiver *Caregivers* - over age 21; live with relative with Alzheimer's disease or related dementia; provided minimum of 4 hrs supervision or direct care per day for at least past 6 months Exclusion: *Caregivers* – involved in another caregiver study; care recipient had terminal or severe illness or disability that would prohibit them from participating in study	Behavior Care (n=85): Improving caregiver's management of care recipient's behavior problems; 25 pamphlets addressing particular behaviors; possible triggers and coping strategies for specific behaviors; sessions no more than 30 min Enhanced Care (n=82): Behavior Care plus improving caregiver's well-being in response to problem behaviors (stress-behavior management – cognitive behavioral skills training); no more than 60 min Both interventions: interventionists met with caregiver during scheduled primary care visits (every 3 months); telephone contacts (10 min or less) with caregivers 2X/month for 1st 6 months; then 1X/ month Length of Follow-up: 2 year active intervention	***Symptom control/ management:*** a. Behavioral functioning: Memory and Behavior Problem Checklist (PR) All outcomes assessed at baseline and every 6 months for 2 years ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: outcome assessors masked to intervention assignment Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: contact time shorter than planned for both groups (3 hrs for Behavior Care, 4 hrs for Enhanced Care) Treatment integrity: NR **Study quality: Poor**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Camberg, 1999[11] Funding Source: Government and University Condition: Alzheimer's disease and dementia **KQ1 ☒ KQ2 ☒** **Intervention Type:** Emotional	N=54 randomized Age (years): 83 Gender (% male): 11 Race/ethnicity (%): *white 95* Marital Status (%): NR Education (%): NR Veterans (%): NR Recruitment Method: nine nursing homes in Massachusetts and New Hampshire (including one VA) Family Characteristics: Relationship to patient: *"family member"* Note: 75% of 54 family members contacted were able to be "callers"; for 14 patients with family members unavailable or unwilling to make SimPres recording, an experienced SimPres staff person conducted recorded conversation Age (years): NR Gender (%female): NR Race/ethnicity (%): NR Education (%): NR Veterans (%): NR	Inclusion: documented diagnosis of ADRD; age ≥50 years; presence of ≥1 agitated behavior/ day (Cohen-Mansfield Agitation Inventory Scale (SCMAI) short form) or 1 indication of withdrawn behavior ("sounding sad" or "crying" that occurred at least "often"); or "seldom" interested in activities, social interaction (from Multidimensional Observation Scale for Elderly Subjects); medically stable; resident in current nursing home for ≥3 months; no planned discharge; verbal interactive capacity Exclusion: subjects who did not tolerate listening through headphones for 5 minutes to a non-personalized interactive conversation tape, or known to have a severe hearing impairment or premorbid history of psychiatric illness	*Crossover design –all patients received each treatment for 17 days over a 4-week course, followed by a 10-day washout period* Intervention (n=54): Simulated Presence (SimPres) – Information packet plus coaching; personalized, interactive audio tape; nursing staff used audio tape ≥2x/day (M-F) in place of usual intervention when patient exhibited agitated behavior; tape played using headset and auto-reverse tape recorder Comparator A (n=54): "placebo" audio tape; same study procedures but recording contained non-family voice reading emotionally neutral articles from newspaper Comparator B (n=54): Usual care Length of Follow-up: NR	***Symptom control/ management:*** a. SCMAI agitated behaviors scale **Proxy report method 3 (weekly staff surveys)** Measurements occurred during the 17 days of treatments ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear – Latin Squares crossover design Blinding: double blinded staff were blinded to which tape was used for treatment, observers were blinded to study intervention Intention-to-treat analysis (ITT): yes Withdrawals/dropouts adequately described: no Treatment adherence: dropouts/ withdrawals not reported Treatment integrity: yes; study monitors were assigned to spend 20 hours/week at each facility to ensure adherence to the protocol and to provide feedback to the staff **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Chang, 1999[71] Funding Source: Foundation Condition: Dementia (MMSE<21); significant dressing and eating problems **KQ1 ☒ KQ2 ☐** **Intervention Type:** Cognitive-behavioral	N=65 (of 87 recruited) Age (years): 79 Gender (% male): NR Race/ethnicity (%): NR Marital Status (%): NR Education (years): 13 Veterans (%): NR Recruitment Method: Alzheimer's association; local support groups; Alzheimer's clinics Family Characteristics: Relationship to patient: *Spouse 85%; daughter 15%* Age (years): 67 Gender (% female): 100 Race/ethnicity (%): w*hite 79; African-American 16* Education (years): 14 Veterans (%): NR	Inclusion: dementia; significant dressing and eating problems (Zarit's memory/ behavioral scale 3 or 4 on tasks of dressing and eating); MMSE <21; both members of dyad English speaking; access to videotape player and telephone Exclusion: none stated	Intervention (n=34): Nurseline video-assisted modeling program (NVAMP); videotape showing assisted modeling behavior (eating and dressing) & Nurseline support (8 weekly guideline-based structured calls for reinforcement, problem solving) Comparator (n=31): 8 weekly calls to assess caregiver general well-being; no specific strategies for eating or dressing; referred caregiver to other resources if needed Length of Follow-up: 4 weeks post-tx	***Physical functioning:*** a. Subscale of Functional Rating Scale (data not provided) (PR, 8 weeks [post tx]) ***Symptom control/ management:*** a. Functional Rating Scale for the Symptoms of Dementia – Overall and Behavioral subscore(PR, 8 weeks [post tx]) ☒ **Negative caregiver outcomes reported** (decreased caregiver satisfaction over time)	Allocation concealment: unclear Blinding: unclear Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: 25% dropped out of study; dropouts had lower baseline MMSE (p=0.04) Treatment integrity: NR **Study Quality: Poor**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Gerdner, 2002[69] Funding Source: Government Condition: Alzheimer's disease (67%) or a related disorder (moderate to severe cognitive impairment with Global Deterioration Scale (GDS) scores from 4-6) **KQ1 ☐ KQ2 ☒** **Intervention Type:** Educational, skill-based	N=237 (of 241 randomized) Age (years): NR Gender (% male): NR Race/ethnicity (%): NR Marital Status (%): NR Education (%): NR Veterans (%): NR Recruitment Method: geriatric assessment clinics & Alzheimer's disease centers affiliated with 1 of 8 universities (brochures, church bulletins, radio, newspaper ads, service clubs, caregiver support groups, and word of mouth) Family Characteristics: Relationship to patient: *Spouse 65%; non-spouse 35%; caregiver residing with care recipient 97%* Age (years): 64.8 Gender (% female): 73.8 Race/ethnicity (%): w*hite* 94; *non-white* 6 Education (%): *HS or less* 44; *Post HS* 56 Veterans (%): NR	Inclusion: unpaid informal caregivers who provided 4 or more hours of care per week to someone with Alzheimer's disease or related disorder; Lived within 125 miles of a study site Exclusion: no to mild cognitive impairment in caregivers as indicated by a GDS of 2 or lower	Intervention (n=132): Progressively Lowered Stress Threshold (PLST) training program – Home visits where a plan of care was developed to increase the structure of the patient's routine, make necessary environmental modifications, and develop activities for the patient, additional referrals provided as needed; 4 hours of in-home intervention; Comparator (n=105): Routine information, community referrals, case management, and support groups; 2 one hour visit 2 weeks apart for providing general information, referrals, and self-help material Length of Follow-up: 3, 6, and 12 months	***Physical functioning:*** a. Subscale from The Memory and Behavior Problems Checklist 1989R (PR) ***Symptom control/ management:*** a. Memory and Behavior Problems Checklist (PR) ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: unclear Intention-to-treat analysis (ITT): yes Withdrawals/dropouts adequately described: partial – exact numbers that dropped out per condition not reported Treatment adherence: 54% dropped out of the study over the 12 month follow up. Authors report attrition rates were similar across treatment conditions and sites. Treatment integrity: unclear **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Gitlin, 2010[10] COPE Funding Source: Government (partial) Condition: Dementia (MMSE score <24) **KQ1 ☐ KQ2 ☒** **Intervention Type:** Multicomponent – increase caregiver skills, provide caregiver education in problem solving ; and caregiver training to address caregiver identified concerns and help reduce stress.	N=209 (of 237 randomized) Age (years): 82 Gender (% male): 32 Race/ethnicity (%): w*hite 70; African-American 27; other 2* Marital Status (%): NR Education (%): NR Veterans (%): NR Recruitment Method: media announcements and mailings by social agencies targeting caregivers Family Characteristics: Relationship to patient: *Spouse 38%; non-spouse 62* Age (years): 62 Gender (% female): 89 Race/ethnicity (%): w*hite 70; African-American 28; other 2* Education (%): *HS or less 31; Post HS 69%* Veterans (%): NR	Inclusion: *patients* had a physician; diagnosis of probable dementia or MMSE score <24; ≥21 years; English speaking; needed help with daily activities or had behavioral symptoms; lived with or within 5 miles of family caregivers *caregivers* provided oversight or care for ≥8 hours weekly; planned to live in area for 9 months; not seeking nursing home placement; reported difficulty managing patient functional decline or behaviors Exclusion: *patients* schizophrenia or bipolar disorder; dementia secondary to probable head trauma; MMSE score of 0; bed –bound *dyads* terminal illnesses with life expectancy < 9 months; active treatment for cancer; > 3 acute hospitalizations in the past year; involvement in another caregiver trial	Intervention (n=117): Care of Persons with Dementia in their Environments (COPE); reduce environmental stressors & enhance caregiver skills (problem solving, communication, engaging patients & simplifying tasks); focus on caregiver identified concerns & patient capabilities; 10 sessions in 4 months with occupational therapists; 1 face-to-face and 1 telephone session with advance practice nurse; patients provided blood, urine samples; lab evaluations and medications reviewed with caregivers Comparator (n=120): 3 20-minute telephone calls from trained staff (not occupational therapists or nurses); educational materials discussed and mailed to caregiver Length of Follow-up: post-treatment and 5 months post-treatment (4 and 9 months post baseline respectively)	***Physical functioning:*** a. Overall function - 15-item FIM-based measure; means and net % improvers b. 7 item ADL FIM-based measure; means only c. 8 item IADL FIM-based measure; means and net % improvers d. Activity engagement (Albert, 1996); means and net % improvers ***Quality of life:*** a. Quality of Life–Alzheimer's Disease scale ***Symptom control/ management:*** a. 16-item Agitated Behavior in Dementia scale All outcomes were by proxy report (caregiver). Outcomes assessed post- treatment and 5 months post-treatment (4 and 9 months post baseline respectively) ☐ **Negative caregiver outcomes reported**	Allocation concealment: adequate Blinding: assessors Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: *outcomes assessed post-tx*: COPE: 102/117 = 87% Comparator: 107/120=89% *sessions completed*: COPE: 78% completed 8-12 sessions; 3% <3 sessions Comparator: received mean 2.8 phone contacts Treatment integrity: Interventionists for both groups trained; COPE treatment fidelity monitored via twice monthly supervision and review of audiotapes; for control group, random phone calls were monitored for adherence; both groups documented interactions for delivery content (reviewed for adherence) **Study Quality: Good**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Gitlin, 2010[75] ACT Funding Source: Government (partial) Condition: Dementia (MMSE score <24) **KQ1 ☒ KQ2 ☐** **Intervention Type:** Multicomponent – provided education, skill building, problem solving techniques, looked for co-morbid medical problems	N=272 Age (years): 82 Gender (%male): 47 Race/ethnicity (%): w*hite 70* Marital Status (%) NR Education (%): NR Veterans (%): NR Recruitment Method: media announcements and mailings by social agencies targeting caregivers Family Characteristics: Relationship to patient: *Spouse 51%; other NR* Age (years): 62 Gender (% female): 82 Race/ethnicity (%): w*hite 70* Education (%): *HS or less 33; Post HS 67* Veterans (%): NR	Inclusion: caregiver of a patient with a physician diagnosis of dementia or MMSE score <24; caregiver 21 years or older, English speaking, planned to live in area for >6 months; not actively seeking nursing home placement, manages problem behaviors, and reports upset with those behaviors (>5 on 10 point scale) Exclusion: *patients* schizophrenia or bipolar disorder, had dementia secondary to probable head trauma, or had an MMSE score of 0 and was bed bound. *For dyads* –either having a terminal illnesses with life expectancy of < 9 months, active treatments for cancer, > 3 acute hospitalizations in the past year, or involvement in another caregiver trial concerning problem behaviors	Intervention (n=137): Advanced Caregiver Training (ACT) 16 weeks; up to 9 occupational therapy (OT) sessions, 2 nursing sessions, and a 16-24 week maintenance phase of 3 brief OT contacts; OTs introduced goals, observed home environment for hazards; caregivers instructed in stress reduction, self-care, problem solving; nurse provided education on medical conditions that can exacerbate problem behaviors; blood samples collected from patients & medications reviewed Comparator (n=135): "Control" – no intervention contact (no further description provided) Length of Follow-up: post 16 week treatment only	***Symptom control/ management:*** a. # problem behaviors at baseline b. frequency of problem behaviors at baseline c. Using validated scales (i.e. RMBPC), selected one problem behavior to target for improvement and measured % whose targeted behavior improved, stayed same, or worsened All outcomes were by proxy report; outcome c assessed post-16 week treatment only ☐ **Negative caregiver outcomes reported**	Allocation concealment: adequate Blinding: none (patients, investigators) Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: Outcomes assessed: ACT: 117/137 = 85% Control: 122/135=90% Treatment integrity: Therapists and nurse received 35 hours training; fidelity monitored via twice monthly meetings and case presentations, home sessions audiotaped and 10% randomly selected for review and feedback from investigator **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Gitlin, 2008[74] TAP Funding Source: Government (partial) Condition: Dementia (MMSE score <24) **KQ1 ☒ KQ2 ☐** **Intervention Type:** Activity-based	N=60 Age (years): 79 Gender (% male): 57 Race/ethnicity (%): w*hite 77; African-American 22; other 2* Marital Status (%): m*arried/cohabiting: (see below)* Education (%): < *HS* 54; < *college* 32; g*raduate degree* 14 Veterans (%): NR Recruitment Method: media notices and social service mailing Family Characteristics: Relationship to patient: *Spouse 62%* Age (years): 65 Gender (% female): 88 Race/ethnicity (%): w*hite* 77; *African-American* 22; *other* 2 Education (%): < *HS* 27; < *college 56; graduate degree 17* Veterans (%): NR	Inclusion: *Patients* - dementia (physician diagnosis or MMSE score <24), English-speaking, able to feed self and participate in ≥2 self-care activities (e.g., bathing, dressing) C*aregivers* - English-speaking, ≥21 years of age, lived with patient, provided ≥4 hours of daily care, and reported dementia patient's boredom, sadness, anxiety, agitation, restlessness, or trouble focusing on a task Exclusion: *Patients* - schizophrenia, bipolar disorder, or dementia secondary to head trauma, MMSE score=0, bed-bound or non-responsive *Caregivers* - involved in another study, seeking nursing home placement, terminally ill, in active cancer treatment, or ≥3 hospitalizations in past year	Intervention (n=30): Tailored Activity Program (TAP); 6 90-minute home visits and 2 15-minute telephone contacts by occupational therapists over 4 months; written plan developed for each activity Comparator (n=30): Wait list Length of Intervention: 4 months; wait list controls then received the TAP intervention and were re-tested 4 months later (8 months from baseline)	***Quality of life:*** a. 12-item Quality of Life-AD scale (PR) ***Symptom control/ management:*** a. Frequency of occurrence of 24 behaviors (PR): 16 from Agitated Behaviors in Dementia Scale, 2 from RMBPC, 4 from previous research, and 2 "others" identified by families - not coded elsewhere ***Depression/anxiety:*** a. 19-item CSDD (SR + PR) All outcomes assessed at 4 months ☐ **Negative caregiver outcomes reported**	Allocation concealment: adequate Blinding: yes (outcome assessment) Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: 4/60 study dropouts (6.7%) Treatment integrity: interventionists documented time spent, who participated (caregiver, patient), and number of activities introduced **Study Quality: Good**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Gitlin, 2003[73] REACH Funding Source: Government Condition: Alzheimer's disease or related disorder (Mini-Mental State Examination score of less than 24 or diagnosis of dementia) **KQ1 ☐ KQ2 ☒** **Intervention Type:** Multicomponent **–** education, problem solving, skill building; home environment focus	N=190 (of 255 enrolled) Age (years): 81 Gender (% male): 33 Race/ethnicity (%): NR Marital Status (%): NR Education (%): NR Veterans (%): NR Recruitment Method: primarily from area agency on aging for 1 county; secondarily via media announcements Family Characteristics: Relationship to patient: *Spouse 35%, non-spouse 65%* Age (years): 60.5 Gender (% female): 76 Race/ethnicity (%): w*hite 45; African-American 53; other 3* Education (%) :*HS or less 57; Post HS 43* Veterans (%): NR	Inclusion: *Patients* - MMSE <24 or diagnosis of dementia *Caregivers* - primary caregiver; reported patient had at least 1 limitation in basic ADL or 2 dependencies in IADLs; ≥21 years old; caregiving for ≥6 months; provide ≥4 hr of care each day Exclusion: *Patients* -bedridden and nonresponsive to touch or environment *Caregivers* - did not live with care recipient; undergoing chemo-therapy or radiation therapy; > 3 hospitalizations in past year; planning to place patient in nursing home within next 6 months	Intervention (n=89): Environmental Skill-Building Program (ESP); protocol; education about dementia & impact of home environment on behaviors & ADL deficits; *instruction in problem solving and developing effective approaches* to manage caregiving concerns involving environment; *implementation of environmental strategies* tailored to caregiver's context; generalization of strategies to emerging problems; 5 90-min home visits & 1 30-min telephone contact over 6 months by occupational therapists. Comparator (n=101): Usual care +resource information at each testing period Length of Follow-up: None reported (6 mo active phase only)	***Physical functioning:*** a. ADL assistance needed (Mobility subdomain of Functional Independence Measure [FIM] - 8 items, bathing, eating, etc.); rated from complete independence (7) to complete dependence (1); total score=average scores across all items (PR) b. IADL assistance needed (7-point FIM scale as described above) (PR) ***Symptom control/ management:*** a. Revised Memory and Behavior Problem Checklist, modified by the REACH initiative; high scores indicate occurrence of greater number of behaviors (PR) All by proxy (caregiver) *Outcomes assessed at baseline and 6, 12, and 18 months post-baseline (only 6 month data reported)* ☐ **Negative caregiver outcomes reported**	Allocation concealment: adequate Blinding: unclear Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: 67/255 (26%) did not complete 6 month interview; significantly higher rate of attrition in experimental group Treatment integrity: interventionists received 25 hours training; formal case reviews (biweekly to monthly); direct observation of randomly selected visits with caregivers; treatment documentation reviewed; brief interviews with caregivers **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Gitlin, 2001[57] Funding Source: Government Condition: Dementia *(*dependence in at least two ADLs*)* **KQ1 ☒ KQ2 ☐** **Intervention Type:** Multicomponent – education and physical and social environmental modifications	N= 171 (of 202 randomized) Age (years): 78 Gender (% male): 34 Race/ethnicity (%): NR Marital Status (%): NR Education (%): NR Veterans (%): NR Recruitment Method: local social service and medical centers; media notices in Philadelphia region Family Characteristics: Relationship to patient: *Spouse 25%; daughter (includes in-laws) 59%; sons/in-laws/grandsons 13%; other 3%* Age (years): 61 Gender (% female): 73 Race/ethnicity (%): *white 74; African-American 25; other 1* Education (years): 14 (mean) Veterans (%): NR	Inclusion: Caregivers of patients with medical diagnosis of Alzheimer's or related disorder; living with patient; perceive themselves as the primary caregiver; report patient dependence ≥ 2 ADLs, and report ≥1 difficulty managing either IADL or ADL assistance or a dementia-related behavior (e.g., wandering, agitation) Exclusion: Caregivers of patients who were bedridden, nonresponsive to touch or physical environment; patients for which environmental adaption would have relatively no benefit (due to severity of their dementia)	Intervention (n=100): Multi-component intervention; protocol; 5 90-min home visits, bi-weekly over 3 months; occupational therapists provided education & suggested physical and social environmental modifications; developed targeted plan with caregiver to address problematic care, educated about disease process, & engaged caregivers in problem solving strategies; provided caregivers coaching, validated and reinforced their strategies Comparator (n=102): Usual care Length of Follow-up: post-treatment only (3 months post-baseline)	***Physical functioning:*** a. ADL dependence, using modified FIM b. IADL dependence using modified FIM ***Symptom control/ management:*** a. Memory and Behavior Problems Checklist – total number of problems Outcomes assessed: All proxy report (by caregivers); baseline and post-tx (3 months post baseline) ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: no Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: Outcomes assessed for: ACT: 93/100 = 93% Control: 78/102=76% (p=0.001) Treatment adherence: 69% participated in ≥4 home sessions 9% in only 1 session Treatment integrity: therapists provided 20 hours training; fidelity monitored through formal case reviews, on-site observation of randomly selected visits, and follow-up interviews with caregivers to evaluate satisfaction **Study Quality: Poor**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Gonyea, 2006[64] Project CARE Funding Source: Foundation Condition: Alzheimer's (mild to moderate [MMSE 10 or higher], at least one neuropsychiatric symptom) **KQ1 ☐ KQ2 ☒** **Intervention Type:** Multicomponent (behavior management, pleasant events training, relaxation training)	N= 80 (of 91 randomized) Age (years): 77 Gender (% male): NR Race/ethnicity (%) NR Marital Status (%): NR Education (%) NR Veterans (%): NR Recruitment Method: media ads, community-based lectures, elder day program referrals Family Characteristics: Relationship to patient: *Spouses 59%, adult children 32%* Age (years): 64 Gender (% female): 67 Race/ethnicity (%): *white 94* Education (%): NR Veterans (%): NR	Inclusion: Caregiver who provides at least 4 hours/week and is willing to accept random assignment; care recipient with a) physician-confirmed diagnosis of Alzheimer's disease, b) mild to moderate dementia severity (MMSE 10+), c) at least 1 neuropsychiatric symptom Exclusion: NR	Intervention (n=40): Behavioral therapy and behavioral activation – to manage care recipient neuropsychiatric symptoms in home environment and caregiver distress Comparator (n=40): General information on aging and Alzheimer's disease, home safety, communication, support Both groups: highly structured weekly meetings of 90 minutes; 5 to 10 caregivers attended (no care recipients) Length of Follow-up: 5 week intervention	***Cognitive function:*** a. Neuropsychiatric Inventory Outcomes assessed at baseline and post-treatment ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: no Intention-to-treat analysis (ITT): no (only included in analysis if completed at least 2 sessions) Withdrawals/dropouts adequately described: no Treatment adherence: 80% completed intervention; 88% of those attended at least 4 of 5 weekly sessions Treatment integrity: investigator met with therapists to review group sessions **Study Quality: Poor**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Jirovec, 2001[58] Funding Source: Government Condition: Memory impairment **KQ1 ☐ KQ2 ☒** **Intervention Type:** Educational (symptom management)	N=118 Age (years): 80 Gender (% male): 31 Race/ethnicity *(%): African-American 30* Marital Status (%): NR Education (years): 10 Veterans (%): NR Recruitment Method: announcements in newsletters, flyers, newspaper advertisements Family Characteristics: Relationship to patient: *Spouse 41%; child 39%; sibling, other family, friend 20%* Age (years): 63 Gender (% female): 67 Race/ethnicity (%): *African-American 30* Education (years): 14 Veterans (%): NR	Inclusion: "Elders" with memory impairment and functional urinary incontinence (UI) Exclusion: NR	Intervention #1 (n=38) Visits every 2 months; individualized scheduled toileting procedure with reminders for patient; monthly telephone calls for progress and difficulties Intervention #2 (n=39): Visits every 6 months; content same as above Comparator (n=41): Control; monthly call for "friendly" visit NOTE: 2 intervention groups were combined for data analysis when no differences were noted in UI at 6 month follow-up Length of Follow-up: post 6 month treatment only	***Symptom control/ management:*** a. % Incontinent episodes (UI) (Caregiver report) b. # patients whose incontinence decreased c. Short Portable Mental Status Questionnaire (SPMSQ) Outcomes measured at baseline post-tx only ☐ **Negative caregiver outcomes reported**	Allocation concealment: adequate Blinding: unclear Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: 37% lost but no difference between groups Treatment integrity: consistency with implementing the protocol was assessed at 6-month visit; caregiver records and self-ratings compared **Study Quality: Poor**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Logsdon, 2010[63] Funding Source: Foundation, Government Condition: Early stage Alzheimer's and dementia; MMSE ≥ 18 **KQ1 ☒ KQ2 ☐** **Intervention Type:** Multi-component - weekly groups providing both education and emotional support of peers	N=142 Age (years): 75 Gender (% male): 51 Race/ethnicity (%): *white 96; African-American 1; other 3* Marital Status (%) Married 72 Education (%): *Post HS (college degree)* 47 Veterans (%): NR Recruitment Method: recruited via referrals from the Alzheimer's Association Western and Central Washington State chapter Family Characteristics: Relationship to patient: *Spouse 68%; adult child 12%; sibling/friend 6%; NR: 15* Age (years): 68 Gender (% female): 58 Race/ethnicity (%): w*hite 96; African-American 1 other 3* Education (%): *Post HS (college degree),*40 Veterans (%): NR	Inclusion: Dementia diagnosis confirmed by the individual's primary care physician; MMSE ≥18; aware of their memory loss and able to communicate verbally; able to participate independently in a group setting (without their family members present); had no significant history of severe mental illness that would impede their ability to take part in support group activities; both the person with dementia and a family care partner agreed to participate. Exclusion: NR	Intervention (n=96): Early Stage Memory Loss (ESML) - Structured Support Group, manualized; weekly 90 minute meetings for 9 weeks. Patient and partner met together for part of session, then separately. Comparator (n=46): Wait List - subjects received written educational materials routinely provided by Alzheimer's Association chapter. Length of Follow-up: post-tx only.	***Physical functioning:*** a. SF-36 physical health component (SR) ***Quality of life:*** a. QOL-AD (Quality of Life-Alzheimer's) (PR) b. SF-36 social functioning scale (PR) ***Depression/anxiety:*** a. Depression - Geriatric Depression Scale (GDS) (SR) b. SF-36 Mental Health component (SR) All outcomes were assessed at post-tx ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: no Intention-to-treat analysis (ITT): yes Withdrawals/dropouts adequately described: no Treatment adherence: *Study dropouts* 6/142=4% no post-tx assessment 4/96=4% ESML 2/46=4% Wait list Treatment integrity: Standardized treatment manual, all facilitators participated in an annual day long training workshop. **Study Quality: Poor**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Martin-Cook, 2005[60] Funding Source: Foundation Condition: Primarily Alzheimer's Dementia; mean MMSE = 19.4 (moderate impairment) **KQ1 ☒ KQ2 ☐** **Intervention Type:** Education, skills-based	N= 47 (of 49 randomized) Age (years): 73 Gender (% male): 63 Race/ethnicity (%): *white 92; African-American 6; other 2* Marital Status(%): NR Education (years): 15 (mean) Veterans (%): NR Recruitment Method: retirement & assisted living facilities Family Characteristics: Relationship to patient: *Spouse 92%; daughter 6%; other 2%* Age (years): NR Gender (% female): 70 Race/ethnicity (%): NR Education (years): 16 Veterans (%): NR	Inclusion: Diagnosed with "various dementing illnesses (primarily AD)" by established clinical criteria; community dwelling; mildly to moderately cognitively impaired; consistent caregiver; if maintained on psychotropic medications and/or cognitive enhancers had been on stable doses ≥1 month before enrollment. Exclusion: NR	Intervention (n=24): 4 weekly skills training sessions, individualized based on functional level of patient and coping level of caregiver; skills based training, safety, education designed to decrease gap between patient's actual abilities and caregiver's expectations; unclear if manualized Comparator (n=23): Wait list; provided information about community services and resources Length of Follow-up: to 17 weeks (12 weeks post-tx)	***Physical functioning:*** a. Mini-Mental Status Examination (MMSE) b. Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory - MCI version (ADCS-MCI) (PR) ***Cognitive functioning:*** a. Neuropsychiatric Inventory (NPI) (PR) **☒ Negative caregiver outcomes reported** Outcomes assessed at 7 weeks (2 weeks post-tx) and 17 weeks (12 weeks post-tx)	Allocation concealment: unclear Blinding: unclear Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: 100% of intervention group completed all 4 sessions. Study dropouts: 96% (47/49) at week 7 96% (45/47) at week 17 Treatment integrity: NR **Study Quality: Poor**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
McCallion, 1999[68] Funding Source: Government Condition: Moderate to severe dementia; weighted mean MMSE = 6.9 **KQ1 ☒ KQ2 ☐** **Intervention Type:** Educational, skill-based, emotional	N=66 Age (years): 86 Gender (% male): 21 Race/ethnicity (%): *White 95; African-American 5* Marital Status (%): NR Education (%): NR Veterans (%): NR Recruitment Method: nursing staff at 5 skilled care nursing homes identified all residents with at least moderate level of dementia and problem behaviors; primary visitor of patient approached regarding patient participation Family Characteristics: Relationship to patient: *Individuals who visited patient regularly, family or "close personal friends for >2 years"; Spouse11%; Adult child 29%; other 60%* Age (years): 59 Gender (% female): 80 Race/ethnicity (%): *White 94; African-American 3; other 3* Education (%): *HS or less 24; Post HS 45; Not reported 29* Veterans (%): NR	Inclusion: Patients with moderate level of dementia and who displayed problem behaviors such as physical aggression, verbally abusive behaviors, disruptive vocalizations, or motor restlessness (as identified by staff judgment and medical records); moderate level of dementia as screened by study staff using Mini-Mental State Exam (MMSE) and Global Deterioration Scale (GDS); patient had to have a primary visitor Exclusion: NR	Intervention (n=32): FVEP (Family Visit Education Program) manualized program addressing: verbal and non-verbal, communication, and effective structuring of family visits; delivered over 8 weeks, four, 1½-hour group sessions and three 1-hour individual family conferences; family sessions had two parts, a therapeutic observation of interaction with in vivo feedback and a face-to-face feedback session with individual family members not in the presence of the resident Comparator (n=34): Usual Care - usual social and recreational programming offered by each facility; UC families offered program after study was complete Length of Follow-up: 1 month and 4 months post-tx follow ups were completed	***Symptom control/ management*** a. MOSES Subscales (PR): -Self care -Disorientation -Irritability -Withdrawal b. CMAI-N (Cohen-Mansfield Agitation Inventory) Nurse completed c. CMAI-O - study assessor ("observer") completed (PR) ***Depression/Anxiety:*** a. MOSES (Multi-dimensional Observation Scale for Elderly Subjects) Depression subscale (PR) b. CSDD (Cornell Scale for Depression in Dementia) Subscales: (SR and PR combined) -Mood related signs -Behavioral disturbance -Physical signs -Cyclic functions -Ideational disturbance Outcomes assessed at baseline and 1 and 4 months post-tx. **☐ Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: outside observers and nursing staff were blinded to study hypotheses (but limitations section noted observers became aware of arm for 30% of study subjects during data collection, due to comments made by family members) Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: outcomes assessed: 86.4% (57/66) (not provided by group) Treatment integrity: videotapes of group and family sessions were reviewed and leaders provided with weekly supervision sessions; written intervention manual, participant workbooks, and a training videotape were prepared and made available to the leaders **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
McCurry, 2005[61] Funding Source: Government and Foundation Condition: Alzheimer's disease (probable or possible; community dwelling; dementia for mean of 5.8 years; mean Mini-Mental State Exam of 11.8) **KQ1 ☐ KQ2 ☒** **Intervention Type:** Multi-component: (educational, skill-based)	N=36 Age (years): 78 Gender (% male): 56 Race/ethnicity (%): *White 92; African-American 0; other 8* Marital Status (%): *Spouse caregiver 58* Education (years): 14 (mean) Veterans (%): NR Recruitment Method: articles, ads, and presentations (all in senior and caregiver media or to senior groups) Family Characteristics: Relationship to patient: *Spouse 58%, Child 33%, other 8%* Age (years): 63 Gender (% female): 72 Race/ethnicity (%): *White 89; African-American 0; other 11* Education (years): 15 (mean) Veterans (%): NR	**Inclusions:** Probable or possible Alzheimer's disease, confirmed in writing by primary care physician; two or more sleep problems on the Neuropsychiatric Inventory Nighttime Behavior Scale occurring 3 or more times per week; community-dwelling, ambulatory, and without an existing primary sleep disorder **Exclusions:** None reported	Intervention (n=17): *Nighttime Insomnia Treatment and Education for Alzheimer's Disease (NITE-AD):* Manualized sleep-education program; 6 1-hour in-home sessions over 2 months; sleep hygiene education; goal setting; individualized sleep hygiene programs; instruction for daily 30 minute walks & daily light exposure; caregivers attended all sessions, typically attended patient's walks, & supervised light exposure Comparator (n=19): *Supportive contact control*: Manualized attention control group; 6 1-hour in-home sessions over 2 months; sleep hygiene education; goal setting; nondirective, supportive approaches Length of Follow-up: 2 (post-tx) and 6 months post randomization	***Cognitive function:*** a. Revised Memory and Behavior Problems Checklist – Memory (PR) ***Symptom control/ management:*** a. Revised Memory and Behavior Problems Checklist – Disruption (PR) b. Sleep outcomes (all measured by wrist movement recorder) 1. Night wake time (hrs) 2. Number of night awakenings 3. % of time asleep 4. Wake index (wakes/hr) 5. Duration of night awakenings (min) ***Depression/anxiety:*** a. Cornell Depression Scale (SR) b. Revised Memory and Behavior Problems Checklist – Depression (SR) ☐ **Negative caregiver outcomes reported** All measures assessed at baseline, post-treatment, 6 month	Allocation concealment: adequate Blinding: yes – assessors blind to condition Intention-to-treat analysis (ITT): partially (ITT for pre-post change scores only) Withdrawals/dropouts adequately described: yes Tx adherence: overall attendance: 90%; no difference between groups *Intervention*: 3/17 dropped out by post-tx (17.6%); 3 more were not assessed at 6 month follow-up due to patient death (35.3% of original sample not assessed) *Control*: 2/19 dropped out by post-tx (10.5%; 1 due to death); 5 more were not assessed at 6 month follow-up (36.8% of original sample not assessed; 2 due to patient death) Tx integrity: yes (sessions recorded and randomly selected for review) **Study Quality: Good**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Mittelman, 2004.[54] 2006[52] Funding Source: Government Condition: Alzheimer's disease **KQ1 ☒ KQ2 ☐** **Intervention Type:** Skill-based, emotional, problem solving or conflict resolution, decision support	N=406 Age (years): 74.3 Gender (% male): NR Race/ethnicity (%): NR Marital Status (%): *Married/cohabiting 100* Education (%): NR Veterans (%): NR Recruitment Method: patient population at New York University Aging and Dementia Research Center (NYU-ADRC), referrals from local Alzheimer's Association; media announcements; adult day care, social worker, physician referral Family Characteristics: Relationship to patient: *Spouse 100%* Age (years): 71.3 Gender (% female): 60.1 Race/ethnicity (%): *white 91; African-American 6; other 3* Education (%): *HS or less 46; Post HS 54* Veterans (%): NR	Inclusion: Spouses of community dwelling patients with a clinical diagnosis of Alzheimer's disease; living with patient (at baseline) and has primary responsibility for AD patient's care; patient or caregiver has at least 1 relative living in metropolitan New York City Exclusion: caregivers could not be participating in another caregiving counseling program at baseline; caregivers could not have a "serious medical condition"	Intervention (n=203): Multi-component and 'indefinite'; 1) 4 months of counseling sessions (2 caregiver only, 4 family but not patient); content determined by caregiver needs; 2) caregiver weekly support groups (ongoing); 3) "ad hoc" counseling (on-going; via telephone when needed) Usual Care (n=203): Usual counseling services for all families & patients at NYU-ADRC (advice & information on requested, no formal counseling sessions); participants could seek additional assistance & support elsewhere Length of Follow-up: For assessments-- 4 years; interview every 4 months during first year; every 6 months thereafter (in person or by phone) For nursing home placement – up to 18 years for first recruited participants	***Physical functioning:*** a. Global Deterioration Scale (GDS) (Patient functioning***)*** (PR) b. Older Americans Resources and Services (OARS) Physical Health portion (PR) ***Symptom control/ management:*** a. Frequency of patient problem behaviors -- Memory and Behavior Problem Checklist - original (MBPC) (PR) ***Utilization*** a. Nursing home placement (PR) ☐ **Negative caregiver outcomes reported**	

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Ostwald, 1999[50] Funding Source: Government Condition: Dementia(mild to severe) **KQ1 ☒ KQ2 ☐** **Intervention Type:** Psychoeducational	N=117 Age (years): 77 Gender (% male): 56 Race/ethnicity (%): NR Marital Status (%): NR Education (%): *HS or less NR; Post HS 57* Veterans (%): Veterans included, % NR Recruitment Method: recruited through memory loss clinics, the Minneapolis VA, senior clinics and health centers and Mpls/ St. Paul Alzheimer's Association, local hospitals and social service agencies. Family Characteristics: Relationship to patient: NR Age (years): 66 Gender (% female): 65 Race/ethnicity (%): NR Education (%): *HS or less NR; Post HS 75* Veterans (%): NR	Inclusion: Caregivers caring for a community dwelling patient with diagnosis of nonreversible dementia (mild to severe); who displays problem behaviors (per caregiver report), and patient is able to accompany caregiver to at least the first 2 weekly intervention sessions; at least one family member, in addition to primary caregiver, needed to be willing to accompany the primary caregiver and patient to all sessions Exclusion: Caregivers of patients who were either on-ambulatory or required total care (score 7b on Functional Assessment Staging Test)	Intervention (n=72): Minnesota Family Workshop (MFW) – Manualized; 7 weekly 2-hr sessions with at least 4 families; provide caregivers with info about dementia; skills; self-efficacy; family communication and cooperation; patients attended testing sessions (2 sessions) then an optional "day care like" group with activities (last 5 sessions); all families given packet of resources available in the community for Alzheimer's care Comparator (n=45): wait list for intervention; all families given packet of resources available in the community for Alzheimer's care Length of Follow-up: Baseline, post-intervention, 2 months post	***Cognitive function:*** a. MMSE [PR] ***Symptom control/ management:*** a. Disruptive behavior subscale of Revised Memory and behavior problem checklist [PR] All measures assessed at baseline, post-treatment, 2 months post-treatment **☒ Negative caregiver outcomes reported**	Allocation concealment: adequate Blinding: yes (those who assessed patients for MMSE were blinded to group allocation) Intention-to-treat analysis: yes Withdrawals/dropouts adequately described: yes; dropouts significantly older-no other significant demographic differences between dropouts and completers Tx adherence: completed assessments Intervention: 60/72 = 83% Wait list: 34/45 = 76% Tx integrity: one investigator monitored each session to ensure adherence to curricular plan **Study Quality: Good**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Quayhagen, 2000[62] Funding Source: Government Condition: Dementia (mild to moderate; score > 100 on Mattis Dementia Rating Scale, Mattis, 1988) **KQ1 ☒ KQ2 ☒** **Intervention Type:** 1) Cognitive Simulation: Skill based 2) Dyadic Counseling: Emotional, problem solving, conflict resolution 3) Dual Supportive Seminar Groups: Educational, skill based, emotional, problem solving 4) Early Stage Day Care: Education, skill based, emotional	N=103 Age (years): 75 Gender (% male): 63 Race/ethnicity (%): *white 93; African-American 2; other 5* Marital Status (%): *Married/cohabiting: 100* Education (years): 15 (mean) Veterans (%): NR Recruitment Method: Alzheimer's Association; Alzheimer's Disease Research Center; and media Family Characteristics: Relationship to patient: *Spouse 100%* Age (years): 72 Gender (% female): 63 Race/ethnicity (%): NR Education (years): 14 (mean) Veterans (%): NR	Inclusion: diagnosed with possible or probable Alzheimer's dementia, cardiovascular dementia, or Parkinson's dementia; mild to moderate stages of dementia; score above 100 on Mattis Dementia Rating Scale (Mattis, 1988); physically capable of participating in intervention activities and willing to drive to intervention sites Exclusion: NR	1) Cognitive Stimulation (n=21): in-home; cognitively oriented; caregiver helped cognitively stimulate patient; 1.5 hour sessions 2) Dyadic Counseling (n=29): in-home; affectively oriented; systems & cognitive behavioral couple therapy approach; 1.5 hour sessions 3) Dual Supportive Seminar Groups (n=22): in community; affectively oriented; group format; information exchange, support, discussion,; 1.5 hour sessions 4) Early-Stage Day Care (n=16): in community, cognitively oriented; group format; education/training for caregivers; supportive environment for patients; 4 hours/wk (patients), 2 sessions (caregivers) 5) Wait List Control (n=15) All interventions: 8 weeks; unclear if manualized Length of Follow-up: none	***Physical functioning:*** a. Problem Solving: Composite of Geriatric Coping Schedule and conceptualization factor from Dementia Rating Scale (DRS) b. Immediate Memory: Composite of Logical Memory I and Visual Reproduction I from Wechsler Memory Scale – Revised (WMS-R) and memory factor of DRS c. Delayed Memory: Composite of WMS-R Logical Memory II and Visual Reproduction II d. Verbal Fluency: Composite of 2 recalled word scales (Benton & Hamsher, 1976; Goodglass & Kaplan, 1953), and initiation factor score on the DRS ***Symptom control/ management:*** a. Behavioral functioning: Memory and Behavior Problem Checklist, Part A All measures assessed at pre and post-tx (3 months) and obtained through self-report **☒ Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: yes (assessors blinded to treatment assignment) Intention-to-treat analysis (ITT): unclear (only 15 dyads randomized to control group agreed to second randomization to a treatment group and therefore were included in analysis) Withdrawals/dropouts adequately described: not reported Treatment adherence: not reported Treatment integrity: ongoing monitoring of performance of individuals involved in interventions and assessment **Study Quality: Poor**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Robison, 2007[53] Funding Source: Government Condition: Dementia (participants were all institutionalized at specialized skilled nursing facilities) **KQ1 ☒ KQ2 ☐** **Intervention Type:** Educational, skill-based	N=388 (of 412 invited for participation) Age (years): NR Gender (% male): NR Race/ethnicity (%): NR Marital Status (%): NR Education (%): NR Veterans (%): NR Recruitment Method: 20 randomly selected skilled nursing facilities with special care units or dementia programs in 3 CT counties; all nursing staff recruited + one family member for each resident; facilities randomly assigned to intervention or control Family Characteristics: Relationship to patient: *Spouse 19.3%; child 80.7%* Age (years): 59.5 Gender (% female): 65 Race/ethnicity (%): w*hite* 86; *African-American*10; *other* 3.4 Education (%): *HS or less* 30; *Post HS* 70 Veterans (%): NR	Inclusion: Nursing staff and one family member of each resident of the 20 selected skilled nursing facilities with special care units or dementia programs in three Connecticut counties	Intervention (n=209): Partners in Caregiving in the Special Care Unit Environment (PIC-SCU) *(Note: Unit of intervention is facility; N=209 family members of residents on intervention unit who participated)* parallel training sessions for family & staff; enhance communication, conflict-resolution skills, & empathy for other group (staff or family); mini-lectures, case discussions, brainstorming sessions, & role plays; unit goals, facility family procedures, & policies; manualized; one 4-5 hour initial training + 2 hour family/staff meeting. Comparator (n=179): (*Note: N=179 reflects family members of residents on unit who participated) U*sual care with usual staff/family interaction Length of Follow-up: 6 month post-treatment	***Symptom control/ management:*** a. Cohen-Mansfield Agitation Inventory (CMAI) (PR) ***Utilization:*** a. # resident transfers off the unit b. # resident transfers out of the facility *Assessments conducted 2 and 6 months post treatment* ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: unclear Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Treatment adherence: rates of intervention drop out not provided; retention rate overall: 92% baseline to 2 month post-tx; 87% 2 month to 6 month post-tx; 84% baseline to 6 month post-tx Treatment integrity: unclear **Study Quality: Poor**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Teri, 1997[70] Funding Source: Government Condition: Alzheimer's disease (and comorbid depression; average baseline dementia duration =35.6 months; MMSE =16.5; Dementia Rating Scale =108.6) **KQ1 ☒ KQ2 ☒** **Intervention Type:** Behavior Therapy – Pleasant Events: multicomponent –educational, skill-based, emotional, problem solving Behavior Therapy – Problem Solving: multicomponent –educational, skill-based, emotional, problem solving	N=72 Age(years): 76.4 Gender (% male): 53 Race/ethnicity (%): NR Marital Status (%): NR Education (years): 14.1 Veterans (%): NR Recruitment Method: referrals from Alzheimer's clinic and research center Family Characteristics: Relationship to patient: *Spouse 79%; adult child 14%; close friend 7%* Age (years): 66.9 Gender (% female): 69% Race/ethnicity (%): NR Marital Status (%): NR Education (years): 14.2 (mean) Veterans (%): NR	Inclusion: Patients meet NINCDS-ADRDA criteria for probable Alzheimer's disease; co-morbid DSM-III-R criteria for major or minor depressive disorder; ≥6 month history of cognitive problems; live with their caregiver in the community. Exclusion: NR	Behavior Therapy – Pleasant Events (BT-PE) (n=23): 9 weekly 60 min sessions; patients & caregivers; identifying, planning, & increasing pleasant activity, caregiver support system, & problem solving strategies for problem behaviors Behavior Therapy – Problem Solving (BT-PS) (n=19): 9 weekly 60 min sessions for patients & caregivers; problem solving; education, support, advice to caregiver; pleasant activity only as appropriate Typical care control (TCC) (n=10): 9 weekly 60 min sessions for patients & caregivers; advice & suggestions of unstructured nature; no homework/ recordkeeping Wait list control (TCC) (n=20): No contact with therapists over 9 wk period Length of Follow-up: Pre and post tx for all; 6 month for active txs	***Cognitive Function:*** a. Mini Mental Status Exam, SR post tx, 6 months b. DRS (Dementia Rating Scale) SR post tx, 6 months ***Depression/anxiety:*** a. HDRS (Hamilton Depression Rating Scale) SR and PR, post tx, 6 months b. CSDD (Cornell Scale for Depression in Dementia), SR and PR, post tx, 6 months c. BDI (Beck Depression Inventory) PR, post tx, 6 months ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: yes – outcome assessors Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: yes Tx adherence: report treatment dropouts (from sessions): Intervention: 33.5% by post tx Control: 28.6% by post tx (difference = NS) Study dropouts 16/88 = 18% (serious medical illness n=4; change in living situation n=4; exclusionary medication prescribed during intervention n=2; caregiver stopped participating n = 6). NS Tx integrity: manualized; interrater reliability assessed by independent ratings of videotapes **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Teri, 2003[12] Funding Source: Government Condition: Alzheimer's disease (moderate to severe cognitive impairment) **KQ1 ☒ KQ2 ☐** **Intervention Type:** Multicomponent –educational, skill-based	N=153 Age (years): 78 Gender (% male): 59 Race/ethnicity (%): w*hite 89; African-American 9; other 3* Marital Status (%): *Married/ cohabiting 82* Education (%): *HS or less NR; Post HS NR* *Mean years: 13* Veterans (%): NR Recruitment Method: from ongoing, community based Alzheimer's disease patient registry and referrals from physician practices and community advertisements Family Characteristics: Relationship to patient: *Spouse 80%; adult child 6%; other 14%* Age (years): 70 Gender (% female): 70 Race/ethnicity (%): w*hite 87; African-American 8; other 5* Education (%): *HS or less NR; Post HS NR* *Mean years: 13.5* Veterans (%): NR	Inclusion: met National Institute of Neurological and Communicative Diseases and Stroke/ Alzheimer's Disease and Related Disorders Association criteria for probable or possible Alzheimer's disease, were required to be community dwelling, ambulatory, and to have a caregiver who was willing to participate in training sessions Exclusion: none stated	Intervention (n=76): Reducing Disability in Alzheimer's Disease (RDAD). Patient-caregiver dyads seen in own homes for 12 1-hr sessions (2 sessions/ wk for first 3 wks, then weekly for 4 wks, and biweekly for next 4 weeks); exercise component goal was for patients to engage in at least 30 min/ day of moderate-intensity exercise; behavioral management component - caregivers given specific instructions about dementia, how to reduce occurrence of behavioral problems, how to identify and modify precipitants of patient distress, how to modulate their own response to problems; positive interactions were encouraged. Comparator (n=77): Routine medical care Length of Follow-up: Post-treatment (3 months post-baseline); and 6, 12, 18, and 24-months post randomization (3, 9, 15 and 21 months post-tx)	***Physical functioning:*** a. SF-36 physical health component [SR] b. Sickness Impact profile – mobility, subscales [SR] c. # of restricted activity days and days spend in bed in past 2 weeks ***Depression/anxiety:*** a. CSDD (Cornell Scale for Depression in Dementia) b. HDRS (Hamilton Depression Rating Scale) *(assessed, but values only reported for most distressed pts)* (both measures assessed by proxy, independent assessor observing caregiver and patient) ***Utilization:*** a. # patients institutionalized **☐ Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: outcome assessments, interviewers blind to treatment assignment Intention-to-treat analysis (ITT): yes Withdrawals/dropouts adequately described: yes Tx adherence: 13 study dropouts to post-treatment (all included in the analyses); 8 of the intervention group dropped out before post treatment (10.5%) and 5 of the routine care group (6.5%); 58% completed the final follow-up Tx integrity: yes **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Teri, 2005[66] Funding Source: Foundation Condition: Alzheimer's disease (moderate impairment; MMSE =14) **KQ1 ☒ KQ2 ☐** **Intervention Type:** Multicomponent –problem-solving, education, and support for the caregiver	N=95 Age (years): 80 Gender (% male): 34 Race/ethnicity (%): *white 86.1; African-American 5.4; other 8.6* Marital Status (%): *Married: 56.7* Education (%): *HS or less 8.4; Post HS 51.6* Veterans (%): NR Recruitment Method: NR Family Characteristics: Relationship to patient: *Spouse 55 %; son/daughter 31%; other 14%* Age (years): 65.1 Gender (% female): 69 Race/ethnicity *(%): white 87.2; African-American 4.3; other 8.6* Education (%): *HS or less 28.5; Post H: 71.5* Veterans (%): NR	Inclusion: Alzheimer's disease and three or more agitated or depressed behavior problems reported by caregivers; occurring at least three or more times in the past week; caregivers were spouse or adult relative caring for person with dementia in the home Exclusion: none stated	Intervention (n=47): STAR Caregivers: Consultants met with caregivers in-home for 8 weekly sessions, followed by 4 monthly phone calls; first 3 sessions focused on teaching caregivers rationale and use of A-B-C problem-solving approach to behavior change; subsequent sessions focused on improving caregiver communication, increasing pleasant events as means to improve care recipients' mood, & developing strategies to enhance caregiver support; manualized program Comparator (n=48): Routine medical care Length of Follow-up: none (6 month treatment)	***Cognitive functioning:*** a. Revised Memory and Behavior Problems Checklist – Memory subscale (PR) ***Quality of life:*** a. Quality of Life-Alzheimer's Disease (QOL-AD) (PR) All outcomes assessed at baseline, 2 months, and 6 months (post-tx) ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: outcome assessments, interviewers blind to treatment assignment Intention-to-treat analysis (ITT): yes Withdrawals/dropouts adequately described: yes Treatment adherence: 83% of caregivers attended 8 or more treatment sessions (mean=7.6 sessions; range=1-10) 12 (13%) dropped out by end of 8 weekly session; 29 (31%) dropped out by end of 6 months Treatment integrity: audiotapes and paperwork reviewed by supervisors **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Wray, 2010[49] Funding Source: Government (Dept. of Veterans Affairs) Condition: Dementia **KQ1 ☒ KQ2 ☐** **Intervention Type:** Education, support	N=158 dyads Age (years): 78 Gender (% male): NR Race/ethnicity (%): *white 92* Marital Status (%): NR Education (years): 12.5 (mean) Veterans (%): 100 Recruitment Method: potential participants identified by encounter coded for dementia diagnosis, clinician referral, or self/family referral in response to information and publicity about study Family Characteristics: Relationship to patient: *spouse or spousal equivalent* Age (years): 74 Gender (% female): NR Race/ethnicity (%): *white 91* Education (years): 12.5 (mean) Veterans (%): NR	Inclusion: *Caregiver* – primary family caregiver (spouse or spousal equivalent); lived with care recipient at least 1 year; at least moderate level of caregiving strain (score of 7 or more on Caregiver Strain Index) *Care Recipient* - Living in own home/apartment; definitive diagnosis of dementia in medical record; spouse or partner living with them for at least 1 year; at least moderate level of dementia (3 or higher on Global Deterioration Scale) or dependent on at least 1 ADL and at least 3 IADLs Exclusion: Caregiver participating in any other caregiver support group at enrollment	Intervention (n=83): Telephone Education Program (TEP); telephone conference with up to 8 caregivers; education about dementia and caregiving skills, coping strategies, & support; 10 weekly 1-hour sessions; workbook for participants; manualized Comparator (n=75): Usual care (all usual VA services) Length of Follow-up: up to 12 months following start of intervention	***Utilization:*** a Total admissions b. Acute admissions c. ICU admissions d. Nursing home admissions e. Outpatient visits All data obtained from VA databases All outcomes summed over 6-month time intervals: 6 months before start of intervention, start of intervention to 6 months after start, and 6-12 months after intervention period ☐ **Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: health care cost and utilization data extracted by blinded investigator Intention-to-treat analysis (ITT): yes Withdrawals/dropouts adequately described: no withdrawals - database data available regardless of participation in intervention Treatment adherence: NR; reported no difference in outcomes for those who completed study vs. those who did not Treatment integrity: monitored by doctoral-level investigators **Study Quality: Fair**

Study, Year Funding Source Medical Condition Intervention Type	Sample Characteristics	Inclusion/Exclusion Criteria	Intervention Comparator Length of Follow-up	Outcomes Assessed	Study Quality
Wright, 2001[67] Funding Source: Foundation Condition: Alzheimer's disease **KQ1 ☒ KQ2 ☐** **Intervention Type:** Educational; skill-based; emotional; problem solving	N=93 Age (years): 77.4 Gender (% male): 24 Race/ethnicity (%): NR Marital Status (%): NR Education (%): NR Veterans (%): NR Recruitment Method: NR Family Characteristics: Relationship to patient: *Spouse 45%; adult daughters 38%; other relative 17%* Age (years): 59.5 Gender (% female): 76 Race/ethnicity (%): *white 68.6; African-American 31.4* Education (years): 12 (mean) Veterans (%): NR	Inclusion: Alzheimer's disease patient admitted to and about to be discharged from behavioral ICU; had primary caregiver living in same household and within an 80 mile radius of the hospital Exclusion: NR	Intervention (n=68): targeted at caregiver; case management & counseling/ education; conducted in-home (2 weeks, 6 weeks, 12 weeks post-discharge) and by phone (6 and 12 months post-discharge); unclear if manualized Comparator (n=25): Usual care; caregivers received phone calls on same time schedule for data collection only (no counseling or case management) Length of Follow-up: none (12 month treatment)	***Physical functioning:*** a. # deceased 12 months post baseline b. Blessed Dementia Rating Scale ***Symptom control/ management:*** a. CMAI (Cohen-Mansfield Agitation Inventory) ***Utilization:*** a. % Institutionalized at 12 months post baseline b. # days at home prior to institutionalization (mean, SD, range) All outcomes proxy report and assessed during intervention at 2 weeks, 6 weeks, 12 weeks, 6 and 12 months (post baseline) **☒ Negative caregiver outcomes reported**	Allocation concealment: unclear Blinding: no Intention-to-treat analysis (ITT): no Withdrawals/dropouts adequately described: no Treatment adherence: NR Treatment integrity: NR **Study Quality: Poor**

Table 10. Memory-Related Disorders – Physical Functioning

Study, Year Interventions	Physical Condition	Baseline Functional Level	IADL or ADL Scale	Baseline	Post-Treatment (SD)	Follow-up* (time assessed)
Brodaty, 2009[59] 1) Donepezil + standard services + psychological caregiver intervention (n=26) 2) Donepezil + standard services (n=26)	Alzheimer's disease	GDS = 4.5 (0.55) MMSE = 20.7 (5.27) ADCS-ADL = 58.1 (13.03) ADAS-Cog = 26.8 (10.79) RMBPCL =10.98 (7.94)	Death, percent		NR	1) 46% (12/26) 2) 54% (14/26) Mean follow-up: 5.4 years, up to 8.5 years
Burgener 1998[65] 1) Educational and behavioral intervention (n=11) 2) Education only (n=12) 3) Behavioral only (n=12) 4) Comparison group (n=12)	Alzheimer's disease or multi-infarct dementia	Baseline mean MMSE=8.9 (moderate to severe)	Composite (OARS, IADL, SCS) (higher score=better self-care ability)	1) 11.8 2) 12.5 3) 8.8 4) 14.6 (Standard deviations not provided)	NR	1) 9.3 (Δ=-2.5)‡ 2) 10.6 (Δ=-1.9) 3) 10.1 (Δ=1.4) 4) 12.6 (Δ=-2.0) ‡Change from baseline to 6 months
Chang 1999[71] 1) Nurseline cognitive-behavioral (n=34) 2) Placebo telephone calls (n=31)	Dementia	Significant dressing and eating problems; MMSE<21	ADL subscale of Functional Rating Scale for the Symptoms of Dementia (higher score = poorer function)	1) 4.6 (2.9) (n=33) 2) 4.9 (3.0) (n=30)	Reported no significant difference over time and no group x time interaction (data not provided)	NR
Gerdner 2002[69] 1) Progressively Lowered Stress Threshold (PLST) training program 2) Routine information, community referrals, case management, and support groups	Alzheimer's disease or a related disorder	Moderate to severe cognitive impairment	Subscale from The Memory and Behavior Problems Checklist 1989R (PR)	NR	NR	NR *Authors report rate of increase in ADLs (B=0.33, p < 0.01) did not vary by treatment group*

Study, Year Interventions	Physical Condition	Baseline Functional Level	IADL or ADL Scale	Baseline	Post-Treatment (SD)	Follow-up* (time assessed)
Gitlin, 2010[10] 1) COPE (n=117) 2) Comparator (n=120)	Dementia	MMSE score <24; needed help with daily activities or had behavioral symptoms	Overall functional dependence (15-item modeled after the FIM; higher score=greater independence)	1) 3.0 (1.2) (n=102) 2) 2.8 (1.3) (n=107)	1) 3.7 (1.3) (n=102) 2) 3.3 (1.3) (n=107) **p=0.02 between groups** Cohen *d*=0.21	NR
			Net % improved overall functional dependence	NA	1) 49% 2) 29% Difference net improvement (95% CI): 19.2 (2.7, 36.0); **p=0.02**	NR
			IADL dependence subscale (8 items, higher score=greater independence)	1) 1.8 (1.0) (n=102) 2) 1.8 (1.0) (n=107)	1) 2.8 (1.2) (n=102) 2) 2.5 (1.1) (n=107) **p=0.007 between groups** Cohen *d*=0.43	NR
			Net % improved IADL dependence	NA	1) 62% 2) 44% Difference net improvement (95% CI): 17.9 (1.9, 34.0) **p=0.03**	NR
			ADL dependence subscale 8 items, higher score =greater independence)	1) 4.3 (1.7) (n=102) 2) 4.1 (1.8) (n=107)	1) 4.6 (1.6) (n=102) 2) 4.3 (1.7) (n=107) p=0.21 between groups	NR
			Activity engagement (high score indicates greater engagement	1) 1.9 (0.4) (n=102) 2) 2.0 (0.4) (n=107)	1) 2.0 (0.4) (n=102) 2) 1.9 (0.4) (n=107) **p=0.03 between groups** Cohen *d*=0.26	NR
			Net % improved Activity engagement	NA	1) 13% 2) -2.0% Difference net improvement (95% CI): 14.6 (-8.8, 38.0); p=0.22	NR

Study, Year Interventions	Physical Condition	Baseline Functional Level	IADL or ADL Scale	Baseline	Post-Treatment (SD)	Follow-up* (time assessed)
Gitlin, 2003[73] (REACH) 1) Environmental Skill-Building Program (ESP) (n=89) 2) Resource information plus usual care (n=101)	Dementia	MMSE <24; baseline mean MMSE=12 (moderate)	ADL requiring assistance-mobility subdomain of FIM (scale 1-6; higher score=greater independence)	1) 4.1 (1.9) (n=89) 2) 4.2 (1.9) (n=101)	6 Months 1) 3.7 (1.7) (n=89) 2) 3.8 (1.9) (n=101) p=0.93 between groups	NR
			IADLs requiring assistance (scale 1-6; higher score=greater independence)	1) 1.9 (1.0) (n=89) 2) 1.9 (1.1) (n=101)	6 Months 1) 1.7 (0.8) (n=89) 2) 1.6 (0.9) (n=101) p=0.69 between groups	NR
Gitlin, 2001[57] 1) Home environment program (n=100) 2) Usual care (n=102)	Dementia	"Minimal" ADL Dependency (mean 3.1/6) "High" IADL Dependency (mean 5.5/6)	ADL dependence (modified FIM - scale 1-6; higher score=greater dependence)	1) 2.9 (1.5) (n=93) 2) 3.2 (1.4) (n=78)	3 months 1) 3.2 (1.6) (n=93) 2) 3.6 (1.4) (n=78) p=0.60 between groups; adj mean diff=-0.06 (95%CI -0.3, 0.18)	NR
			IADL dependence (modified FIM - scale 1-6; higher score=greater dependence)	1) 5.4 (0.6) (n=93) 2) 5.6 (0.5) (n=78)	**1) 5.5 (0.6) (n=93)** **2) 5.8 (0.4) (n=78)** **p=0.03 between groups**; adj mean diff=-0.13 (95%CI -0.24, -0.01)	NR
Logsdon, 2010[63] 1) Early Stage Memory Loss (ESML) (n=96) 2) Wait List (WL) (n=46)	Dementia	Early stage Alzheimer's and dementia; (inclusion criteria was MMSE ≥ 18; but mean for enrolled patients was 23.4)	SF-36 Physical Component	1) 42.0 (11.8) (n=96) 2) 43.9 (11.0) (n=46)	1) 41.4 (11.0) (n=92) 2) 42.0 (11.1) (n=44) **p=NR, ns**	NR
Martin-Cook, 2005[60] 1) Caregiver skills training (n=24) 2) Wait List (n=23)	Dementia (primarily Alzheimer's disease)	Baseline mean MMSE=19.4 (moderate)	Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-MCI version (ADCS-MCI) (score 0-69, higher score=greater functioning)	**1) 35.2 (SE=3.1) (n=24)** **2) 31.7 (SE=3.3) (n=23)** **p=0.03**	7 weeks (2 weeks post-tx) **1) 39.1 (SE=3.2) (n=24)** **2) 31.1 (SE=3.3) (n=23)** **p=0.03**	NR

Study, Year Interventions	Physical Condition	Baseline Functional Level	IADL or ADL Scale	Baseline	Post-Treatment (SD)	Follow-up* (time assessed)
Mittelman, 2006 [52] 1) Multi-component intervention (n=203) 2) Usual care (n=203)	AD	Global Deterioration Scale baseline of 4 = 33%; 5 to 7 = 67% (moderate to moderately severe)	Older Americans Resources and Services (OARS) Physical Health rating (1-10; higher score indicates worse health)	1) 2.20 (0.72) (n=203) 2) 2.17 (0.73) (n=203) p=NR	NR	NR
			Global Deterioration Scale (GDS) (1-7, higher score indicates worse functioning)	GDS = 4 1) 72/203 (35.5%) 2) 64/203 (31.5%) p=NR GDS = 5 1) 91/203 (44.8%) 2) 77/203 (37.9%) p=NR GDS = 6 or 7 1) 40/203 (19.7%) 2) 62/203 (30.5%) p=NR	NR	NR
Teri, 2003[12] 1) Reducing Disability in Alzheimer's Disease (n=76) 2) Routine medical care (n=77)	Alzheimer's disease	Baseline MMSE = 16.8 *moderate to severe*	SF-36 physical health component (higher score indicates better functioning)	1) 62.2 (36.6) 2) 67.9 (35.1)	1) 72.1 (33.0) (n=68) 2) 50.7 (39.1) (n=72) p<0.001	21 months post-tx 1) 60.0 (41.1) (n=45) 2) 57.4 (40.2) (n=44) p=0.01 p<0.01 (longitudinal, all post-tx assessments)
			Sickness Illness Profile: Mobility (higher score indicates worse functioning)	1) 16.3 (19.2) 2) 14.2 (13.8)	1) 16.0 (17.1) (n=68) 2) 15.2 (17.1) (n=72) p=0.17	21 months post-tx 1) 18.9 (17.1) (n=45) 2) 21.0 (18.8) (n=44) p=0.01 p=0.02 (longitudinal, all post-tx assessments)
			# of restricted activity days and days spend in bed in past 2 weeks	1) 0.6 (2.2) 2) 0.4 (4.5)	1) 0.1 (0.4) 2) 0.6 (2.5) p<0.001	21 months post-tx 1) 0.9 (3.2) 2) 0.0 (0.3) p=NR p=0.45 (longitudinal, all post-tx assessments)
Wright 2001[67] 1) Education and counseling (n=68) 2) Usual care (n=25)	Alzheimer's disease	Moderate loss of memory; enrolled following in-patient treatment for agitation	% Deceased	NA	12 months 1) 11% (7/61) 2) 22% (5/23) p=ns	NR

*Last follow-up reported only if > 6 months post-treatment

[1]Standard error

ES=effect size; NR=not reported; ns=not statistically significant

Table 11. Memory-Related Disorders – Cognitive Function

Study, Year Interventions	Physical Condition	Baseline Functional Level	Assessment Tool	Baseline	Post-Treatment	Follow-up* (time assessed)
Gitlin, 2003[73] (REACH) 1) Environmental Skill-Building Program (ESP) (n=89) 2) Resource information + usual care (n=101)	Dementia	MMSE <24; baseline mean MMSE=12 (moderate)	RMBPC – memory subscale	1) 4.9 (1.5) 2) 4.6 (1.6)	6 months 1) 4.6 (1.5) 2) 4.6 (1.6) p=0.12 between groups Adj mean diff=-0.27 (95%CI -0.60, 0.07)	NR
Gonyea, 2006[64] 1) Behavioral 2) General information (Number randomized not reported)	Alzheimer's disease	Mild to moderate (MMSE 10 or higher)	Neuropsychiatric Inventory (higher scores=greater impairment)	1) 22.9 (13.0) (n=40) 2) 21.7 (12.9) (n=40)	1) 16.4 (10.1) (n=40) 2) 19.4 (12.3) (n=40)	NR
Jirovec, 2001[58] 1) Intervention – scheduled toileting (N=77) 3) Control "friendly" monthly call only (N=41) Note: 2 intervention groups (visits conducted every 2 or 6 months, were combined for analysis due to no differences between groups)	Memory impairment	NR	Short Portable Mental Status Questionnaire (SPMSQ) (higher score=greater cognitive impairment)	1) 6.6 (2.2) (n=44) 2) 6.7 (2.1) (n=30) p=NR, ns	1) 6.7 (2.1) (n=44) 2) 7.1 (2.3) (n=30) p=NR, ns	NR
Martin-Cook, 2005[60] 1) Caregiver skills training (n=24) 2) Wait List (n=23)	Dementia (primarily Alzheimer's disease)	Baseline mean MMSE=19.4 (moderate)	Neuropsychiatric Inventory (NPI) (score range 1-114, higher score=poor functioning)	1) 13.6 (SE=2.5) (n=24) 2) 12.5 (SE=2.6) (n=23) p=NR	7 weeks (2 weeks post-tx) 1) 12.6 (SE=2.5) (n=24) 2) 12.0 (SE=2.6) (n=23) p=NR (ns)	NR
			Mini-mental state examination (MMSE)	1) 19.4 (SE=1.4) (n=24) 2) 19.0 (SE=1.5) (n=23) p=NR	7 weeks (2 weeks post-tx) 1) 20.8 (SE=1.5) (n=24) 2) 18.6 (SE=1.5) (n=23) p=NR (ns)	NR
McCurry 2005[61] 1) Nighttime Insomnia Treatment and Education for Alzheimer's Disease (NITE-AD; n=17) 2) Supportive contact control (n=19)	Alzheimer's disease	Community-dwelling and ambulatory; dementia for 5.8 years on average; Mini-Mental State Exam of 11.8 on average	RMBPC – ***Memory***** (Average frequency of behaviors over past week)	1) 3.3 (0.6) (n=17) 2) 2.9 (1.0) (n=19)	1) 3.1 (0.6) (n=13) 2) 2.6 (0.9) (n=16)	1) 3.2 (0.6) (n=11) 2) 2.6 (0.8) (n=12) (6 months)
Ostwald, 1999[50] 1) Minnesota Family Workshop (MFW), n=72 2) Workshop wait list, n=45	Dementia	Signs of mild to severe dementia	Mini-mental state examination (MMSE)	1) 17.6 (7.1), n=45 2) 19.8 (6.9), n=29 p=NR	1) 17.4 (7.3), n=45 2) 18.9 (7.6), n=29 Intervention effect: p=0.32 Intervention by time: p=0.45	

Study, Year Interventions	Physical Condition	Baseline Functional Level	Assessment Tool	Baseline	Post-Treatment	Follow-up* (time assessed)
Quayhagen, 2000[62] 1) Cognitive stimulation (n=21) 2) Dyadic counseling (n=29) 3) Dual supportive seminar (n=22) 4) Early day care (n=16) 5) Wait list (n=15)	Dementia (possible or probably Alzheimer's disease, or cardio vascular multi-infarct)	Mild to moderate	Problem solving-composite of Geriatric Coping Schedule and conceptualization factor from DRS (higher score=better problem solving)	1) 66.4 (SE=2.7) 2) 64.5 (SE=2.6) 3) 66.4 (SE=2.6) 4) 66.6 (SE=4.9) 5) 67.5 (SE=4.7) p=ns	3 months (1 month post-tx) (n=103) 1) 72.3 (SE=3.8)‡ 2) 65.2 (SE=3.2) 3) 66.8 (SE=3.2) 4) 65.8 (SE=3.1) 5) 64.9 (SE=6.3) p=0.073 (‡p=0.009 for 1st intervention over time)	NR
			Immediate Memory - composite of Logical Memory I and Visual Reproduction 1 from Wechsler Memory Scale – Revised (WMS-R) and memory factor of Dementia Rating Scale (DRS)	1) 41.2 (SE=3.5) 2) 39.5 (SE=2.7) 3) 37.8 (SE=3.1) 4) 40.3 (SE=4.4) 5) 39.0 (SE=4.2) p=ns	3 months (1 month post-tx) (n=103) 1) 43.5 (SE=4.4) 2) 39.2 (SE=2.6) 3) 37.6 (SE=3.1) 4) 41.3 (SE=3.8) 5) 38.3 (SE=5.2) p=ns	NR
			Delayed Memory - composite of WMS-R Logical Memory II and Visual Reproduction II	1) 6.9 (SE=1.9) 2) 7.1 (SE=1.9) 3) 6.9 (SE=2.4) 4) 8.6 (SE=3.5) 5) 5.9 (SE=2.9) p=ns	3 months (1 month post-tx) (n=103) 1) 10.1 (SE=2.5) 2) 7.8 (SE=1.9) 3) 7.6 (SE=2.3) 4) 9.6 (SE=4.0) 5) 6.3 (SE=3.2) significant time main effect (p=0.03) due to improvement in group 1; "less change" in other groups	
			Verbal Fluency: Composite of 2 recalled word scales and initiation factor score on DRS	1) 65.9 (SE=5.5) 2) 60.2 (SE=3.4) 3) 61.6 (SE=3.9) 4) 63.4 (SE=4.9) 5) 61.4 (SE=5.7) p=ns	3 months (1 month post-tx) (n=103) 1) 70.1 (SE=6.3) 2) 58.7 (SE=3.5) 3) 60.6 (SE=4.5) 4) 63.2 (SE=4.4) 5) 59.9 (SE=7.7) p=ns	

Study, Year Interventions	Physical Condition	Baseline Functional Level	Assessment Tool	Baseline	Post-Treatment	Follow-up* (time assessed)
Teri, 1997[70] 1) Behavior Therapy-Pleasant Events (BT-PE) (n=23) 2) Behavior Therapy-Problem-solving (BT-PS) (n=19) 3) Usual care (n=10) 4) Wait list (n=20)	Alzheimer's disease and depression	Baseline MMSE = 16.5	Mini Mental Status Exam	1) 15.8 (7.8) 2) 15.7 (7.4) 3) 16.8 (5.4) 4) 17.9 (7.9) Group differences=ns	Mean change 1) -0.9 (3.1) 2) -1.0 (2.9) 3) 0.1 (4.1) 4) -0.7 (3.6) Group differences=ns	
			DRS (Dementia Rating Scale)	1) 105.8 (30.7) 2) 106.8 (24.2) 3) 111.2 (14.5) 4) 112.1 (22.0) Group differences=ns	Mean change 1) -5.0 (11.9) (n=16) 2) -1.3 (8.2) (n=9) 3) 2.6 (15.3) (n=8) 4) 3.6 (6.3) (n=14) Group differences=ns	
Teri, 2005[66] 1) STAR Caregivers (n=47) 2) Routine medical care (n=48)	Alzheimer's disease	Baseline MMSE = 14 *moderate*	RMBPC – Memory subscale	1) 3.0 (0.7) 2) 3.0 (0.8)	6 months **1) 2.8 (0.8) (n=32)** **2) 3.1 (1.0) (n=31)** **p=0.031** (longitudinal, adjusted for baseline values, includes 2 & 6 month assessments)	NR

*Last follow-up reported only if > 6 months post-treatment

**Data obtained from author

ES=effect size; NR=not reported; ns=not statistically significant

Table 12. Memory-Related Disorders – Quality of Life – Global Functioning

Study, Year Interventions	Physical Condition	Baseline Functional Level	Quality of Life Assessment Scale	Baseline	Post-Treatment	Follow-up* (time assessed)
Belle, 2006[55] 1) Multicomponent (n=323) 2) Attention control (check-in calls) (n=319)	Alzheimer's or related disorders	NR; required to have diagnosed disease	Single question – Did participation in this project help improve care recipient's life?	NA	**"A great deal"** **1) 40.4% (n=323)** **2) 16.3% (n=319)** **RR=2.47 [1.86, 3.27]**	NR
Gitlin, 2010[10] 1) Care of Persons with Dementia in their Environments (COPE) (n=117) 2) Comparator (n=120)	Dementia	MMSE score <24; needed help with daily activities or had behavioral symptoms	Quality of Life–Alzheimer's Disease scale (12 items, scale 1-4; higher scores indicated better quality of life)	1) 2.1 (0.4) (n=102) 2) 2.1 (0.5) (n=107)	1) 2.2 (0.5) (n=102) 2) 2.1 (0.5) (n=107) p=0.06 between groups Cohen's *d*=0.14	NR
Gitlin, 2008[74] 1) Tailored Activity Program (TAP) (n=30) 2) Wait list (N=30)	Dementia	MMSE <24; able to feed self and participate in ≥ 2 self-care activities; baseline mean MMSE=12 (moderate)	12-item Quality of Life-Alzheimer's Disease (QOL-AD) scale; score is mean response (1=poor, 4=excellent)	1) 2.2 (0.3) (n=27) 2) 2.0 (0.4) (n=29)	4 Months 1) 2.4 (0.4) (n=27) 2) 2.1 (0.5) (n=29) p=0.095 between groups	NR
Logsdon, 2010[63] 1) Early Stage Memory Loss (ESML) (n=96) 2) Wait list (WL) (n=46)	Dementia	Early stage Alzheimer's and dementia; (inclusion criteria was MMSE ≥ 18; but mean for enrolled patients was 23.4)	Quality of Life-Alzheimer's Disease (QOL-AD) (13-item measure, with a higher score indicating greater improvement)	1) 39.0 (6.0) (n=96) 2) 38.8 (5.6) (n=46)	1) 39.6 (5.3) (n=92) 2) 37.8 (6.3) (n=44) **p<0.01; β=1.74** **Effect size=0.44** # improved by group: 1) 48% 2) 30% p<0.05	NR
Teri, 2005[66] 1) STAR Caregivers (n=47) 2) Routine medical care (n=48)	Alzheimer's disease (possible or probable)	Baseline mean MMSE=14 (moderate)	13-item Quality of Life-Alzheimer's Disease (QOL-AD) (higher score=better QOL)	1) 27.8 (5.5) 2) 28.3 (4.9)	6 months **1) 28.4 (5.4) (n=32)** **2) 28.2 (4.6) (n=34)** **p=0.031** (longitudinal, adjusted for baseline values, includes 2 & 6 month assessments)	NR
Wright, 2001[67] 1) Education and counseling (n=68) 2) Usual care (n=25)	Alzheimer's disease	Moderate loss of memory; enrolled following in-patient treatment for agitation	Blessed Dementia Rating Scale (scale 0-17; higher score=more severe dementia)	1) 7.87 (3.47), n=68 2) 9.62 (3.38), n=25 p=0.03 Used as covariate to explain agitation; correlation with agitation (r=0.40, p<0.0001)	"Over time" (unclear if 12 months) 1) 10.5 2) 12.4 (SD not reported) Correlation with agitation (r=0.21, p=ns)	NR

*Last follow-up reported only if > 6 months post-treatment
[1]Scale of -3 to +3; higher score indicates better well-being
ES=effect size; NR=not reported; ns=not statistically significant

Table 13. Memory-Related Disorders – Symptom Management/Control

Study, Year Interventions	Physical Condition	Baseline Functional Level	Measure of Problem Behavior	Baseline	Post-Treatment	Follow-up* (time assessed)
Belle, 2006[55] 1) Multicomponent (n=323) 2) Attention control (check-in calls) (n=319)	Alzheimer's or related disorders	NR; required to have diagnosed disease	3 questions for memory, depression, and disruption; scale of 1 (substantial improvement) to 5 (substantial decline); total 3 to 15 with higher score indicating greater decline		Hispanic or Latino 1) 45% improved; 13% worsened 2) 23% improved; 28% worsened White or Caucasian 1) 32% improved; 20% worsened 2) 26% improved, 27% worsened Black or African American 1) 27% improved, 33% worsened 2) 25% improved, 27% worsened (significance not reported)	NR
Bourgeois, 2002[72] 1) Patient-change 2) Self-change 3) Visitation control (Number randomized not reported)	Alzheimer's disease	MMSE score of 20 or less	Behave-AD *Total Score* (max score of 75, higher score=perception of more severe problems)	1) 16.9 (10.2) (n=18) 2) 18.4 (7.7) (n=18) 3) 18.6 (8.8) (n=15)	1) 15.2 (10.1) 2) 13.5 (6.3) 3) 18.4 (10.8) **Group 2 vs Group 3: p<0.05** All other p values, NR, ns	1) 17.5 (10.4) 2) 14.8 (10.5) 3) 23.1 (11.4) **Group 2 vs Group 3: p<0.01** All other p values, NR, ns
			Behave AD - *Aggressivity/ Activity Disturbance Subscale*	1) 6.4 (4.3) (n=18) 2) 5.8 (2.5) (n=18) 3) 6.7 (3.0) (n=15)	1) 5.4 (4.2) 2) 5.3 (3.4) 3) 6.9 (3.3) All p values, NR, ns	1) 5.6 (3.8)* 2) 5.2 (3.6)** 3) 8.4 (2.4) **Group 1 vs Group 3: p<0.05** **Group 2 vs Group 3: p<0.01** All other p values, NR, ns
			Behave AD *Psychosis/ Delusion Subscale*	1) 4.6 (4.0) (n=18) 2) 6.9 (6.3) (n=18) 3) 6.9 (5.0) (n=15)	1) 4.8 (4.0) 2) 4.8 (4.3) 3) 5.8 (5.4) All p values, NR, ns	1) 6.8 (5.1) 2) 5.5 (6.3) 3) 7.6 (7.1) All p values, NR, ns
			Frequency of Problem Behaviors (weekly average)	1) 2.5 (1.9) (n=12) 2) 2.0 (0.8) (n=16) 3) 1.7 (0.9) (n=15)	1) 1.3 (2.1) 2) 2.0 (0.7) 3) 2.0 (0.8) **Group 1 vs Group 3: p<0.05** All other p values, NR, ns	1) -0.2 (3.4) 2) 1.5 (1.9) 3) 1.9 (1.2) **Group 1 vs Group 3: p<0.01** All other p values, NR, ns

Study, Year Interventions	Physical Condition	Baseline Functional Level	Measure of Problem Behavior	Baseline	Post-Treatment	Follow-up* (time assessed)
Burgener 1998[65] 1) Educational and behavioral intervention (n=11) 2) Education only (n=12) 3) Behavioral only (n=12) 4) Comparison group (n=12)	Alzheimer's disease or multi-infarct dementia	Baseline mean MMSE=8.9 (moderate to severe)	Dementia Behavior Disturbance Scale (DBDS) (higher score=increased level of difficult behavior)	1) 28.4 2) 36.8 3) 25.9 4) 25.6 (SD not reported)	NR	1) 27.9 (Δ=-0.56)‡ 2) 36.6 (Δ=-0.21) 3) 28.1 (Δ=2.22) 4) 28.3 (Δ=2.71) ‡Change from baseline to 6 months
Burns, 2003[51] 1) Behavior Care (n=85) 2) Enhanced Care (n=82)	Alzheimer's disease and related disorders	Medical diagnosis or <24 on MMSE and limitations in ADLs/IADSLs	Revised Memory and Behavior Problems Checklist (RMBPC) (0 to 96, higher score=greater bother)	1) 19.6 (11.6) (n=37) 2) 11.8 (12.7) (n=39) p=0.007	1) 14.8 (10.2) (n=37) 2) 9.2 (12.8) (n=38) group effect: p=0.92 group x time interaction: p=0.98	NR
Camberg, 1999[11] 1) SimPres audio tape 2) Placebo audio tape 3) Usual care Crossover trial, n=54	Alzheimer's disease	Average MMSE = 5.1(4.4) – severe cognitive impairment	SCMAI agitated behaviors scale –lower score = more positive well-being (weekly staff surveys)	NR	1) 25.5 2) 27.1 3) 25.1 All 3 groups: F=3.9, df 2616, p=0.021 Group 1) vs 2) p=0.134 Group 1) vs 3) p=0.714 Group 2) vs 3) p=0.017	NR
Chang, 1999[71] 1) Nurseline cognitive-behavioral (n=34) 2) Placebo telephone calls (n=31)			Functional Rating Scale for the Symptoms of Dementia (14 items scores 0-3; higher score = poorer function; <21 able to stay at home longer)	Overall Function 1) 18.4 (8.9) 2) 18.5 (8.4) Behavior Subscore 1) 13.6 (9.0) 2) 13.8 (6.4)	**1) 19.5 (8.6)** **2) 20.0 (9.0)** **p=0.03 over time (interaction p=ns)** **1) 14.9 (6.3)** **2) 15.1 (6.5)** **p=0.02 over time (interaction p=ns)**	NR

Study, Year Interventions	Physical Condition	Baseline Functional Level	Measure of Problem Behavior	Baseline	Post-Treatment	Follow-up* (time assessed)
Gerdner 2002 1) Progressively Lowered Stress Threshold (PLST) training program 2) Routine information, community referrals, case management, support groups	Alzheimer's disease or a related disorder	Moderate to severe cognitive impairment	The Memory and Behavior Problems Checklist (PR)	NR	NR	NR For non-spouse caregivers: 1) *B* = 0.00, ns 2) *B* = 0.77, *p* < .01 (increase in behavior problems) For spouse caregivers: 1) *B* = 0.18, ns 2) *B* = 0.18, ns
Gitlin, 2010[75] 1) Advanced Caregiver Training (ACT) (n=137) 2) Control (n=135)	Dementia	MMSE score <24	# problem behaviors at baseline (ABID) Frequency of problem behaviors/month (RMBPC)	1) 9.4 (3.7) (N=117) 2) 9.9 (4.0) (N=122) p=0.34 1) 12.1 (13.4) (N=117) 2) 13.5 (11.7) (N=122) p=0.21	NR NR	NR NR
			Targeted behavior improved (Selected one problem behavior to target for improvement)	NA	1) 67.5% (N=117) 2) 45.8% (N=122) **p=0.002**	NR
			Targeted behavior stayed the same	NA	1) 14.0% (N=117) 2) 22.5% (N=122)	
			Targeted behavior worsened	NA	1) 18.4% (N=117) 2) 31.7% (N=122)	
Gitlin, 2010[10] 1) COPE (n=117) 2) Comparator (n=120)	Dementia	MMSE score <24; needed help with daily activities or had behavioral symptoms	Agitated Behavior in Dementia scale – higher score indicates greater number and frequency of agitated behaviors	1) 11.0 (14.6) (n=102) 2) 9.8 (10.7) (n=107)	1) 6.7 (10.6) (n=102) 2) 5.5 (8.0) (n=107) p=0.59 between groups	NR
Gitlin 2008[74] 1) Tailored Activity Program (TAP) (n=30) 2) Wait list (N=30)	Dementia	MMSE <24; able to feed self and participate in ≥ 2 self-care activities; baseline mean MMSE=12 (moderate)	Frequency of occurrence of 24 behaviors; caregivers indicated occurrence (yes or no) and, if yes, frequency in past month	1) 30.5 (30.3) (n=27) 2) 41.5 (70.5) (n=29)	**4 months** **1) 18.8 (17.6) (n=27)** **2) 60.8 (85.3) (n=29)** **d=0.72; p=0.009 between groups**	NR
			Number of behaviors occurring	1) 8.0 (3.8) (n=27) 2) 7.5 (4.5) (n=29)	4 months 1) 7.2 (4.1) (n=27) 2) 7.7 (3.7) (n=29) p=0.249 between groups	NR

Study, Year Interventions	Physical Condition	Baseline Functional Level	Measure of Problem Behavior	Baseline	Post-Treatment	Follow-up* (time assessed)
Gitlin 2003[73] (REACH) 1) Environmental Skill-Building Program (ESP) (n=89) 2) Resource information + usual care (n=101)	Dementia	MMSE <24; baseline mean MMSE=12 (moderate)	Modified RMBPC - number of disruption-related behaviors (higher score=occurrence of increased number of behaviors)	1) 2.1 (1.6) 2) 2.2 (1.8)	6 months 1) 1.9 (1.6) 2) 2.0 (1.9) p=0.74 between groups	NR
Gitlin 2001[57] 1) Home environment program (n=100) 2) Usual care (n=102)	Dementia	"Minimal" ADL Dependency (mean 3.1/6) "High" IADL Dependency (mean 5.5/6)	Total number of problem behaviors (from 29-item MBPC + 4 related behaviors) (higher score=greater number of problem behaviors)	1) 20.3 (5.4) (n=93) 2) 18.7 (6.3) (n=78)	3 months 1) 17.2 (7.7) (n=93) 2) 14.4 (9.8) (n=78) p=0.11 between groups Adj mean diff=1.85 (95%CI -0.42, 4.13)	NR
Jirovec, 2001[58] 1) Intervention – scheduled toileting (N=77) 2) Control "friendly" monthly call only (N=41) Note: 2 intervention groups (visits every 2 or 6 months) combined for analysis due to no differences between groups	Memory impairment	NR	% Urinary Incontinence (UI) (incontinent episodes divided/ total voiding episodes)	1) 43% (23%) (n=44) 2) 47% (31%) (n=30) p=NR, ns	1) 37% (28%) (n=44) 2) 49% (36%) (n=30) p=NR	NR
			# patients whose incontinence decreased	NA	1) 28/44=64% 2) 15/30=50% **Z=-1.83, p<0.05**	
McCallion, 1999[68] 1) FVEP (Family Visit Education Program) (n=32) 2) Usual Care (UC) (n=34)	Dementia	Severe impairment – weighted mean MMSE=6.9	MOSES (Multidimensional Observation Scale for Elderly Subjects)	Self-care 1) 24.7 (5.1) 2) 24.0 (5.6) Disorientation 1) 28.6 (6.3) 2) 25.6 (6.2) Irritability 1) 16.7 (6.2) 2) 14.6 (4.7) Withdrawal 1) 23.1 (4.2) 2) 22.4 (5.4)	Self-care 1) 25.0 (5.7) 2) 24.8 (5.8) p=NR, ns **Disorientation** **1) 29.0 (7.8)** **2) 24.5 (7.5)** **p=0.046** Irritability 1) 17.2 (7.3) 2) 14.0 (4.7) p=NR, ns Withdrawal 1) 23.4 (5.4) 2) 21.9 (5.4) p=NR, ns	NA

Study, Year Interventions	Physical Condition	Baseline Functional Level	Measure of Problem Behavior	Baseline	Post-Treatment	Follow-up* (time assessed)
McCallion, 1999[68] (continued)			Cohen-Mansfield Agitation Inventory CMAI Nursing staff report: Likert scale rating resident's behavior over 2 week period Trained study observer version: # behavior observations/20 minute period, while patient was visiting with family member	(n's by group=NR) Physically aggressive behavior *Nurse Staff:* 1) 12.5 (7.1) 2) 10.6 (4.6) *Study observer:* 1) 0.0 (0.0) 2) 0.0 (0.0) Physically non-aggressive behavior *Nurse Staff:* 1) 14.3 (7.6) 2) 10.6 (5.6) *Study observer:* 1) 0.5 (1.4) 2) 0.3 (1.2) Verbally agitated behavior *Nurse Staff:* 1) 10.6 (9.6) 2) 11.6 (7.7) *Study observer:* 1) 1.7 (3.2) 2) 0.5 (1.2)	(n's by group=NR) Physically aggressive behavior *Nurse Staff:* 1) 11.7 (6.1) 2) 9.7 (3.2) p=NR, ns *Study observer:* 1) 0.3 (1.5) 2) 0.0 (0.0) p=NR, ns Physically non-aggressive behavior *Nurse Staff:* 1) 12.5 (7.2) 2) 10.6 (5.2) p=NR, ns *Study observer:* 1) 1.4 (4.4) 2) 1.1 (6.0) p=NR, ns Verbally agitated behavior *Nurse Staff:* 1) 13.9 (8.6) 2) 10.6 (7.5) p=NR, ns *Study observer:* 1) 1.9 (3.8) 2) 0.9 (2.0) p=NR, ns	NA

Study, Year Interventions	Physical Condition	Baseline Functional Level	Measure of Problem Behavior	Baseline	Post-Treatment	Follow-up* (time assessed)
McCurry 2005[61] 1) Nighttime Insomnia Treatment and Education for Alzheimer's Disease (NITE-AD; n=17) 2) Supportive contact control (n=19)	Alzheimer's disease	Community-dwelling and ambulatory; dementia for 5.8 years on average; Mini-Mental State Exam of 11.8 on average	RMBPC – ***Disruption****** (Average frequency of behaviors over past week)	1) 1.1 (0.7) (n=17) 2) 1.0 (0.5) (n=19)	1) 0.8 (0.6) (n=13) 2) 0.8 (0.6) (n=16)	1) 0.9 (0.6) (n=11) 2) 0.7 (0.6) (n=12) (6 months)
			RMBPC – ***Memory****** (Average frequency of behaviors over past week)	1) 3.3 (0.6) (n=17) 2) 2.9 (1.0) (n=19)	1) 3.1 (0.6) (n=13) 2) 2.6 (0.9) (n=16)	1) 3.2 (0.6) (n=11) 2) 2.6 (0.8) (n=12) (6 months)
			Sleep activity: Night wake time (hours)	1) 1.9 (1.4) (n=17) 2) 1.6 (1.3) (n=19)	1) 1.1 (0.9) (n=13) 2) 1.6 (1.0) (n=16) p<0.05	**1) 1.2 (0.8) (n=11) 2) 1.8 (1.8) (n=12) (6 months) p=0.03**
			Number of night awakenings	1) 12.4 (11.6) (n=17) 2) 9.9 (7.9) (n=19)	1) 7.1 (6.4) (n=13) 2) 11.3 (7.6) (n=16) p=0.09	**1) 8.2 (7.1) (n=11) 2) 12.2 (11.3) (n=12), p=0.01**
			Percentage of time asleep (sleep hrs/time in bed)	1) 79.9 (12.4) (n=17) 2) 83.1 (11.1) (n=19)	1) 87.6 (9.4) (n=13) 2) 83.9 (9.0) (n=16) p=0.19	1) 85.9 (9.3) (n=11) 2) 82.4 (16.2) (n=12), p=0.12
			Wake index (wakes/hour)	1) 2.6 (5.4) (n=17) 2) 1.4 (1.1) (n=19)	1) 0.9 (0.8) (n=13) 2) 1.5 (1.1) (n=16) p=0.14	**1) 1.1 (1.1) (n=11) 2) 1.5 (1.4) (n=12) p=0.03**
			Duration of night awakenings (minutes)	1) 8.2 (1.7) (n=17) 2) 7.6 (1.1) (n=19)	1) 8.0 (2.0) (n=13) 2) 7.9 (1.2) (n=16) p=0.26	**1) 8.0 (2.0) (n=11) 2) 8.3 (1.6) (n=12) p=0.04**
Mittelman 2004[54] 1) Multicomponent intervention (n=203) 2) Usual care (n=203)	Alzheimer's disease	Global Deterioration Scale baseline of 4 = 33%; 5 to 7 = 67% (moderate to moderately severe)	Frequency of Problem Behaviors - Memory Behavior Problems Checklist (MBPC) (sum of 5 point Likert scale for 29 troublesome behaviors; higher score indicates greater frequency	**1) 41.2 (18.3) (n=203) 2) 46.7 (19.4) (n=203) p=0.004**	NR	NR; p=NR but "virtually no differences reported" Growth model: Group 1) vs 2) t=0.19, p=0.8469 Group x time: t=-0.04, p=0.9695
Ostwald, 1999[50] 1) Minnesota Family Workshop (MFW) (n=72) 2) Workshop wait list (n=45)	Dementia	Signs of mild to severe dementia	RMPBC – disruptive behavior subscale	1) 6.8 (5.8), n=52 2) 5.3 (4.1), n=31 p=NR	1) 6.2 (5.3), n=52 2) 4.9 (3.5), n=31 Intervention effect: p=0.43 Intervention by time: p=0.08	

Study, Year Interventions	Physical Condition	Baseline Functional Level	Measure of Problem Behavior	Baseline	Post-Treatment	Follow-up* (time assessed)
Quayhagen 2000[62] 1) Cognitive stimulation (n=21) 2) Dyadic counseling (n=29) 3) Dual supportive seminar (n=22) 4) Early day care (n=16) 5) Wait list (n=15)	Dementia (possible or probably Alzheimer's disease, or cardio vascular multi-infarct)	Mild to moderate	MBPC part A (Zarit et al., 1985)	1) 21.8 (SE=3.2) 2) 22.0 (SE=2.4) 3) 24.8 (SE=3.5) 4) 27.8 (SE=4.2) 5) 25.4 (SE=5.1) p=ns	3 months (1 month post-tx) (n=103) 1) 22.3 (SE=3.7) 2) 22.0 (SE=2.7) 3) 25.2 (SE=3.6) 4) 30.5 (SE=4.5) 5) 25.9 (SE=5.4) p=ns	NR
Robison 200753** 1) Partners in Caregiving in the Special Care Unit Environment (PIC-SCU) (n=209) 2) Control unit (n=179)	Dementia	All institutionalized at specialized skilled nursing facilities	Cohen-Mansfield Agitation Inventory (CMAI) (5 point scale, 1 = resident never engages in specific behavior, 5 = manifests behavior on average several times/hour). *7 of 14 behaviors on CMAI reported; remaining 7 behaviors not shown (treatment group showed more improvement than control group, however, differences between groups non-significant)* *repeated measures analyses (not single time point comparisons)*	N=561 total (n by group NR); all p=NR Cursing or verbal aggression 1) 1.84 2) 1.74 Other aggression, self-abuse, or sexual advances 1) 1.35 2) 1.23 Inappropriate dress or disrobing 1) 1.41 2) 1.20 Constant requests for attention or help 1) 1.76 2) 1.63 Grabbing people, destroying property 1) 1.46 2) 1.49 Pacing, wandering 1) 1.35 2) 1.23 Restlessness 1) 2.05 2) 1.80	NR	NR
Wright 200167 1) Education and counseling (n=68) 2) Usual care (n=25)	Alzheimer's disease	Moderate loss of memory; enrolled following in-patient treatment for agitation	Cohen-Mansfield Agitation Inventory (CMAI) (higher score=greater agitation)	1) 65.9 (21.9) 2) 74.1 (21.4) p=0.13	1) NR 2) NR Controlling for dementia rating - group x time p=0.52	NR

*Last follow-up reported only if > 6 months post-treatment

**Note: Unit of intervention is the facility special care unit – not individual family members. N's above reflect family members of residents living on the unit that participated. CMAI outcome reported for ALL patients on randomized units, regardless of whether or not the patient's family members participated in intervention.

***Data obtained from author

[1]Univariate analyses of covariance, with baseline measures of HbA1c, FBP and diabetes knowledge as covariates (no significant differences between groups at baseline)

ES=effect size; NR=not reported; ns=not statistically significant

Table 14. Memory-Related Disorders – Patient Depression/Anxiety

Study, Year Interventions	Physical Condition	Baseline Functional Level	Assessment Tool	Baseline	Post-Treatment	Follow-up* (time assessed)
Gitlin 2008[74] 1) Tailored Activity Program (TAP) (n=30) 2) Wait list (N=30)	Dementia	MMSE <24; able to feed self and participate in ≥ 2 self-care activities; baseline mean MMSE=12 (moderate)	Cornell Scale for Depression in Dementia (CSDD); sum of combined ratings of patient and caregiver (0=not present, 2=severe)	1) 9.2 (5.1) (n=27) 2) 8.1 (4.5) (n=29)	4 Months 1) 9.0 (4.6) (n=27) 2) 8.7 (4.7) (n=29) p=0.34 between groups	NR
Logsdon, 2010[63] 1) Early Stage Memory Loss (ESML) (n=96) 2) Wait list (WL) (n=46)	Dementia	Early stage Alzheimer's and dementia; (inclusion criteria MMSE ≥ 18; mean for enrolled patients was 23.4)	Geriatric Depression Scale (GDS) (higher score indicates higher level of depression)	1) 5.3 (3.5) (n=96) 2) 5.3 (3.4) (n=46)	1) 5.1 (3.5) (n=92) 2) 5.9 (4.0) (n=44) **p<0.01; β=-1.34** **Effect size=0.36**	NR
McCurry 2005[61] 1) Nighttime Insomnia Treatment and Education for Alzheimer's Disease (NITE-AD; n=17) 2) Supportive contact control (n=19)	Alzheimer's disease	Community-dwelling and ambulatory; dementia for 5.8 years on average; Mini-Mental State Exam of 11.8 on average	Revised Memory and Behavior Problems Checklist (RMBPC) – depression (average frequency of behavior over 1 week)	1) 1.1 (0.6) (n=17) 2) 0.8 (0.6) (n=19) ns	**1) 0.8 (0.6) (n=13)** **2) 0.7 (0.7) (n=16)** **Comparisons between pre to post-treatment change scores** **p=0.04**	**6 months** **1) 0.9 (0.7) (n=11)** **2) 0.9 (0.9) (n=12)** **p=0.007**
			Cornell Depression Scale*** (8+=mild depression; 12+= moderate depression)	1) 9.2 (5.0) (n=17) 2) 7.1 (2.6) (n=19)	1) 7.1 (3.8) (n=13) 2) 6.2 (3.0) (n=16)	1) 7.5 (6.0) (n=11) 2) 7.5 (4.2) (n=12)
McCallion, 1999[68] 1) FVEP (Family Visit Education Program) (n=32) 2) Usual Care (UC) (n=34)	Dementia	Severe impairment – weighted mean MMSE= 6.9	MOSES (Multidimensional Observation Scale for Elderly Subjects) – Depression subscale	1) 19.2 (7.3) 2) 14.6 (6.0) (n by group=NR)	1) 20.8 (7.8) 2) 15.1 (6.6) (n by group=NR) p=NR, ns	NR

Study, Year Interventions	Physical Condition	Baseline Functional Level	Assessment Tool	Baseline	Post-Treatment	Follow-up* (time assessed)
McCallion, 1999[68] (continued)			CSDD (Cornell Scale for Depression in Dementia) - subscales (higher score indicates greater level of depression)	(n by group=NR) Mood-related signs 1) 2.9 (2.1) 2) 2.2 (1.7) Behavioral disturbance 1) 1.3 (1.0) 2) 1.5 (1.3) Physical signs 1) 0.9 (1.2) 2) 0.9 (1.6) Cyclic functions 1) 1.2 (1.4) 2) 1.9 (1.7) Ideational disturbance 1) 0.5 (1.1) 2) 0.2 (0.6	(n by group=NR) **Mood-related signs** **1) 2.6 (2.1)** **2) 2.7 (1.6)** **p=0.003** Behavioral disturbance 1) 1.4 (1.6) 2) 1.4 (1.2) p=nr, ns **Physical signs** **1) 0.5 (1.1)** **2) 1.1 (1.8)** **p=0.024** **Cyclic functions** **1) 0.9 (1.4)** **2) 1.0 (1.3)** **p=0.020** **Ideational disturbance** **1) 0.4 (1.1)** **2) 0.4 (1.0)** **p=0.040**	NA
Teri, 1997[70] 1) Behavior Therapy-Pleasant Events (BT-PE) (n=23) 2) Behavior Therapy-Problem-solving (BT-PS) (n=19) 3) Usual care (n=10) 4) Wait list (n=20)	Alzheimer's disease and depression	Baseline MMSE = 16.5 (moderate)	Hamilton Depression Rating Scale	1) 16.3 (5.3) 2) 16.0 (4.0) 3) 14.1 (4.0) 4) 14.5 (3.5) Group differences=ns	Mean change 1) -5.3 (4.0) 2) -3.8 (2.3) 3) -0.3 (4.7) 4) 0.3 (3.5) 1 > 3 & 4, p<0.01 2 > 3 & 4, p<0.01 1 vs 2=ns	6 months, groups 1 and 2 combined but not compared controls
			Cornell Scale for Depression in Dementia	1) 14.8 (4.2) 2) 15.1 (3.5) 3) 13.9 (4.6) 4) 14.0 (4.2) Group differences=ns	Mean change 1) -4.2 (4.5) 2) -3.7 (3.8) 3) 0.0 (2.0) 4) 0.1 (3.5) 1 > 3 & 4, p<0.01 2 > 3 & 4, p<0.01 1 vs 2=ns	NR

Study, Year Interventions	Physical Condition	Baseline Functional Level	Assessment Tool	Baseline	Post-Treatment	Follow-up* (time assessed)
Teri, 1997[70] (continued)			Beck Depression Inventory	1) 15.5 (7.1) 2) 21.7 (7.9) 3) 17.9 (9.2) 4) 17.1 (8.4) Group differences=ns	Mean change 1) -1.3 (6.3) 2) -4.5 (4.5) 3) 1.9 (5.8) 4) 0.5 (3.5) 1 > 3 & 4, p<0.01 2 > 3 & 4, p<0.01 1 vs 2=ns	NR
			Clinically significant improvement**	NR	1) 52% 2) 68% 3) 20% 4) 20% Overall p<0.005	NR
Teri 2003[12] 1) Reducing Disability in Alzheimer's Disease (n=76) 2) Routine medical care (n=77)	Alzheimer's disease	Baseline MMSE = 16.8 (moderate)	Cornell Scale for Depression in Dementia (higher score indicates greater impairment)	1) 5.7 (3.9) (n=76) 2) 5.8 (4.5) (n=77)	1) 5.2 (3.6) (n=72) 2) 6.2 (3.8) (n=68) **p=0.02**	21 months post-treatment 1) 6.4 (4.5) (n=44) 2) 7.4 (5.0) (n=45) p=0.10 (longitudinal)
			Hamilton Depression Rating Scale (higher score indicates greater impairment)	NR	Only patients with CSDD≥ 6 at baseline: Post-tx (n=NR) 1) improved 2.0 (4.9) 2) declined 0.6 (5.1) Adj mean difference: **2.21 (95% CI, 0.22-4.20), p=0.04**	Only patients with CSDD≥ 6 at baseline: 21 months post-treatment, values NR; Adj mean difference: **2.14 (95% CI, 0.14-4.17), p=0.04**

*Last follow-up reported only if > 6 months post-treatment; [1]higher score indicates higher level of emotion; [2]higher score indicates poorer adjustment
**% no longer meeting criteria for major depression (if major depression at pre-treatment) or no longer meeting criteria for minor or major depression (if minor depression at pre-treatment)
***Data obtained from author
ES=effect size; NR=not reported; ns=not statistically significant

Table 15. Memory-Related Disorders – Hospitalization or Institutionalization

Study, Year Interventions	Physical Condition	Baseline Functional Level	Measure of Hospitalization or Institutionalization	Baseline	Post-Treatment	Follow-up* (time assessed)
Bass, 2003[56] 1) Care consultation (N=109) 2) Usual care (N=73)	Dementia, Alzheimer's disease, memory loss	Not reported	# Emergency Department Visits past 12 months (range 0-5 for total sample)	1) 0.4 (1.0) (n=NR) 2) 0.4 (0.9) (n=NR)	1) 0.5 (1.0) (n=NR) 2) 0.7 (1.1) (n=NR) p=NR, ns	NR
			# Hospital Admissions past 12 months (range 0-4 for total sample)	1) 0.2 (0.6) (n=NR) 2) 0.3 (0.6) (n=NR)	1) 0.2 (0.6) (n=NR) 2) 0.3 (0.6) (n=NR) p=NR, ns	NR
			# Physician Visits past 12 months (range 0-27 for total sample)	1) 2.9 (2.8) (n=NR) 2) 2.9 (2.6) (n=NR)	1) 5.2 (4.0) (n=NR) 2) 5.2 (4.5) (n=NR) p=NR, ns	NR
Belle, 2006[55] 1),Multicomponent (n=323) 2) Attention control (check-in calls) (n=319)	Alzheimer's or related disorders	NR; required to have diagnosed disease	Institutionalization (permanent as reported by caregiver)	NR	1) 4.3% (n=261) 2) 7.2% (n=257) p=0.118 (no difference between groups for any racial/ethnic group)	NR
Brodaty, 2009[59] 1) Donepezil + standard services + psychological caregiver intervention (n=26) 2) Donepezil + standard services (n=26)	Alzheimer's disease	GDS=4.5 (0.55) MMSE=20.7 (5.27) ADCS-ADL=58.1 (13.03) ADAS-Cog=26.8 (10.79) RMBPCL=10.98 (7.94)	Admitted to nursing home	NR	NR	1) 27% (7/26) 2) 23% (6/26) Mean follow-up = 5.4 years, up to 8.5 years
Mittelman, 2006 [52] 1) Multicomponent intervention (n=203) 2) Usual care (n=203)	Alzheimer's disease	Global Deterioration Scale baseline of 4 = 33%; 5 to 7 = 67% (moderate to moderately severe)	Nursing Home (NH) Placement		NR	At 18 years: 1) 49% (99/203) 2) 55% (111/203) p=0.23
			Median Time to NH placement; Model predicted mean time; Hazard Ratio (HR) with 95% confidence interval			At 18 years: 1) 1,766 days (n=203) 2) 1,181 days (n=203) Univariate unadjusted: HR=0.71 [95%CI 0.54, 0.94], p=0.015 Multivariate baseline adjusted: HR=0.72 [95%CI 0.54, 0.96], p=0.024

Study, Year Interventions	Physical Condition	Baseline Functional Level	Measure of Hospitalization or Institutionalization	Baseline	Post-Treatment	Follow-up* (time assessed)
Teri, 2003[12] 1) Reducing Disability in Alzheimer's Disease (n=76) 2) Routine medical care (n=77)	Alzheimer's disease	Baseline MMSE = 16.8 (moderate)	# patients institutionalized	NR	NR	21 months post-tx For any reason: 1) 21/76 (28%) 2) 22/77 (28%) p=0.84 Due to behavior problems of pt: 1) 4/76 (5%) 2) 11/77 (14%) p=NR Pt impairment/illness: 1) 4/76 (5%) 2) 4/77 (5%) p=NR Due to increased ADL impairment: 1) 5/76 (7%) 2) 6/77 (8%) p=NR Due to ill health or death of caregiver: 1) 8/76 (10%) 2) 1/77 (1%) p=NR
Wray, 2010[49] 1) Telephone Education Program (n=83) 2) Usual care (n=75)	Dementia	At least moderate level	Total admissions	1) 0.4 (0.9) 2) 0.3 (0.9)	1) 0.4 (0.9) 2) 0.5 (0.9) Time effect: p=0.02 (baseline to intervention period; no difference between groups; no interaction)	1) 0.4 (0.9) 2) 0.2 (0.5)
			Acute admissions	1) 0.2 (0.6) 2) 0.2 (0.6)	1) 0.2 (0.7) 2) 0.2 (0.6) p=ns	1) 0.2 (0.9) 2) 0.1 (0.6) p=ns
			ICU admissions	1) 0.0 (0.1) 2) 0.0 (0.0)	1) 0.0 (0.2) 2) 0.0 (0.2) p=ns	1) 0.0 (0.2) 2) 0.0 (0.0) p=ns
			Nursing home admissions	1) 0.2 (0.7) 2) 0.1 (0.4)	1) 0.1 (0.4) 2) 0.2 (0.6) p=ns	1) 0.2 (0.5) 2) 0.1 (0.3) p=ns

Study, Year Interventions	Physical Condition	Baseline Functional Level	Measure of Hospitalization or Institutionalization	Baseline	Post-Treatment	Follow-up* (time assessed)
Wray, 2010[49] (continued)			Outpatient visits	1) 12.5 (13.5) 2) 14.6 (16.5) p=ns	1) 11.2 (12.9) 2) 14.1 (16.5) p=ns	1) 12.4 (14.8) 2) 13.4 (17.4) Time effect: p=0.03 (baseline to follow-up; no difference between groups; no interaction)
Wright, 2001[67] 1) Education and counseling (n=68) 2) Usual care (n=25)	Alzheimer's disease	Moderate loss of memory; enrolled following in-patient treatment for agitation	% Institutionalized	NR	12months 1) 28% (17/61) 2) 22% (5/23) p=ns	NR
			# days at home before institutionalization	NA	NR	12 months post baseline: 1) 121 (107.6) Range: 5-362 2) 126 (110.5) Range: 5-360 p=0.891

*Last follow-up reported only if > 6 months post-treatment

ES=effect size; NR=not reported; ns=not statistically significant