

MODERATING VARIABLES IMPACTING ADHERENCE TO
THE REDUCING DISABILITY IN DEMENTIA (RDAD) INTERVENTION

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Abstract

Moderating Variables Impacting Adherence To The Reducing Disability In Dementia

(RDAD) Intervention

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Purpose: Current evidence demonstrates the superior efficacy of non-pharmacologic psychosocial interventions to address the impacts of dementia for both the person with dementia (PWD) and caregiver. The Reducing Disability in Dementia (RDAD) intervention capitalizes on the benefits of both behavioral skill training and exercise, and is currently being implemented in the community via a translational trial. Exploration of moderating variables furthers the mission of translational science by evaluating who will benefit most, allowing for improved clinical application and efficient resource allocation. This study sought to explore how dyad characteristics may impact the most proximal measures of the intervention, adherence to the targets that theoretically lead to improved outcomes; physical activity, pleasant events, and behavioral modification plans.

Methods: A hierarchical regression approach was used to evaluate how the variables of caregiver gender, baseline depression, behavioral burden, PWD gender, baseline cognitive impairment, behavioral disturbance, and dyad relationship affect adherence to two of the key targets of the intervention, pleasant events and attempting behavioral plans. Due to the over-dispersion of the physical activity adherence outcome a negative

binomial regression was applied to evaluate the same participant factors on adherence to physical activity.

Results: The sample PWDs had a mean age of 81, gender was 51% male, mean (SD) Mini-Mental State Exam (MMSE) score was 15.48 (7.17); indicating a broad range of cognitive impairment. Informal caregiver mean age was 69, were predominately female (74%), 64% were spouses, 29% were adult children, and the remaining 7% of caregivers were friends or other relatives. Neither caregivers nor PWD factors significantly moderated adherence to pleasant event frequency. Completion of behavioral plans was significantly moderated by PWD gender and cognitive impairment, $b = 0.11$, $SE = 0.05$, $t_{(177)} = 2.26$, $p < 0.05$; PWD gender and relationship to the caregiver $b = -4.84$, $SE = 2.24$, $t_{(177)} = -2.16$, $p < 0.05$; and dyad relationship and behavioral disturbance $b = -2.62$, $SE = 1.07$, $t_{(177)} = -2.46$, $p < 0.05$. The impact of RDAD on increases in physical activity was significantly moderated by PWD gender $\chi^2 = 3.77$, $p=0.05$; cognitive impairment $\chi^2 = 8.03$, $p<0.05$, and behavioral disturbance $\chi^2 = 9.91$, $p<0.01$.

Conclusion: These results suggest PWD factors impact adherence to the physical activity and behavioral plan components of RDAD, while caregiver factors have no significant influence. This is one of the first studies to identify which member of the dyad exerts more influence on intervention uptake. The implications for future intervention refinement and clinical application are substantial.

INTRODUCTION

Currently 13% of the US population is over the age of 65; by 2030, in less than 20 years, 1 in 5 Americans will be over the age of 65 (Federal Interagency Forum, 2011). With this rapid increase in the older adult population, the incidence of dementia and cognitive impairment will rise. The 2010 census prevalence estimates projected the incidence of dementia to triple to 13.8 million people with Alzheimer's disease (AD) by 2050 (Hebert, et al 2013). The combination of cognitive impairment, anxiety, and depression present in dementia can lead to a constellation of challenging behaviors, increasing the level of disability for the individual and the burden of care for families and professional caregivers. Considering the lack of pharmacologic efficacy to address the symptoms of dementia (Ballard et al., 2005; Gareri, et al. 2013), the exploration of non-pharmacologic interventions is critical to the care of those living with dementia.

Efforts to address this growing need have produced multiple efficacious interventions to support both the person with dementia (PWD), and the caregiver. The evidence suggests interventions that focus on comprehensive caregiver skill building provide significant improvements for both the PWD and the caregiver, or dyad (Kales, et al. 2014; Olazaran, et al. 2010;). In addition to skill building, physical activity offers benefits to both members of the dyad; preservation of physical function benefits both the PWD and the person providing care by reducing the physical care demands, and evidence also suggests physical activity can attenuate the behavioral and psychological symptoms of dementia (BPSD) (de Souto Barreto, et al. 2015). The Reducing Disability in Dementia (RDAD) intervention capitalizes on the benefits of each strategy by combining

behavioral skill training and exercise into a program to improve outcomes for the dyad (Teri, et al. 2003).

RDAD, like many efficacious interventions, is currently undergoing a large-scale translational trial. The next step in the process of moving these interventions to the community so that they can benefit those for whom they were developed is translational, or dissemination and implementation, research. We know well that therapy “works,” i.e., is responsible for change, but have limited empiric knowledge of why, or how, and for whom it works best (Fixsen, et al. 2009). Conceptually, moderators identify on whom and in what circumstances treatments have different effects. There is a small increase in the current observational literature exploring the impact of moderating variables for PWDs and caregivers. This information advances the field, and suggests targets for intervention development.

Currently, there is a lack of research into the moderating variables that impact response to interventions for dyads living with dementia. Moderating variables can inform future intervention work by identifying which factors strengthen or weaken intervention impacts, and who will benefit most. Furthermore, there appears to be no published evidence exploring which member of the dyad may exert more influence in the response to an intervention. This information would serve both a theoretical and practical purpose; theoretically, finding that one member of the dyad has more impact would provide guidance to refine intervention targets and methods. From a clinical perspective, this would allow treatment choice to be targeted accordingly. This secondary analysis of data from the RDAD implementation trial involved exploration of potential PWD, caregiver, and dyad moderating factors that influence adherence to key targets of the

intervention, physical activity, behavioral modification, and pleasant events. The aims of this study were:

- To evaluate the impact of Caregiver factors on adherence to exercise frequency, behavioral plan implementation, and application of pleasant events with the PWD
- To evaluate the impact of PWD factors on adherence to the same intervention components
- To evaluate which member of the dyad demonstrates more predictive value in adherence to the intervention components

LITERATURE REVIEW

Theory

Scientific interventions should be built upon sound theoretical foundations (Pillemer, et al. 2003). Theory can inform interventions in a number of ways, from identifying theoretical constructs to be targeted (self-efficacy) or mechanisms underlying particular behavior change techniques (learning via modeling), to selecting participants most likely to benefit (PWDs with high levels of BPSD). Theories and models, validated within the field, provide rationale for selection of specific intervention strategies to achieve an objective. Hypotheses, interventions, and randomized controlled trials (RCTs) can be designed around the theories that drive selection of specific methods or strategies based on targeted changes. Behavioral theory and social learning theory are the most prevalent, and tested, theories used in dementia care research. These two models provide the theoretical basis of most structured caregiver training in evidence today.

The seminal behavioral theories began with Pavlov, Watson, and Skinner's work defining behavior and operant conditioning. Bandura (1977) advanced the concept with Social Learning Theory, which combines both cognitive and behavioral frameworks to explain the evolution of behavior. His theory utilizes a three-part description of "person," "behavior," and "environment" interacting dynamically in a process called "reciprocal determinism". Social Learning Theory introduces the construct known as self-efficacy (confidence in one's ability to do a specific task), which influences the effort a participant is willing to expend to achieve a goal. Social Learning Theory is used as a framework for imparting skills to caregivers of persons with dementia, while more rudimentary behavioral principles are taught directly to caregivers to improve their ability to manage and cope with challenging aspect of care, thereby affecting outcomes for both members of the dyad. Use of behavior change theories and models when designing and implementing dementia care interventions and protocols enables scientists to leverage proven strategies to enhance intervention effectiveness. These theories provide the rationale for individualizing interventions to meet the needs of dyads who may demonstrate varying degrees of motivation, confidence, environmental support, and skills.

There are several theoretical strategies that can be used in an intervention to facilitate adoption of skills and enhance self-efficacy. According to Bandura (1977) the following strategies facilitate the learning process: observational learning, sequential goal setting, task breakdown, and skill development training. Using the principles of social learning, interventions can help caregivers engage in 'behavioral rehearsal' by simulating a behavioral situation and talking the scenario through; they can also model the behavior

with the PWD. A majority of the current efficacious interventions to support caregivers working with PWDs, either informal or professional caregivers, utilize these theories (Kasl-Godley & Gatz, 2000; Ostwald, et al. 1999; Wisniewski, et al. 2003).

Behavior Analysis/Modification theories (Bandura, 1969; Skinner, 1984) postulate a method to alter behavior/consequence relationships in such a way as to strengthen adaptive and weaken maladaptive behaviors. These theories give relatively more credence to quantifiable observable behaviors and their environmental determinants and question the scientific relevance of cognitive processes such as knowledge, attitudes, and emotions. This focus on observable events and antecedent/consequence methods is ideally suited for care of those with dementia and management of challenging behaviors. The premise of behavior modification as an approach to dementia care focuses on observable behaviors; this involves identifying the antecedent for a targeted behavior and evaluating the consequences for those in the environment, then establishing a desired replacement behavior, and developing consequential strategies to change such behavior. In the “triple-term contingency,” antecedent stimuli set the stage for the behavior, which in turn is strengthened or weakened by the reinforcing or punishing consequences. Once the caregiver has been taught the skills to address a problematic behavior, they can then identify and work towards reinforcement for appropriate behavior (and extinguish problem behavior).

Another key theoretically based component of many interventions for dyads living with dementia are Lewinsohn’s Behavioral Therapy (BT) approaches (Lewinsohn & MacPhillamy, 1974; Lewinsohn, Sullivan, & Grosscup, 1982). These techniques are focused on increasing pleasant interactions, decreasing unpleasant interactions, and

developing skills necessary to alter the environment to obtain positive outcomes (Teri & Logsdon, 1990). When the caregiver acquires these various theoretically based skills, he/she is then free to select those approaches that will ensure continued improvement in managing challenging behaviors, thus creating an individualized program.

INTERVENTION SCIENCE

Caregiver Skill Building/Behavioral Interventions

Development of interventions to support persons with dementia and their caregivers has continued to evolve for more than forty years. Initially many interventions focused on the person with dementia (PWD) and separately provided social support for the caregivers. With exploration of dyad dynamics and progressive understanding that the caregiver is the primary source of a PWD's environment and engagement with the world, a shift began towards intervention components aimed at skill building for caregivers. Since that time scientists have demonstrated interventions that offer active solutions (skill-building, behavioral problem-solving, activities, and environmental adaptation) are more effective than passive interventions that provide only education and therapeutic listening (Ayalon, et al. 2006; Brodaty, et al. 2003).

The body of literature available demonstrates a dramatically increasing focus on interventions to prepare/train caregivers to acquire the skills to address care needs of the PWD, manage behavior, and attend to their own psychological needs and self-care. Rosa and colleagues (2010) found that a majority of caregivers surveyed desired education about communication and behavioral management strategies. Considering the lack of pharmacologic efficacy for the most challenging symptoms of dementia, and the significant risks to morbidity and mortality for the PWD (Ballard et al., 2005; Gareri, et

al. 2013), the exploration for non-pharmacologic interventions based in established theory and tested with rigorous scientific method is critical to the advancement of the field, not to mention the care of those living with dementia. These skill building interventions in turn improve outcomes for both members of the dyad by reducing dementia related behaviors, improving depression and anxiety for both, ameliorating burn-out, and maintaining care continuity. The caregiver is typically targeted for training in the use of behavioral strategies, as they have the greatest control of the environment, and it is their response to the PWD that has the most potential to effect change.

The research into these interventions is expanding, demonstrating that firm theoretical foundations and established efficacy of intervening at the caregiver level lead to improved outcomes for the dyad. Twenty-eight studies, meeting Administration on Aging criteria for ‘evidence-based’, investigating caregiver training interventions have been published in English language peer-reviewed journals in the past 15 years and were reviewed (Table 1). Increasing numbers of these interventions are undergoing more rigorous trials to test their efficacy and effectiveness for both PWDs and caregivers, reaching beyond pilot studies and moving to full scale multi-site randomized controlled trials with large sample sizes, and a select few have progressed to translational projects that seek to disseminate and implement the intervention into the “real world”.

An overwhelming majority of the programs focus on the family caregiver. However, given the significant differences in the caregiving skills needed and experience of family caregivers vs. professional staff the available literature is divided here into family caregiver and professional caregiver training interventions. Twenty-three of the trials focused on the informal caregiver/PWD dyad living in the community; of these 15 were

delivered individually, while the others employed either a hybrid of group and individual sessions, solely group format, or a DVD based format. Dose was even more variable than the delivery method; most family caregiver interventions were delivered over a 6-12 month period, frequency was generally weekly or biweekly, and the majority had a session duration of 1-2 hours. When evaluating specific features of the programs, several similarities emerge. An overwhelming majority include training on behavioral modification strategies, problem-solving, and communication (Burgio, et al. 2003; Hepburn, et al. 2007; Teri, et al. 2005). Many include content designed to provide information/education about dementia and the disease process, training to address environmental adjustments/adaptations, safety issues, and pleasant events (Gitlin, et al. 2010; Huang, et al. 2003; Teri, et al. 2003). The most frequently included content aimed at improving the caregivers' coping skills featured techniques to address stress, strategies to self-manage mood, methods to improve social or support engagement, and cognitive restructuring processes (Kurz, et al. 2010; Teri, et al. 2005a; Ulstein, et al. 2007).

Approximately half of the programs incorporated content aimed at supporting both the PWD and the caregiver, and the remaining programs focused only on skills related to caring for the PWD and family caregiver stress and coping. Training aspects aimed to improve caregiving skills included (in order of frequency included); behavioral modification strategies, education about dementia and the disease process, training to address environmental adjustments/ adaptations and safety, pleasant events, problem-solving skills, communication, and recognizing physical symptoms. Content aimed at improving the caregiver's coping skills included techniques to address stress or burden, strategies to self-manage mood, methods to improve social or support engagement,

cognitive restructuring processes, and self-care monitoring.

Outcomes evaluated in many of the trials reflect the multivariate goals of training. While the intervention focus is the caregiver, the PWD is the primary focus of outcomes, continuing the concept that the caregiver is the catalyst for change for the PWD. Principal outcomes in many of the trials are behavioral and psychological symptoms of dementia (BPSD), further support that management of these distressing symptoms can improve other outcomes for the dyad. Additional PWD outcomes measured include mood, functional status, quality of life, agitation/anxiety, and sleep (Farran, et al. 2004; Graff, et al. 2007; McCurry, et al. 2005). Caregiver outcomes are evaluated with equal frequency, again reflecting the dual task of caregiver training programs. The most frequent outcomes are caregiver burden and mood, in addition to self-efficacy/confidence, quality of life, social engagement, health, and sleep (Gonyea, et al. 2006; Liddle, et al. 2012; Moore, et al. 2013). Many currently utilized measurements are highly validated and reliable to address the specific constructs that are important to dementia care and assessment of the dyad, further supporting increasingly rigorous scientific testing of these interventions. While early research in this area focused on institutional placement rates as a principal outcome, the recent published research appears to be moving away from this as a primary end point; only 2 of the 28 trials included this outcome.

The most frequently impacted outcomes reaching significance were caregiver mood, burden, caregiver self-efficacy/confidence, BPSD, and PWD mood (Martin-Carrasco, et al. 2009; Moniz-Cook, et al. 2008; Teri, et al. 2003). Many programs were able to significantly impact outcomes for both the caregiver and the PWD. Dosing of the more

successful programs appears to average 5-10 sessions of 60-90 minutes delivered individually over 6 months. Intriguingly, those training programs that focus on components aimed at building caregiving skills had the most significant impact on both members of the dyad. These effective interventions share several components: behavior management skills, environmental adaptations/safety, general problem-solving, communication, pleasant events, and self-care/coping for the caregiver. Delivery of a program that can impact both members of the dyad is a more efficient use of resources.

Five of the trials evaluated training programs for formal caregivers, or direct care workers (DCW), in a variety of long-term care residential settings; all but two were reportedly delivered in group training format (Finnema, et al. 2005), one with individual consults with adult family home staff (McCurry, et al. 2012), and the STAR program (Karlin, et al. 2013; Teri, et al. 2005) was delivered in a hybrid format using interactive group workshops and individualized consultations. Dosing was also variable across this field; program duration was between 4 weeks and 7 months, session frequency was generally weekly, though ranged between twice weekly and monthly, and duration of workshops/sessions was between 90 minutes and 2.5 days.

All DCW focused programs included skills training targeting behavioral modification skills, communication, and knowledge of the dementia disease process, once again, supporting the theory that improvements in caregiving skills will lead to improvements for the PWD. Four of the five interventions demonstrated significant improvements in PWD BPSD, mood, and sleep (Finnema, et al. 2005; Karlin, et al. 2013; McCurry, et al. 2012; Teri, et al. 2005). All of the trials that evaluated outcomes for the DCW found significant improvements in job satisfaction, stress, and reactions to BPSD; this may lead

to reduced turn-over rates in LTC, and consequently improve continuity of care and overall reduced costs.

The programs reviewed sought to support informal caregivers and DCWs in a variety of ways, including providing skill training in behavioral management, communication, problem-solving and environmental adaptation. Although the caregivers were the focus of treatment, as theorized, outcomes revealed both caregiver and PWD benefits. The most successful caregiver interventions cover specific content and are tailored to the method or site in which treatment is provided.

In summary, interventions to support PWDs and their caregivers are most efficient and effective when the caregiver is targeted and taught theoretically driven skills for dementia care that include behavioral principles, communication, and environmental adaptation. Intervention programs for caregivers of PWDs should be standardized, yet flexible to accommodate the individual complexities of each dyad. They should also have a theoretical and scientific foundation while being clinically relevant and applicable for translation into practice (Teri, et al. 2005). The current published review literature has similarly concluded that successful caregiver interventions are dependent on content features and delivery format; multi-component programs that can be individualized to the needs of the dyad and include content focusing on caregiving skills, such as behavioral problem solving, environment, and communication are superior to information and/or support alone (Ayalon, et al. 2007; Brodaty, et al. 2003; Kales, et al. 2014; Logsdon, et al. 2007; Olazaran, et al. 2010; Parker, et al. 2008)

Physical Activity

Substantial evidence has demonstrated the multiple benefits of physical activity (PA) for older adults, showing improvements in both physical and mental health outcomes (Lautenschlager, et al. 2008; Liu & Latham, 2009). These impacts extend to most physiologic systems; cardiovascular and respiratory capacity are increased, leading to improved perfusion to the brain and strengthening of skeletal muscle (Lavie, et al. 2015). There are well established benefits to hormonal balance and regulation of the HPA-axis in response to stressors that can impair cognition and mood (Archer, et al, 2014). Regular PA has demonstrated reductions in oxidative stress and circulating levels of C-Reactive Protein, indicating reduced inflammation in the body and protection from its damaging effects (Lavie, et al. 2011). Circulating cholesterol is reduced by regular PA, in addition to a healthy diet (Ribeiro, et al. 2015). Vascular risk factors including high cholesterol levels increase the risk of cognitive decline (McGuinness, et al. 2016). Based on the evidence of the physiologic benefits of exercise, or regular physical activity, it is not surprising that PA is an accepted protective factor against cognitive decline (Bherer, et al. 2013), and can promote neurologic plasticity (Kempermann, et al. 2010).

Recently, a growing body of evidence has emerged to support the effectiveness of physical activity interventions to attenuate the biologic, psychological, and functional progression of dementia (de Souto Barreto, et al. 2015). As early as 2003, Toulotte and colleagues demonstrated fall reduction and improved balance using a physical activity intervention that targeted endurance, flexibility and balance in demented, frail elderly participants compared to controls. Interventions that focus on exercise components have demonstrated significant impact on multiple outcomes: mood, behavior, sleep, ADLs, mobility, and balance for the PWD, as well as caregiver burden. Eighteen studies of

physical activity interventions were reviewed: Thirteen randomized controlled trials (RCT) (two publications from the same intervention trial), one non-randomized controlled trial, two quasi-experimental designs with controls, and two pilot pre-post studies (Table 2). Advancement into the investigation of this area is demonstrated by the substantial number of RCTs, providing increased rigor and strength of the evidence available. Studies were excluded if details of the intervention were not specified, the trial used non-validated measures, or the sample size was less than ten per cell. Of the studies that utilized a control condition, seven were ‘usual care’, seven used attention controls, and three included an alternate treatment arm. Seven of the evaluated trials had samples larger than one hundred subjects. The majority of interventions were conducted in long term care settings (nine) and were implemented in groups (seven), two of the interventions in long term care were designed for the individual, and four group exercise programs were delivered in the community. The five remaining interventions were delivered as individual oriented interventions with the primary caregiver in the community.

Eleven of these interventions were comprehensive in nature, incorporating aerobic/endurance exercise with strength/flexibility/balance activities in an intervention program, while three programs focused on walking, two on dance-type activity, and the remaining trialed yoga and an in-home exercise machine focused intervention. It is worth noting that three of the physical activity interventions were combined with adjunct psychosocial interventions. There appears to be a consensus regarding ‘dose’ or duration of activity session; all but one of the interventions utilized between a 30-60 minute duration, with ten using 30 minute sessions, and the other seven employing 45-60

minutes per session; the remaining program employed a 2 hour session. Frequency is also somewhat consistent across the field; an overwhelming thirteen of the eighteen programs are delivered three or more times per week, while only three were twice per week, and two programs were delivered weekly. Intervention length was more variable; one study lasted less than 4 weeks, thirteen of the interventions lasted between 5-16 weeks, and four were long term intervention trials lasting greater than 6 months.

Primary outcomes were generally multiple and variable across the field; a strength of the recent literature is the use of validated measures to evaluate outcomes. The two most common outcomes evaluated were mood (eight) and ADL function (eight), followed by behavior (seven), caregiver burden (five), sleep (two), quality of life (two), motor performance and balance (two), cognitive function (two), and agitation (two). The measures used to determine these conceptual outcomes were even more variable. Across studies the most common measure was the Cornell Scale for Depression in Dementia (CSDD), seven out of eight used this measure; additional measures of mood included the Montgomery-Asberg Depression Rating Scale and the Hamilton Rating Scale for Depression. The Neuropsychiatric Inventory was a common measure for behavior, in addition to the Revised Memory and Behavior Problem Checklist. The use of thirty-seven different measures to evaluate outcomes illuminates the variety of instruments available in the field of physical activity intervention with persons with dementia. It is interesting to note that while the primary focus of these interventions was physical activity, only two of these trials evaluated a physical function as an outcome and eight utilized a measure of ADL function. The decline in physical function for PWDs

contributes significantly to caregiver burden, therefore evaluation of improvement or stability of physical performance in these interventions is an important outcome.

Fourteen of these studies found significant impacts on the outcomes discussed with a variety of physical activity interventions. The most successful programs were the comprehensive interventions, such as the Reducing Disability in Alzheimer's Disease (RDAD) intervention (Teri, et al. 2003) focusing on reducing the decline in physical function of persons with dementia and improving affect by training informal family caregivers to engage the person with dementia in a program of exercise that encompasses endurance, strength, balance, and flexibility for 30 minutes each day. The most significant findings from physical activity interventions were benefits in ADL function (Aman & Thomas 2008; de Andrade, et al, 2013; Hauer, et al. 2012; Pitkala, et al. 2013; Roach, et al. 2011; Rolland, et al. 2007; Steinberg, et al. 2009; Teri, et al. 2003), and four demonstrated impact on mood (Edwards, et al. 2008; Stella, et al. 2011; Teri, et al. 2003; Williams & Tappen 2008). Comprehensive programs showed reductions in anxiety/agitation (Aman & Thomas 2008; Edwards, et al. 2008), impacted behavioral symptoms (Holthoff, et al. 2015; Stella, et al. 2011), improved cognitive function (de Andrade, et al. 2013), and found improvement in quality of life (Conradsson, et al. 2010). All of the comprehensive programs were delivered a minimum of 2 times weekly, and for 30-60 minutes each session, one was delivered for 120 minutes.

The yoga intervention program (Fan & Chen, 2011) also demonstrated significant improvements in mood, physical function, and behavior with delivery 3 times per week for 55 minutes. The dyad focused walking intervention (Lowery, et al. 2014) demonstrated only improvements in caregiver burden, but no significant improvement in

BPSD. Of the two walking intervention trials targeting sleep, McCurry and colleagues (2011) demonstrated improvements in sleep, while Eggermont, et al. (2010) did not find significant measurement impact. The dance interventions did not demonstrate significant change in the measured outcomes of behavior. Of the five interventions delivered to the PWD and family caregiver dyad in the community, two demonstrated reductions in caregiver burden (Lowery, et al. 2014; Stella, et al. 2011)

The published literature in physical activity intervention research with persons with dementia demonstrates a move towards increased methodological rigor, with larger sample randomized controlled trials in the most recent publications. The outcome data provided in these studies may further inform the development and translation of effective physical activity interventions for persons with dementia and their caregivers. The benefits for the caregiver are substantial, supported by the significant number of trials that were able to show PWD improvements in functional dependence and BPSD, two factors that contribute significantly to caregiver burden, increased care costs (Hurd, Martorell & Langa, 2013), psychotropic medication use (Grace, et al. 2015), and institutionalization (Buhr, Kuchibhatla, & Clipp, 2006). Consistent with these findings, recent meta-analyses have found that physical activity interventions have been successful in improving or slowing the decline in physical function prevalent in dementia (Pitkala, et al. 2013) and improving affective and behavioral symptoms of dementia (de Souto Barreto, et al. 2015; Thune-Boyle, et al. 2012), as well as mild improvements in cognitive function (Groot, et al. 2016). While much of the current literature has involved examination of mood, function, cognition, and behavioral outcomes, de Souto Barreto and colleagues (2015) observed in a recent meta-analysis that there are scarce data on the

impact of exercise on inappropriate medication use; this suggests more investigation is needed into the far reaching impacts of PA. All of these reviews similarly critiqued the methodological quality of the current studies and called for larger sample sizes, randomized control designs, and examination of broader implications for this type of therapy.

TRANSLATION SCIENCE

General

Scientific inquiry into how to improve the lives of the population has grown dramatically over the past half century. The communities that seek methods to effectively address human need have successfully established a plethora of evidence based interventions aimed at prevention, treatment, and policy advancements. However, the methods to effectively put these interventions into practice, dissemination and implementation, are not nearly as established or rigorous. In other words, the scientific community has an abundant supply of the “what” (evidence-based interventions), and a lack of “how” (evidence-based dissemination and implementation strategies) (Dearing & Kee, 2012). In recognition of this imbalance, the National Institutes of Health (NIH) and other agencies with similar interest in translating effective interventions to improve population health have pushed to advance the science of ‘how’.

Current discourse regarding translational science, also known as dissemination and implementation research or knowledge translation, regards this as an emerging field. However, the concept of moving scientific discovery to “real world” use is not a new pursuit. As early as 1902, Gabriel Tarde and Georg Simmel separately described the phenomenon of innovation adaptation in terms of societal change; identifying the “S-

shaped” curve of adoption. Their individual theories postulated a process by which society and individuals engage in a recursive process towards change (Dearing, 2008). Following this description, anthropologists in the 1920’s began to explore the ‘diffusion’ of ideas and practices; both how these spread through societies, and how culture affected the innovations themselves, a very early incarnation of what we now call “implementation research” (Valente & Rogers, 1995). In 1962 Everett Rogers published the seminal work, *Diffusion of Innovations*, widely considered the impetus for the field of translational research; he outlines the logistic growth curve of implementation; linking macro-level processes of change to the micro-level of human behavior, further supporting the theories of Garde and Simmel.

Current translational research is a multi-dimensional pursuit with several distinct objectives. Deering and Kee (2012) describe two primary objectives for translational research: the dissemination objective is the identification of targets, agencies, organizations, or communities for uptake of a new intervention or program. The implementation objective focuses on understanding what is done with or to the intervention or program in a sample to enhance usability for the target. Additionally, many projects include end-user outcomes to compare with the original trial.

The gold standard in clinical intervention research of the randomized controlled trial (RCT) is useful and critical for discovery and efficacy establishment for new interventions. However, moving these interventions into practice and the process of care within organizations and agencies requires alternate designs to further the rigor for internal and external validity. In a seminal *JAMA* article, Berwick (2008) states that scientific discovery and dissemination and implementations research are “2 great streams

of endeavor with little prospect for merging” and that the goal of each aimed towards “improving clinical evidence and improving the process of care” are not mutually exclusive. He goes on to propose that RCTs are not the optimal design for the investigation of healthcare process improvement within complex social and organizational environments, further suggesting that other methods, drawn from engineering and quality improvement, such as time series analysis and factorial experiments, are better suited to inform the researcher about mechanisms of change and context.

The NIH Roadmap initiative for clinical research has identified three types of research that directly lead to improvements in healthcare: “basic research that informs the development of new interventions”, “treatment development that crafts interventions and tests their efficacy in carefully controlled trials”, and “implementation research...where treatments and interventions are brought into and tested in usual-care settings” (Zerhouni, 2003). Currently there is a lack of consensus in the field regarding the best methods to achieve the goals of implementation or translational research. These include disseminating evidence based practices to clinicians and patients, effective implementation of interventions as intended (fidelity) for effect and applicability, and investigation of the process involved in accomplishing the first two goals for future use.

In Dementia Interventions

While there are multiple intervention programs for PWDs and their caregivers that have demonstrated statistically significant impacts for both members of the dyad, the field of programs that have published translational efforts is small. These programs have not yet effectively reached those for whom they were meant; the majority of dyads living

with dementia in the community do not have access to these programs outside of an academic study and do not receive appropriate treatment (Chapman, et al. 2006). Clearly the methods to effectively translate these interventions into practice are not nearly as established or rigorous as the intervention studies themselves. In recognition of this gap, the National Institutes of Health (NIH) and other agencies have pushed to advance the science of 'how'. In the pursuit of more rigorous methods for translation, several frameworks have been developed. The more prominent frameworks used in translation science are RE-AIM (Glasgow, Vogt, & Boles, 1999), Fixsen & Blasé's method (Fixsen, et al. 2009), Consolidated Framework for Implementation Research (CFIR) (Damschroder, et al. 2009), and Knowledge to Action (K2A) (Wilson, Brady, & Lesesne, 2011).

Several of the more established programs for PWDs and caregivers have been moved from their academic, controlled, environments to the community at large to withstand the test of translation. All of the published translational projects found similar impacts for participant dyads as was demonstrated in the original RCTs. This indicates the impact of the intervention for the dyad is well established, and the field will benefit from increased attention to the implementation process for these interventions. The programs from Resources for Enhancing Alzheimer's Caregiver Health (REACHII) (Belle, et al. 2006) have been translated in a variety of settings with several publications (Burgio, et al. 2009; Easom, et al. 2011; Lykens, et al. 2014). Two projects utilized the RE-AIM framework to evaluate implementation and found promising results for efficacy and implementation as reflected in the high acceptability of the intervention components (Cheung, et al. 2014; Stevens, et al. 2012), while another (Nichols, et al. 2014) employed the Fixsen & Blasé

method, demonstrating success in large part due to the flexibility of the program to fit the organization's needs and the support of both leadership and clinical staff. Most recently, a mid-course assessment of REACHIII translation efforts found a need to tailor training, target recruitment, and clarify component flexibility to improve fidelity (Altpeter, et al. 2015).

Another widely translated model is the Seattle Protocols (Teri, Logsdon, & McCurry, 2002). The Reducing Disability in Alzheimer's Disease (RDAD) (Teri, et al. 2003) program was first translated in Ohio (Menne, et al. 2014); demonstrating positive impacts for dyads mediated by number of sessions. Application of the RE-AIM framework found that implementation can be successful through an iterative reciprocal process that involves key stakeholders (Primetica, et al. 2014). Staff Training in Assisted Living Residences (STAR) (Teri, et al. 2005) and STAR-Caregivers (STAR-C) (Teri, et al. 2005a) were designed with translation in mind to be standardized yet flexible to meet the needs of the sites and participants (Teri, et al. 2012). The Veteran's Administration adopted the STAR program (Karlin, et al. 2014), supporting the feasibility and effectiveness of implementing the STAR intervention into a real-world setting while still maintaining significant outcomes.

The New York University Caregiver Intervention (NYUCI) (Mittelman, et al. 2006), was funded by the Administration on Aging for translation in six states. Mittelman and colleagues (2014) identify efforts to improve fidelity and gain 'buy-in' from leadership as key factors to improve success. Paone (2014) provided an in-depth analysis of the Minnesota translation using the RE-AIM framework, providing valuable insights about the initial perceived value and intention associated with an intervention and the 4 year

follow-up indicating a lack of resources to sustain and continue the program. The North Dakota Assistance Program for Dementia Caregivers (Klug, Halaas, & Peterson, 2014) was modeled after the NYUCI and “modified to reflect local resources and access to care” and demonstrated significant cost benefit to the community; intervention costs over two years were \$1.2 million, compared to the savings of \$40 million from delayed long-term care placement and reduced use of medical services.

The Savvy Caregiver program (Ostwald, et al. 1999) has been implemented in two separate efforts. The Colorado experience (Smith & Bell, 2005) did not discuss specific elements of the translation process; however, a more recent evaluation of the 3-year Maine project was designed with the RE-AIM framework (Samia, et al. 2014) and reported on the value of trainer resources, reciprocal partnerships, and effective planning as key factors for successful implementation. The translation of the Skills2Care (formerly Environmental Skill-building Program or ESP) program (Gitlin, et al. 2001) was evaluated with the RE-AIM framework (Gitlin, Jacobs, & Earland, 2010); results indicated the integration of Skills2Care into occupational therapy was moderately successful and fidelity to certain components was low. This is the only published report of an intervention qualifying as a Medicare reimbursable service.

Deering & Kee (2012) explain that translation should focus on understanding what is done with or to the intervention to enhance usability for the target. While the existing frameworks have utility, there is a dearth of validated measures to evaluate the dissemination and implementation process. The field must distinguish between intervention outcomes and the outcomes of the dissemination and implementation process. An increased focus on mixed methods to evaluate these outcomes and how

interventions are implemented for increased acceptability and sustainability will advance the science of ‘how’ and improve access to programs so that dyads in the community can receive appropriate treatment.

In any implementation trial a central question to answer is how to improve intervention application and resource allocation. This can be accomplished via analysis of mediating and moderating factors. Evaluating who most benefits from intervention, who is most at risk, and who responds as well as those who do not respond, is important for the advancement of intervention science. Examination of variables and the differential responses among sub-groups can assist in further tailoring the intervention.

MODERATING AND MEDIATING VARIABLES

Much of the current literature in the field of interventions for PWDs and their caregivers has focused on direct effect relationships between variables and outcomes; however, recently a burgeoning exploration of indirect effects has begun to add to our understanding of what factors strengthen or weaken relationships within various aspects of dementia care research. This can provide valuable insights in intervention work, helping to explore factors that may impact clinical choice of intervention, resource allocation, and in short, identify ‘what works for whom’.

While there are multiple intervention programs for persons with dementia (PWDs) and their caregivers that have demonstrated statistically significant impacts for both members of the dyad (Belle, et al. 2006; Gitlin, et al. 2001; Mittelman, et al. 2006; Teri, et al. 2003), there is a lack of focus on what dyad factors influence the success of an intervention. The endeavor to disseminate these interventions into the community to be used by those for whom they were intended is the most recent pursuit to further validate

the interventions. Evaluation of moderating variables, especially in the context of translating psychosocial interventions, is important to identifying which interventions will work best for certain dyads and support the effective movement of interventions into practice.

Conceptually, moderators identify on whom and in what circumstances treatments have different effects, while mediators identify how and why treatments have effects. The issue of mediators and moderators in a general framework has long been discussed in the psychology literature, particularly stimulated by the seminal work of Baron and Kenny (1986). Certain fields have made progress in this endeavor. For example, the child/adolescent risk and prevention literature as well as the occupational literature, have recently begun to utilize mediator and moderator analysis in research to elucidate these details (Bernabe & Botia, 2015; Holmbeck, 1997; Thompson, et al. 2005) in order to analyze the factors that provide for stronger or weaker relationships to outcomes for intervention participants.

While an RCT may show that treatment compared to control leads to therapeutic change, demonstrating effect does not say for whom effect was greatest. A moderator refers to a characteristic that influences the direction or magnitude of the relation between the intervention and outcome (Baron & Kenny, 1986). If treatment outcome varies as a function of characteristics of the participant or delivery method, this may help clarify to investigators which factors affect outcomes, allowing a more efficient allocation of resources. This may also suggest which participants might be most responsive to certain components of the treatment and for which patients other, more appropriate components might be emphasized (Kraemer, et al. 2002). Thus, understanding the role of moderators

may also provide new and valuable information to guide future restructuring of intervention flexibility and treatment decision-making. Translational studies that seek to evaluate differential response rates will more effectively determine the best routes, settings, and targets for delivery (Woolf, 2008). Further downstream, developing an understanding of which interventions work for different individuals has implications for clinicians and therapeutic choice in practice.

To wit, there has been a recent increase in the exploration of moderating effects for caregivers. Hooker and colleagues (1998) posited a key question for the research community when they asked why caregivers in similar circumstances demonstrate such variability in their responses to caregiving. Factors such as coping styles, social support, financial resources, physical health, and self-efficacy have since been found to have moderating effects on various outcomes. Evaluating these factors as moderators rather than using main effect analysis yields richer information about how they exert influence in the caregiving process. Moderators can help identify those who are at greater risk for poor outcomes, those who will benefit from intervention, and/or what factors could be enhanced for improved outcomes.

As early as 1989, Pruchno and Resch evaluated the concept of coping style as a moderator for outcomes of the stressors of caregiving; this was not supported and coping style was found to mediate, rather than moderate, the relationship between stressors of caregiving and outcomes. Pot and colleagues (2000) similarly established that neither resources available, nor coping strategies, moderated the appraisal of caregiving on psychological well-being. DiBartolo and Soeken (2003) explored the moderating effects of the personality quality 'hardiness' on caregiver stress and negative outcomes. This

was the first research to find significant moderator effects of a caregiver variable on outcomes. Coon, et al. (2003) examined the moderator effects of baseline depression and outward expression of anger, finding that those with higher levels of depression and anger increased the impact of the respective interventions targeting reducing anger and depression.

In 2006 several explorations of self-efficacy as a key moderating factor were published. Gilliam and Steffen (2006) evaluated the potential for caregiving self-efficacy to moderate depressive symptoms; however, they did not find significant moderating effects of self-efficacy between cognitive impairment or BPSD and the caregivers' depressive symptoms. Rabinowitz and colleagues (2006) were the first to investigate caregiver moderator effects in the context of differential intervention impacts. They found that lower baseline self-efficacy moderated the effects of a skill building intervention, demonstrating a stronger relationship between improved outcomes and the intervention. This suggests that those with lower self-efficacy scores at baseline would benefit more from the intervention. This type of finding is helpful for identifying future participants who would benefit most and aids in resource allocation. In a similar analysis of the moderating effect of self-efficacy (Rabinowitz, et al. 2009), female caregivers with higher self-efficacy to manage BPSD were at lower risk of depression. Self-efficacy had a moderating effect between objective stressors and several negative outcomes. The results demonstrated self-efficacy did indeed moderate the relationship between BPSD and caregiver depression. The authors suggested that interventions that improve a caregiver's sense of self-efficacy may reduce rates of depression, and further suggested

that this identification can help clinicians direct those caregivers with low self-efficacy to skill-building interventions rather than support or social interventions.

A study by Hilgeman and colleagues (2007) provides another example of moderation analysis in dementia intervention research. Positive aspects of caregiving were found to moderate treatment outcome in a secondary analysis of the REACH I project; they found that those participants who scored lower on a measure of positive aspects of caregiving at baseline benefited most from the intervention at 12 months. They suggest that further evaluation of moderators in intervention research may help program developers to better tailor future intervention efforts to the caregiver's needs and to identify those who benefit most from an intervention.

Hilgeman and colleagues (2009) also evaluated a test of the stress process model in caregiving, investigating race or ethnicity as a moderator of resource impact on strain; demonstrating that Caucasian caregivers reported more strain than minority caregivers when resources were high. The stress process model was also explored by Pioli (2010), who investigated the moderating role of 'mastery' of the caregiving role, a similar construct to self-efficacy. He found that mastery functions as a moderator in the relationship between subjective demands of dementia caregiving and depression and anxiety.

Further exploration of the self-efficacy construct as a moderator for caregiving impacts was conducted by Romero-Moreno and colleagues (2011) in a study involving evaluation of the potential moderating effects of two separate areas of self-efficacy: ability to manage problem behaviors and controlling upsetting thoughts. There was no support for self-efficacy to manage problem behaviors as a moderator between behavior

frequency and burden; however, self-efficacy to control upsetting thoughts did moderate the relationship between burden and distress as measured by depression and anxiety.

In an evaluation of which moderating factors influence response to use of adult day services (ADS) versus control, Kim and colleagues (2012) found that kin relationship, spouse versus adult child, moderated outcomes with use of ADS as opposed to controls. Daughters demonstrated greater benefit from the intervention on the 'overload' outcome, kin relationship did not moderate the effect of the intervention on depressive symptoms, and wives showed decline in positive affect with the intervention. The authors concluded that kin relationship did moderate use of ADS; clearly benefiting daughters more than wives. In a study to examine caregiver personal leisure and depression, Romero-Moreno and colleagues (2014) found that feelings of guilt moderated the effect of leisure activities on depression, but did not moderate the relationship between the two for sons or spousal caregivers. Zhang and colleagues (2014) explored the moderating effects of caregiver self-efficacy on the relationships between two variables that have established direct effects on caregiver burden, levels of PWD BPSD and social support. Their team found that the degree to which BPSD and social support influenced caregiver burden was dependent upon the degree of caregiver self-efficacy.

In summary, investigation into moderating variables provides insight into factors that may strengthen or weaken the impact of a given intervention. Applying this type of analysis to intervention outcomes with PWDs and caregivers has value and can help to influence clinical utility of the intervention for those providing care in the community. Clinically, moderators may help to explain why one individual responds well to a stressor

and another responds poorly to the same stressor, likewise why one person may demonstrate significant improvement after intervention and another only minimal change.

CURRENT STUDY

The Reducing Disability in Dementia (RDAD) intervention is a behavioral skill training and exercise intervention that was designed to reduce behavioral problems associated with dementia and increase the level of physical activity in PWDs. During the intervention, caregivers are taught to (1) encourage physical activity that increases endurance, strength, balance, and flexibility, with a goal of 30 minutes of exercise daily, and (2) identify and modify PWD behavioral problems that impair function and adversely affect the dyad interactions. The initial efficacy trial of RDAD demonstrated significant initial promise for improving outcomes in both members of the dyad (Teri, et al. 2003). Findings included significant improvements in physical function and mood outcomes, as well as sustained improvements reducing institutionalization rates due to behavior disturbance. The RDAD program was first studied in a translational trial, or implementation study, in Ohio via a partnership between the Ohio Department of Aging, the Alzheimer's Association Chapters in Ohio, and the Benjamin Rose Institute on Aging (Menne, et al. 2014); this effort demonstrated positive impacts for participating dyads, improvements in mood, physical function, and caregiver burden, in direct proportion to the number of sessions.

The current ongoing translation of RDAD is being implemented in the communities served by Area Agencies on Aging (AAA) in both Washington state and Oregon. This current trial is testing the effectiveness of the intervention on a broader, more inclusive sample, while simultaneously investigating the process and implementation of RDAD among community based agencies that serve the target population. The ongoing translational trial will compare dyad outcomes to the original RCT results to evaluate

goals of the intervention for both the person with dementia as well as the caregiver; these include health, psychosocial, and quality of life measures. Translation outcomes include satisfaction with the intervention from delivery agents and participants, as well as broader agency satisfaction with the utility of this intervention. Program costs will be evaluated and contrasted with the healthcare costs incurred by the participants.

A major challenge for translational studies is to balance internal and external validity; the nature of translation implies a greater focus on external validity, while preserving the rigor of internal validity controls, increased attention to methods to make evidence more generalizable is needed. In this translation of RDAD two well-established models will be applied to examine internal and external validity as well as implementation process to ensure that the proposed research study outcomes have maximum generalizability and relevance to community providers: the NIH Behavior Change Consortium to evaluate fidelity outcomes and the RE-AIM framework to establish external validity of the findings.

While the benefits of randomization are well established, the multi-level nature of implementation research creates challenges to this design, especially as the trial evaluates interventions at the organizational level. This translational trial of RDAD utilizes an interrupted time series design. This is a viable alternative to randomized controlled trials in the practical world of translation (Glasgow, et al. 2005). This method has greater statistical power, provides a reduction in exogenous/confounding factors, and is logistically more feasible for training large numbers of participating delivery agents.

STUDY AIMS

In any implementation trial a central question to answer is how to improve intervention application and resource allocation. This can be accomplished via analysis of mediating and moderating factors. Evaluation of who most benefits from an intervention, who responds, as well as those who do not respond can add to the information gained for future iterations. Examination of variables and the differential responses among sub-groups can assist in further tailoring the intervention. Conducting moderating variable analysis will help to identify those factors that may indicate which intervention aspects may work better for a particular dyad. This information is particularly useful in translational trials to move interventions into the community, thereby showing investigators who most benefits from intervention, who is most at risk, and who responds, as well as those who do not respond.

The current study seeks to evaluate recipients of the intervention, differential response rates, and factors impacting adherence to intervention components, utilizing dyad variables to predict intervention engagement with the goal of identifying potential moderators to program adherence. This analysis will examine those dyad factors that moderate adherence to the intervention so that future applications of RDAD can target those dyads that may benefit most. Theorizing that as the RDAD intervention targets the dyad via the caregiver, and the caregiver's actions are influenced by the PWD and vice-versa, examining individual and dyad moderator effects on the same intervention components will yield information about the influence of each. This can then allow exploration into which member of the dyad, PWD or the caregiver, is more influential by evaluating the same dependent variables.

Study aims are as follows:

(1) Evaluate the impact of Caregiver factors on adherence to exercise frequency, behavioral plan implementation, and application of pleasant events with the PWD.

(2) Evaluate the impact of PWD factors on adherence to the same intervention components.

(3) Evaluate whether caregiver, PWD, or dyad variables were more significant modifiers of intervention adherence.

METHOD

Procedure

This translational trial of RDAD was an interrupted time series design; dyads served as controls and then participated in the intervention. After providing informed consent, dyads completed a comprehensive in-person baseline assessment. All intervention sessions were conducted by interventionists (called ‘coaches’) from the AAAs, or other community and university agencies trained in the RDAD intervention. The coaches visited dyads in their homes for 9 one-hour sessions on a schedule of 2 sessions per week for the first 3 weeks, weekly sessions for 3 weeks, and 4 monthly follow-up phone calls. Subsequent assessments occurred 6 weeks after baseline, this served as a ‘post-control’ phase assessment and as the pre-treatment assessment. The next assessment took place at 12 weeks, and served at the post-treatment assessment; subsequent follow-ups occurred at 7 months, following the 4 monthly phone contacts, and a final assessment at 13 months.

Sample

Participant dyads were recruited from existing service recipients of the participating AAAs, as well as through community outreach; enrollment began in August of 2012 and

ended in March 2016. The Institutional Review Board of the University of Washington reviewed and approved the project. Written consent was obtained from both the person with dementia (PWD) and caregiver; additionally, caregivers and/or a representative with power of attorney provided consent on behalf of the PWD. Written consent was obtained from both caregiver and care-recipients. Additionally, caregivers and/or a representative with power of attorney provided consent on behalf of the PWD. Dyad eligibility was broader than the original RCT, in keeping with the goal of translational projects to improve external validity. Care recipients were eligible if they were 65 years old or older, met DSM-IV-R criteria for dementia, exercised less than 150 minutes per week, and had a primary caregiver living in the community; each care recipient had to obtain approval from their primary care physician to participate in RDAD. Dyads were excluded if either were non-ambulatory, blind, deaf, had been hospitalized for psychiatric illness within the past 12 months, if there were plans to move to a long-term residential care setting within 6 months, or expectations to move from the study geographic area during the study period, either had a known terminal illness. A total of 239 participants with a dementia diagnosis and their family caregivers had completed the post-treatment assessment as of December 30, 2015, and were used in this analysis.

Participating PWDs ranged in age from 49 to 97, with a mean age of 81 years old. Gender was almost evenly distributed (51% male), while race was predominately Caucasian (90%). The mean Mini-Mental State Exam (MMSE) score was 15.48 ($SD = 7.17$; range 0-30), indicating a broad range of cognitive impairment. Informal caregivers who enrolled in the trial were spouses or adult relatives living with the PWD, or who spent greater than 4 hours per day providing care. The mean age of caregivers was 69

years old (ranged in age from 29 to 93 years), caregivers were predominately female (74%), and Caucasian (88%). Spouses comprised 64% of the sample, 29% were adult children, and the remaining 7% of caregivers were friends or other relatives.

Measures

A comprehensive battery of measures was included in each assessment. The current moderation analysis will utilize only the baseline data to explore predictors and moderators of adherence to the intervention targets and post-treatment assessment of adherence outcomes.

Demographic and Process Measures. At baseline, caregivers provided demographic information including age, gender, race, and education of the PWD and caregiver, living situation, co-morbidities, and relationship between the dyad. PWD cognitive status was assessed at baseline using the Mini-Mental Status Exam (MMSE). Caregivers completed an adverse symptom checklist at each visit.

Care-recipient Measures. The larger trial's primary PWD outcome measures are physical health, function, and BPSD. Caregivers completed the assessments as proxy for the PWD. The Medical Outcome Study 36-item Short Form Health Survey (SF-36) was obtained to assess physical health and function; this measure is psychometrically sound and has been used extensively with older adults (Liang, et al. 1985; Stewart, et al. 1988; Ware, et al. 1992). BPSD was assessed using the Revised Memory and Behavior Problem Checklist (RMBPC), a widely utilized measure demonstrating psychometric reliability and validity (Teri, et al. 1992)

Caregiver Measures. The larger trial's primary caregiver outcomes were physical health and mental health. Caregivers completed a SF-36 measures assessing their own physical

health. Mental health of caregivers was assessed using both the mental health sub-scale of the SF-36 as well as the Center for Epidemiologic Studies Depression Scale (CES-D); this measure is psychometrically reliable and has demonstrated validity (Jackson, et al. 2014; Lewinsohn, et al. 1997; Radloff, 1977).

Adherence measures. This study utilized three key outcomes to evaluate uptake of the intervention and enactment by dyads: frequency of physical activity, frequency of pleasant events, and frequency of behavioral plan completion. During each session coaches completed a RDAD Progress Note Form, in order to evaluate adherence to the skill building component of the intervention, coaches recorded the number of ABC plans attempted to evaluate the caregiver's engagement with the behavioral management goal of the intervention. Similarly the number of attempted pleasant events was asked and recorded, providing a measure of adherence to the mood improvement strategy target of RDAD. As discussed, a target of RDAD to preserve PWD function and reduce behavioral disturbance is exercise, caregivers are asked at each assessment "During the past week, how many days did you walk for exercise or do some other aerobic activity for a total of at least 30 minutes?", the number of days provided in response was used to evaluate frequency of exercise.

Analysis plan

Preliminary analyses to facilitate the screening and cleaning of the data were conducted according to procedures outlined by Tabachnick and Fidell (2012). Analyses were performed using the statistical software package Stata Release 14. In order to examine the potential dyad factors that influence adherence to the key components of the RDAD intervention, the distribution of all variables was examined for normality, with further inspection of variable skew/kurtosis.

Multiple linear regression (MLR) was applied to explore how caregiver gender, depression, and behavioral reaction, may moderate adherence to two of the key components of the intervention: pleasant events and attempting behavioral plans. Similarly, another model was run using MLR to explore how PWD gender, relationship to the caregiver, level of cognitive impairment, and behavioral disturbance may predict the same key components of pleasant events and enacted behavioral plans following the RDAD intervention. To adjust for correlated data, clustering by dyad and robust standard errors were used in all models. Interaction terms were created by multiplying the variables after mean centering the continuous variables to ease interpretation. In the caregiver models incidence of Pleasant Events and incidence of behavioral plan frequency was regressed onto gender, CES-D score, and RMBPC reaction sub-scale scores, and the new interaction terms, respectively. In the PWD models, frequency of the aforementioned intervention components was regressed onto gender, relationship, MMSE score, RMBPC total score, and the new interaction terms. Significant interaction terms provided evidence of a moderating effect.

The method employed to evaluate predictors and moderators of physical activity adherence necessitated an alternate regression approach due to the clustered/longitudinal and over-dispersed nature of the post-treatment frequency of physical activity. A Poisson regression was considered; however, given that the variances within each group were orders of magnitude larger than the mean, we chose a negative binomial regression to model the physical activity count variables. This method is used for over-dispersed count outcome variables, and adjusts the variance independently from the mean. Generalized estimating equations were applied to extend the generalized linear model to allow for correlated observations; this accounts for the correlation between observations of physical activity by use of an empirical variance estimator and characterizes the average response for observations that share the same covariates.

RESULTS

After completion of the RDAD intervention dyads completed an average of 3.87 ABC Plans ($SD = 2.20$), ranging from no ABC Plans to eight plans completed over the course of treatment. Dyads engaged in an average of 3.03 Pleasant Events ($SD = 1.60$) each week per the coaches' progress notes, and ranged from zero to nine pleasant events per week. Physical activity was evaluated at baseline, pre-treatment, and post-treatment, again as dyads may have been engaging in exercise prior to the intervention, the increase was the measure of adherence to this component. At baseline, the mean days of exercise was 1.38 ($SD = 1.99$), pre-treatment average exercise was 1.55 ($SD = 2.01$), and after receipt of RDAD dyads exercised an average of 2.87 days ($SD = 2.43$). Engagement in exercise increased after the RDAD intervention, by an average of 1.35 days ($SD = 2.32$), and ranged from a decrease of 5 days to an increase of 7 days.

ABC Plans

The multiple linear regression (MLR) evaluating caregiver factors predicting completion of ABC plans was not significant. Block 1 was comprised of caregiver gender, CES-D score, and RMBPC Bother score, $R^2 = 0.006$ ($RMS = 2.21$), $F_{(3,175)} = 0.37$, $p=0.77$; results indicate that the caregiver variables, gender, depression level, and behavioral bother did not account for significant variance (slope coefficient t -test p -values = -0.41, 0.76 and 0.50, respectively). The interaction terms for each of the predictors were entered into Block 2 and did not account for significant variance in completion of ABC plans either, $R^2_{\text{change}} = 0.01$, $F_{\text{change}(4,175)} = 1.92$, $p = 0.11$.

The MLR used to predict completion of ABC plans by PWD variables (PWD gender, cognitive impairment, and behavioral disturbance) while not significant, did reveal

moderating effects. Block 1 was comprised of PWD gender, MMSE score, RMBPC score and relationship to caregiver, $R^2 = 0.008$, $F_{(4,177)} = 0.33$, $p=0.86$, ($RMS = 2.22$); results showed that gender, MMSE score, RMBPC score, and relationship did not account for significant variance in ABC plan completion (slope coefficient t -test p -values = 0.39, 0.74, 0.79, and 0.72, respectively). The interaction terms for each of the predictors were entered into Block 2 and approached significant explanation of the variance in ABC Plan completion, $R^2_{\text{change}} = 0.08$, $F_{\text{change}}(10,177) = 1.81$, $p = 0.06$, ($RMS = 2.18$).

There were several significant moderating effects of PWD factors on completion of ABC plans by participating caregivers. Results from the final block, with all predictors and interactions entered into model, showed that the average completion was 3.56 ABC Plans ($SE = 0.34$), for a female PWD with an average MMSE score (15.5) with an average RMBPC total score (1.9) and a non-spouse caregiver, $t_{(177)} = 10.6$, $p < .001$. When the interactions were entered into the model there was a significant interaction between several variables: gender and MMSE on ABC Plan completion, $b = 0.11$, $SE = 0.05$, $t_{(177)} = 2.26$, $p < 0.05$. To understand the nature of the interaction, predicted values were plotted for gender by MMSE score (low and high average), as illustrated in Figure 1. This means that ABC completion was highest for dyads in which the PWD was female with more advanced dementia and male with milder cognitive impairment, while dyads in which the PWD was female with milder cognitive impairment were least likely to complete ABC plans.

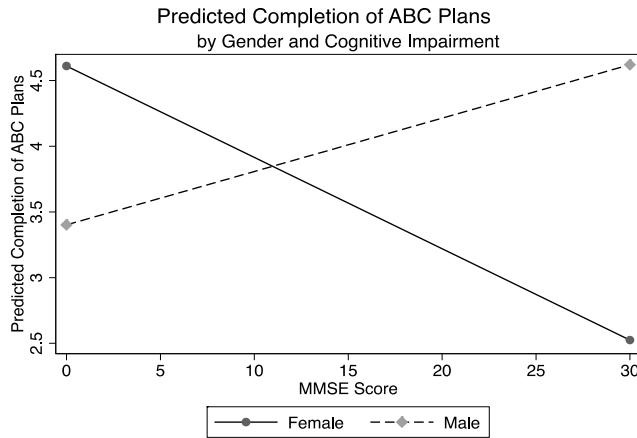


Figure 1.

The relationship between the PWD and the caregiver also has a significant interaction with level of behavioral disturbance, $b = -2.62$, $SE = 1.07$, $t_{(177)} = -2.46$, $p < 0.05$. To understand the nature of the interaction, predicted values were plotted for level of BPSD (high and low average) by caregiver relationship, as illustrated in Figure 2. This means that ABC completion was highest for dyads in which the caregiver was a non-spouse and the PWD had higher level of behavioral disturbance, whereas those dyads in which the caregiver was a spouse and the PWD had low levels of behavioral disturbance were more likely to complete ABC plans.

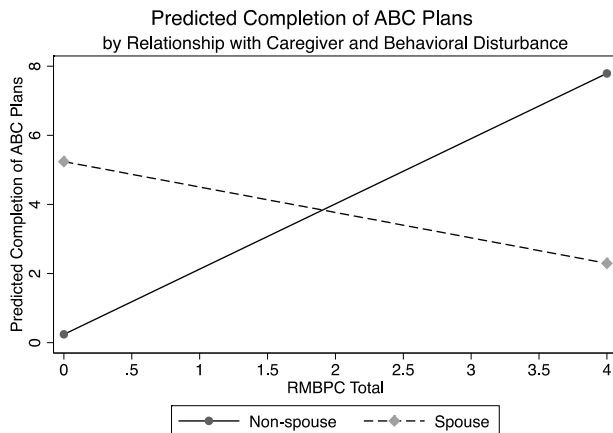


Figure 2.

Pleasant Events

The MLR evaluating the caregiver factors predicting engagement in Pleasant Events was not significant. Block 1 was comprised of caregiver gender, CES-D score, and RMBPC Bother score, $R^2 = 0.02$ ($RMS = 1.61$), $F_{(3,175)} = 0.87$, $p=0.46$; results indicate caregiver gender, depression level, and behavioral bother did not account for significant variance (slope coefficient t -test p -values = 0.57, 0.48 and 0.39, respectively). The interaction terms for each of the predictors were entered into Block 2 and once again did not account for significant variance in Pleasant Event engagement, $R^2_{\text{change}} = 0.01$, $F_{\text{change}(4,175)} = 0.59$, $p = 0.67$.

The MLR to predict engagement in pleasant events by PWD variables (PWD gender, cognitive impairment, behavioral disturbance, and dyad relationship) was also not significant. Block 1 was comprised of PWD gender, MMSE score, RMBPC total score, and relationship, $R^2 = 0.003$ ($RMS = 1.61$), $F_{(4,177)} = 0.17$, $p=0.95$; results indicate that PWD gender, cognitive impairment, behavioral disturbance, and dyad relationship did not account for significant variance (slope coefficient t -test p -values = 0.48, 0.97, 0.67, and 0.68, respectively). The interaction terms for each of the predictors were entered into Block 2 and once again did not account for significant variance in frequency of pleasant events, $R^2_{\text{change}} = 0.01$, $F_{\text{change}(4,177)} = 0.79$, $p = 0.53$.

Physical Activity

As described in the analysis plan, an alternate regression model was used to evaluate the moderators of physical activity. In the moderation models of frequency of attempted ABC plans and pleasant events the analysis was cross-sectional using post-test data only, as prior to the intervention dyads were not engaging in ABC plans and pleasant events as

taught in the intervention. However, for physical activity, dyads may have been engaging in physical activity. For this reason, we controlled for baseline level of physical activity and evaluated the pre vs. post treatment effect so that actual intervention effect was accounted for in the negative binomial regression (NBR) models.

The NBR model comprised of caregiver variables (caregiver gender, CES-D score, and RMBPC reaction scores) fit the data (*Wald* $\chi^2_{(5)} = 76.19, p < 0.001$) (Table 5). Receipt of the RDAD intervention test of time ($\chi^2_{(1)} = 55.6, p < 0.001$) significantly contributed to the regular exercise of participants in this study. However, none of the caregiver factors, gender ($b = -0.22, p = 0.16$), depression ($b = -0.01, p = 0.17$), nor behavioral bother ($b = 0.16, p = 0.19$) independently contributed to physical activity increases.

Next, to evaluate whether the effects of RDAD on physical activity were moderated by caregiver factors, a second NBR was run using interactions between the potential moderators and time. The regression model fit the data (*Wald* $\chi^2_{(20)} = 89.05, p < 0.001$). These interactions were further evaluated by applying Chi-square tests to evaluate whether the caregiver characteristic significantly moderated differences between days exercised accounting for the pre-test and post-test assessments. None of the contrasts were significant: caregiver gender by RDAD intervention period ($\chi^2_1 = 0.08, p = 0.78$), caregiver depression by intervention period ($\chi^2_1 = 0.63, p = 0.43$), or caregiver bother by intervention period ($\chi^2_1 = 0.27, p = 0.61$); similarly none of the interactions between the combinations of caregiver predictors and RDAD intervention period were significant. These findings further confirmed that RDAD contributed to increases in physical activity regardless of individual caregiver predictors.

The NBR model to evaluate impacts of PWD factors comprised PWD gender, MMSE score, RMBPC total score, and relationship to the caregiver fit the data ($Wald \chi^2_{(6)} = 80.04, p < 0.001$) (Table 6). Again, receipt of the RDAD intervention test of time ($\chi^2_1 = 54.6, p < 0.001$) significantly contributed to the regular exercise of participants in this study. However, none of the PWD factors, gender ($b=0.18, p=0.22$), cognitive impairment ($b=-0.002, p=0.77$), behavioral disturbance ($b=0.01, p=0.96$), nor having a spouse vs. non-spouse caregiver ($b=0.19, p=0.19$) independently contributed to physical activity increases.

Next, to evaluate whether the effects of RDAD on physical activity are moderated by PWD factors, a second NBR was run using interactions between the potential moderators and time. The regression model fit the data ($Wald \chi^2_{(32)} = 135.22, p < 0.001$). Several of the three-way interactions were significant: PWD gender by cognitive impairment by time ($\chi^2_2 = 7.77, p < .05$), cognitive impairment by relationship by time ($\chi^2_2 = 12.4, p < 0.05$), behavioral disturbance by relationship by RDAD intervention ($\chi^2_2 = 5.62, p = .06$), although the RDAD intervention period was significant $\chi^2_1 = 4.36, p < .05$.

These findings suggest that increases in physical activity predicted by RDAD are moderated by several key PWD factors. To understand the nature of the interactions, predicted values were plotted for each of the significant interactions. The first significant interaction was between PWD gender and MMSE score (low and high average) by time, as illustrated in Figure 3. This means that increases in physical activity after RDAD were highest for dyads in which the PWD was male with less severe cognitive impairment, while dyads in which the PWD was male with advanced cognitive impairment were less likely to increase physical activity after the RDAD intervention. As demonstrated in

Figure 3, increases in physical activity occurred for dyads in which the PWD was female, though did not vary in relation to level of cognitive impairment.

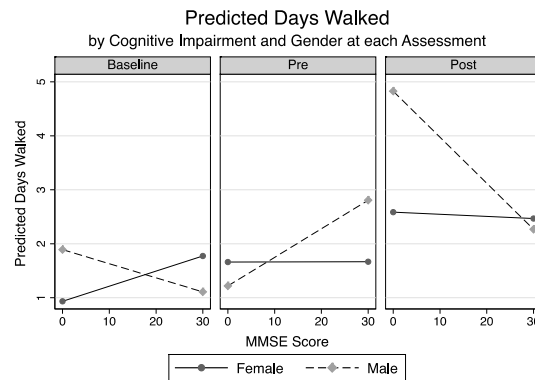


Figure 3.

The next significant interaction was plotted between dyad relationship, spouse or non-spouse caregiver, and MMSE score (low and high average) by time and is illustrated in Figure 4. This means that increases in physical activity after RDAD were highest for dyads in which the caregiver was a spouse and the PWD had milder cognitive impairment, while dyads in which the caregiver was a non-spouse and the PWD had more advanced cognitive impairment were less likely to increase physical activity after the RDAD intervention.

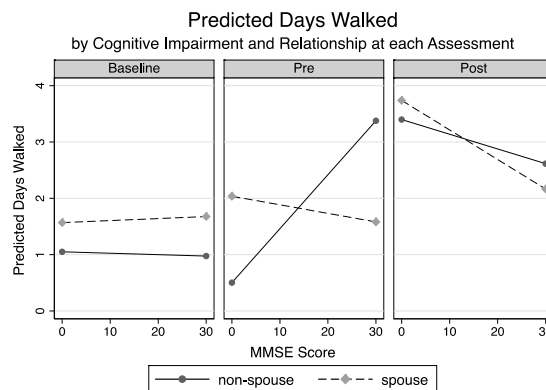


Figure 4.

The final significant interaction was plotted between dyad relationship and RMBPC Total score (low and high average) by time and is illustrated in Figure 5. This means that

increases in physical activity after RDAD were highest for dyads in which the caregiver was a non-spouse and the PWD demonstrated high levels of behavioral disturbance, while dyads in which the caregiver was a spouse and the PWD had high levels of behavioral disturbance were less likely to increase physical activity after the RDAD intervention.

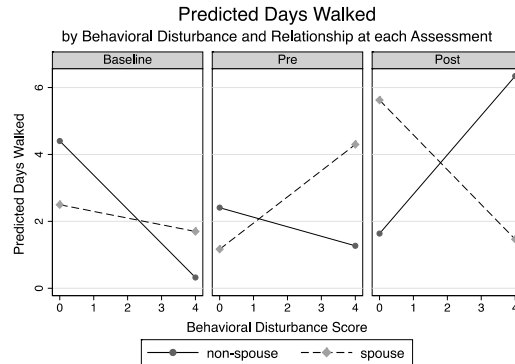


Figure 5.

In summary, the findings of this study indicate that the gender of the PWD, level of cognitive impairment, level of behavioral disturbance, and relationship between the PWD and caregiver (spouse versus non-spouse) moderate adherence to the behavioral plan component of RDAD. None of the caregiver or PWD factors explored, or the relationship of the dyad, moderated adherence to engagement in pleasant events. As with the behavioral component, adherence to the physical activity component was also moderated by PWD gender, level of cognitive impairment, level of behavioral disturbance, and relationship type between the dyad.

DISCUSSION

This study sought to explore the PWD, caregiver, and dyad variables that influence adherence to the three core components of RDAD: physical activity, pleasant events, and ABC plans. The goal was to further the translational efforts by identifying dyad factors that strengthened or weakened response to RDAD intervention components. As with pharmacologic interventions, adherence to the prescribed regimen in psychosocial interventions is critical to achieving the intended outcomes. Maxwell and colleagues (2014) reviewed the predictors and moderators of adherence with pharmacologic regimens for dementia, and found several significant relationships including patient age, gender, and relationship with the caregiver. Understanding predictors and moderators of adherence to intervention components as the most proximal outcome measure can guide future intervention delivery methods to improve adherence and ultimately the outcomes they precede. Clinical and translational research can seek even greater improvement in health outcomes by understanding the variables that strengthen or weaken adherence and response to our interventions, thereby providing better, more individualized care to patients, families, and the community.

These results have several implications for the translational efforts of RDAD. Findings support the broad applicability of the intervention, it appears that the participating dyads did not significantly differ in their adherence to the intervention components of physical activity, behavior modification plans, and pleasant events. There were however significant moderators to adherence to physical activity and behavioral plan completion. This information can provide insight to help enhance intervention delivery.

Results demonstrating the moderating effects of PWD factors on adherence is perhaps the most valuable finding. Improving our understanding that dyads for whom the PWD is female and mildly cognitively impaired are least likely to engage in the behavioral plan component will aid in future iterations of delivery. Allowing coaches to identify barriers with those dyads and stress the value of this component, despite the possible perception that this is not applicable to the caregiver's situation, suggesting the goal is to develop the skill if needed later. Similarly, understanding that dyads in which the caregiver is a spouse, and the PWD demonstrates a high degree of behavioral disturbance will be less likely to adhere to the exercise goals has value. This knowledge can help coaches work to identify barriers and encourage this important aspect of the RDAD intervention, perhaps focusing on the preservation of function outcome and reduced behavioral disturbance when working with the caregiver. These findings do not suggest that these dyads are unable to adhere to the components, or benefit from the intervention, but rather guide our efforts to make the intervention stronger for those recipients.

The relationship between the PWD and the caregiver is a significant modifying variable in the adherence to physical activity and behavioral plan completion. This too provides valuable insight into dyad adherence and will serve to strengthen the delivery to spousal dyads and non-spousal dyads by further individualizing the intervention. Armed with this knowledge, coaches can adjust their approach to spouses by acknowledging relationship differences, asking about barriers to adherence for those most at risk of not engaging in physical activity or behavioral plans, and finding solutions to focus on the utility of behavioral plans if the caregiver is a spouse and the PWD has high levels of behavioral disturbance, or in dyads in which the caregiver is a non-spouse and the PWD

has minimal behaviors. Several studies have demonstrated that dyad relationship has a significant influence on multiple outcomes, such as costs, stigma, long term care placement, and use of community services (Cepiou-Martin, et al. 2016; Kahn, et al. 2016; Rattinger, et al. 2016; Robinson, et al. 2013), and Kim, et al. (2012) found that relationship moderated the caregiver's response to adult day services.

Finally, the results suggest the caregiver characteristics of gender, depression, and behavioral reaction do not significantly moderate intervention adherence. Prior literature suggests that these caregiver factors have been found to impact distal outcomes, such as depression, burden, and behavioral disturbance (Arguelles, et al. 2001; McCurry, et al. 2010; Pinquart & Sorensen, 2006; Sink, et al. 2006), however they do not appear to impact the more proximal measure of adherence to RDAD components. For the prospective dyad, this is good news; finding that adherence to components of RDAD are not significantly influenced by the caregiver's baseline qualities supports continued focus on the caregiver as the catalyst for change in the PWD. Trainers and coaches can leverage these collective results to help the caregiver by understanding, and addressing, the potential barriers that exist for adherence, such as relationship type and degree of cognitive and behavioral impairments, the coach can alert the caregiver to risks for non-adherence and together work towards finding solutions. These findings contribute to the field in that none of the available literature into intervention moderators examine PWD, caregiver, or dyad factors on measures of adherence; only to the more distal outcomes of caregiver mood and burden (Table 3).

PWD factors and the caregiving relationship between the dyad are the more significant moderators of RDAD adherence than the caregiver factors explored in this

study. Who benefited the most? In this study, male PWDs with low levels of cognitive impairment and behavioral disturbance, and a spousal caregiver, were more likely to increase PA, and non-spousal caregivers of male PWDs with high behavioral disturbance were most likely to complete behavioral plans. Who benefited least? Male PWDs with high levels of cognitive and behavioral disturbance, who had a spousal caregiver were least likely to exercise, while non-spouse caregivers of female PWDs with milder cognitive impairment and minimal behavioral disturbance were less likely to engage in the behavioral aspect of the intervention. This information will help to further individualize RDAD delivery with the immediate goal of increasing adherence and improving outcomes for every dyad.

The broader implications provide insight for the development and refinement of interventions for those with dementia and their caregivers, as well as their clinical application. Intervention research may benefit from increased understanding of dyad factor influence, namely that the level of cognitive impairment and behavioral disturbance influences adherence. Current and future interventions can apply this knowledge to adjust approaches for dyads with these qualities, for example considering higher frequency and longer session duration to support the caregiver with problem-solving to increase adherence to behavioral plans and physical activity. Another option would be to refine the intervention using these findings by altering the structure or schedule of the components, allowing flexibility in what components are addressed first depending on the dyad factors at pre-treatment, and focusing on that component of which the dyad is most at risk for non-adherence. Yet another possible option would be to assign coaches depending on dyad factors, matching those coaches with more experience

and qualifications to those dyads most at risk for non-adherence. Clinically, these findings may allow the clinician to select treatment or intervention choice based on likelihood to adhere. Conversely, the interventionist can use these results to initiate a discussion of perceptions, objections, and barriers to enhance those at risk for non-adherence.

Limitations

This study was a secondary analysis, and did not include the full sample due to time constraints; while the study was adequately powered, a larger sample may have provided more information. Additionally, inclusion of the full follow-up data would provide information about how these PWD, caregiver, and dyad factors may moderate which dyads sustain the effects and who does not. Another limitation was the lack of racial diversity, due to the racial demographics of Washington state and Oregon (both states are over 77% Caucasian) (U.S Census data 2014) where this RDAD translation has been conducted. Examination of a more nationally representative sample would have greater external validity; although as a first step, this sample does represent the states in which it was conducted. A primary goal of translational projects is to implement the intervention in the population for whom it was intended, by having minimal inclusion/exclusion criteria for a more pragmatic design, the benefit of certain sample selection techniques, such as a stratified random sample, may lead to less than ideal representation. This is a readily debated issue in translational trials, how best to conduct a pragmatic trial in the ‘real-world’ environment while balancing internal and external validity.

Future Directions

There are multiple future directions suggested by these results. Conducting further moderation analyses using other factors, such as interactions between caregiver age, caregiver gender, and dyad relationship, as well as PWD baseline physical functioning and co-morbidities to suggest a few. It would be a worthwhile endeavor to explore further the nature of the relationship differences and how spousal caregivers approach caring for the PWD versus adult children, other questions of interest include quality of the relationship, duration, and how these factors impact intervention perception and outcomes. Exploring a potential generational difference between spouse caregivers and non-spouse caregivers in their application of the behavioral principles, or asking if it is the nature of the relationship between a spouse and an adult child in their approach to caring for a PWD would provide more information about the differences in adherence to the behavioral component. Perhaps the most interesting, and valuable in terms of translation, would include conducting a mediation analysis to explore the mechanism of action and influence of each component onto the trial outcomes. The mediating relationship between proximal intervention adherence to each component on the more distal outcomes of caregiver mental health, patient functional status, behavioral disturbance, and affect would allow greater understanding about why RDAD improves outcomes, which components are the most impactful.

Psychosocial interventions for dyads with dementia with demonstrated efficacy should be moved into the community. These efforts should focus on adaptations of evidence based interventions to improve adherence, acceptability, and usability for agency implementation. Gitlin and colleagues (2015) reviewed current efforts to

translate non-pharmacologic interventions for dementia, they identify one of the common goals of translational studies is to evaluate uptake of the intervention by both community agencies and the families using the intervention by “determining which subgroups benefit the most.” This study is consistent with that aim, evaluating the uptake, and possible differential response rates among dyads to key components of the intervention, physical activity, ABC plans, and pleasant events. These results may have application in both research and clinical practice. Improving understanding of moderators to intervention adherence will provide guidance for treatment refinement and will inform the translation and future implementation research of the RDAD intervention. From a clinical perspective, exploring individual and dyad factors that strengthen or weaken adherence to an intervention can inform therapeutic choice and lead to improved outcomes.

This is one of the few studies of non-pharmacologic interventions that are being translated into the community to evaluate predictors and moderators of adherence to the intervention targets. Much of the available literature in this field has focused on direct effects, or distal outcomes of the intervention. This project sought to start with more proximal factors, in the interest of translational science, seeking to evaluate “what comes before” in an effort to fully evaluate the variables that impact implementation of the intervention into ‘real world’ environments. This provides for a more comprehensive understanding of the intricacies that impact distal outcomes of the intervention (Judd, Yzerbyt, & Muller). By evaluation of predictors of adherence and moderating factors we can improve the flexible, yet standardized nature of interventions like those encompassed in the Seattle Protocols. Gaining understanding of who responds and adheres to the

components of the intervention, theoretically leading to improvements in outcomes, may allow us to improve strategies to increase adherence.

CONCLUSION

In the context of translational trials, these results imply that the RDAD intervention is suitable to be implemented with any dyad, and will be similarly adhered to by most dyads. The significant moderators discovered will help to refine intervention delivery to ameliorate potential factors that may impact reduced adherence. Trainers and coaches now have more information with which to support caregivers of PWDs living in the community, and knowledge that identifies potential barriers to intervention uptake. This knowledge can be applied to individualize the therapeutic interaction for improved adherence to the prescribed components. This supports the further improvement and implementation of RDAD in communities at large consistent with the goals of translational science.

Table 1. Caregiver Skill Building/Behavioral Interventions

Citation	Study Design (Sample Size) (Control)	Setting (Country)	Intervention Components -Interventionist -Duration & Frequency
Caregiver Training			
Caregiver Focused			
Belle, et al., 2006	RCT (N=642) Treatment= REACH Control = information packet and limited phone "check-in"	Community (US)	REACH : specialized one-on-one education and support for informal caregivers - "certified interventionists with at least a Bachelor's degree" - 6 months with 12 sessions with the interventionist and 5 support group calls
Burgio, et al., 2003	RCT (N=118) Treatment=STC Control = minimal support intervention	Community (US)	Skills Training Condition (STC): 3 foci - behavioral management techniques, problem-solving to increase self-care, social engagement and pleasant events, and cognitive restructuring - "REACH interventionist" - 12 months beginning with a group workshop followed by 16 in home visits over 12 months
Davis, et al., 2004	RCT (N=61) Treatment A = In home training Treatment B = telephone training Control = friendly call	Community (US)	Caregiver support - in home vs telephone - 'trained staff interventionists' - weekly intervention sessions for 45-60min for 12 weeks
Farran, et al., 2004	RCT (N=272) Treatment = Caregiver Skill Building (CSB) Control=Information and Support Oriented (ISO)	Community (US)	Comparison of skill building and support - Extensively trained professional staff (nurses, social workers) with geriatric experience - 5 group sessions, 7 individual phone contacts, 2 group boosters, and as needed phone contact for 12 months
Finkel, et al., 2007	RCT (N=36) Treatment =Ecare Control=printed information	Community (US)	Ecare: an online psycho-educational program for family caregivers of PWD (based on REACH) - 'technology (online) based intervention' - 6 months with 2 in home visits and 12 screen phone encounters
Finnema, et al., 2005	RCT (N=146) Treatment =Emotion oriented care Control=usual care	SNF (Netherlands)	Integrated emotion-oriented care - Individualized Care plans and bios - training staff in empathetic communication skills 24/7 - "nursing assistants trained in emotion-oriented care" - 7 days spread over 7 month, with "homework"
Gavrilova, et al., 2009	RCT (N=60) Treatment = Cg education and training Control = usual care	Community (Russia)	Caregiver training and support - in person focusing on dementia assessment, education, and training regarding addressing BPSD - Multi-purpose Health Worker - 5 weekly 30min sessions
Gitlin, et al., 2010	RCT (N=209) Treatment =COPE Control= limited attention	Community (US)	Care of Persons with Dementia in their Environments (COPE) - Occupational Therapist and Nurse team - 10 sessions with OT and 2 sessions with a nurse over 4 months
Gitlin, Winter, et al., 2003	RCT (N=190) Treatment = HES program Control = usual care	Community (US)	Home Environmental Skill Building (HES) - Occupational Therapists trained in REACH protocols - Five 90-min home visits and one 30-min over 6 months
Gitlin, Winter, et al., 2010	RCT (N=272) Treatment = ACT Control = usual care	Community (US)	Advanced Caregiver Training (ACT) - Occupational Therapist and Nurse team - 16 week active phase of 9 OT sessions, 2 nursing sessions - maintenance phase of 16-24 weeks of 3 brief OT phone contacts to reinforce treatment
Gonyea, et al., 2006	RCT (N=80) Treatment = project CARE Control = "standard" psycho-educational group	Community (US)	Project CARE (multi-session training) -Behavioral training - skills training - for Family cg with primary outcomes for cg. - 'therapists trained in the intervention' - 90min groups sessions 1x/week for 5 weeks

Citation	Study Design (Sample Size) (Control)	Setting (Country)	Intervention Components -Interventionist -Duration & Frequency
Graff, et al., 2007	RCT (N=135) Treatment = In home OT Control = not specified	Community (Netherlands)	In-home OT: training for caregivers regarding activity and environmental adjustments - Occupational Therapists - 10 1-hour sessions over 5 weeks
Hepburn, et al., 2007	RCT multi-site (N=52) Treatment = SAVVY Cg Control = waitlist	Community (US)	SAVVY Caregiver: training program for informal caregivers in the community focusing on skills, knowledge, and outlook - 'persons with educational or clinical background in family caregiving and dementia' - 6 2-hour sessions
Huang, et al., 2003	Pilot (N=48) Treatment = Caregiver training Control = social contact only	Community (Taiwan)	Training of family caregivers of PWDs in behavior, environmental, and stress reduction - Gerontological Research Nurses - Initial 2-3 hour training followed by another 2-3 hour visit the following week
Person with Dementia Focused			
Huang, et al., 2013	RCT (N=129) Treatment = Home-Training Control = Information only	Community (Taiwan)	Individualized training of family caregivers of PWDs in behavioral and environmental strategies. - Gerontological Research Nurses - Initial 2-3 hour training with care manual followed by another 2-3 hour visit the following week with follow-up phone calls after and then monthly during follow-up
Karlin, et al., 2013	Pilot (N=64) Treatment = STAR Control = none	LTC (US)	STAR-VA: Staff Training in Assisted Living Residences focusing on behavioral principles for direct care workers. - Doctoral level Mental Health Provider - Initial training workshop with clinicians over 2.5 days. And weekly follow-up consult phone calls 90min, for 6 months
Kurs, et al., 2009	RCT multi-site (N=292) Treatment = education and skill training Control= not described	Community (Germany)	Informal caregiver training focusing on knowledge building and individual problem solving - Psychologists or Social Workers - 7 bi-weekly group sessions 90 min each, then 6 bi monthly refresher meetings over 15 months
Liddle, et al., 2012	RCT (N=29) Treatment = training DVD Control = usual care	Community (Australia)	DVD training program using memory and communication strategies - DVD - 2 45min baseline trainings, provision of the DVD
Martin-Carrasco, et al., 2009	RCT (N=115) Treatment = PIP Control = usual care	Community (Spain)	PIP – Psycho-educational Intervention Program - individual training - Clinical psychologist, Nurse, or Social Worker - 8 individual sessions for 90 min approximately every 1-2 weeks, over 4months
Martin-Carrasco, et al., 2013	RCT (N=238) Treatment = group PIP Control = usual care	Community (Spain)	PIP – Psycho-educational Intervention Program - group training - Clinical psychologist, Nurse, or Social Worker - Biweekly 7 group sessions of 90-120 min
McCurry, et al., 2005	RCT (N=36) Treatment = NITE-AD Control = contact control	Community (US)	NITE-AD: program for informal caregivers focusing on knowledge, sleep hygiene principles, and behavioral management - Geropsychologist - Six 1 hour in-home sessions over 2 months
McCurry, et al., 2012	RCT (N=47) Treatment = SEP Control = usual care	Adult Family Home (US)	Sleep Education Program (SEP) - Master's level gerontological Social Worker - 4 weekly workshops delivered to AFH staff
Moniz-Cook, et al., 2007	RCT pragmatic (N=113) Treatment = training in home Control= usual care	Community (UK)	Psychosocial education and support to decrease behavioral symptoms -Community Mental Health Nurse -4 consecutive weekly in-home visits and follow-up as needed over 18 months
Moore, et al., 2013	RCT (N=100) Treatment = PEP Control=information and support	Community (US)	Pleasant Events program (PEP) -Master's level mental health clinicians -4 in home 1 hour therapy sessions with 2 follow-up phone calls after the tx

Citation	Study Design (Sample Size) (Control)	Setting (Country)	Intervention Components -Interventionist -Duration & Frequency
Teri, et al., 2005	RCT (N=95) Treatment = STAR-C Control = usual care	Community (US)	STAR-C – training of community consultants to provide skills and behavior management for informal caregivers in the community -Clinical Geropsychologists -8 weekly sessions followed by 4 monthly phone calls
Teri, et al., 2005	RCT (N=120) Treatment = STAR Control = usual care	LTC (US)	STAR: Staff Training in Assisted Living Residences, dementia specific behavioral management and skill building for direct care workers -Clinical psychologist and Nurse -2 half day workshops and 4 individual sessions
Ulstein, et al., 2007	RCT (N=171) Treatment =Education Control = usual care	Community (Norway)	Psycho-educational program re: dementia and structured problem solving -Physicians (Geriatricians and Psychiatrists) -4.5 months, initial 3 hr session, then 6 group 2hr sessions
Visser, et al., 2007	RCT (N=52 Staff; N=76 PWD) Treatment =education Placebo=peer support Control=usual training	Residential facilities (Australia)	Formal caregiver education -Not specifically stated -8 sessions delivered twice weekly for 90 min

Table 2. Physical Activity Interventions

Citation	Study Design (Sample Size) (Control)	Setting (Country)	Intervention Components -Interventionist -Duration & Frequency
Physical Activity			
Group			
Aman & Thomas, 2009	Prospective Comparative (N=40) Treatment = Structured exercise Control = none	Memory Care Unit (US)	Structured aerobic and resistance exercise program - Interventionist not described - 30min 3x weekly for 3 weeks
Conradsson, et al., 2010	RCT cluster (N=191) Treatment=HIFE Control = OT directed activities group	Residential facilities (Sweden)	High-Intensity functional exercise (HIFE) : designed by Physical Therapists, 41 structured, weight bearing exercises designed to increase functionality - OT/PT - 45min sessions, 5 sessions in each 2 week period for 13 weeks
Edwards, et al., 2008	Pilot pre-post (N=36) Treatment = Chair exercises Control = none	SNF memory care units (US)	Chair-based exercises - Exercise physiologist - 30 min 3x weekly for 12 weeks
Fan & Chen, 2010	Quasi-experimental (N=59) Treatment=Silver Yoga program Control=not described	Residential facilities (Taiwan)	Silver Yoga - yoga program designed for older adults - “certified SY instructors” - 3x per week, 55 minutes each time for 12 weeks
Hokkenen, 2009	RCT (N=29) Treatment=DMT Control=placebo social group	Residential facilities (Finland)	Dance/Movement therapy - Interventionist not described - 9 weekly sessions 30 -45 min each
Pitkala, et al., 2013	RCT (N=210) Treatment A= group exercise at adult day care Treatment B= home based individual exercise Control=usual care	Community (Finland)	FINALEX - multi, focus on endurance, balance, strength training, and functional exercises. - Physiotherapists - 1 hour of training/exercise 2x week for 1 year. Mean exercise time was 1h/d
Roland, et al., 2007	RCT (N=134) Treatment = structured exercise program Control = usual care	SNF (France)	Structured Group Exercise program - aerobic, strength, flexibility, and balance (walking was at least half) - OT - 1 hour afternoon sessions 2x weekly for 12 months
Stella, et al., 2011	RCT (N=32) Treatment=group exercise program in community sites Control = usual care	Community (Brazil)	Structured exercise program at a center 3 times weekly for 60 min - “expert in physical education” - 60min 3x weekly for 6 months
Van de Winckel, et al., 2004	RCT (N=25) Treatment=daily group musical exercise Control= conversation	Gero-Psych units (Belgium)	Music-based exercise - “exercise therapist” - Daily 30 min sessions for 3 months
Individual			
Eggermont, et al., 2010	RCT (N=112) Treatment = daily walking Control = social visit	SNF (Netherlands)	Walking - Student research assistant - 30 min sessions 5x weekly for 6 weeks
McCurry, et al., 2011	RCT (N=132) A=walking B=Bright light C=both Control=contact	Community (US)	Walking and Bright light - Master’s level Healthcare professional - 8 week tx period

Citation	Study Design (Sample Size) (Control)	Setting (Country)	Intervention Components -Interventionist -Duration & Frequency
Roach, et al., 2011	RCT (N=82) Treatment A= functional exercise Active Control = supervised walking Control = conversation	LTC (US)	Activity specific exercise focusing on functional activities - Not specifically stated - 30min 5x weekly for 16 weeks
Steinberg, et al., 2009	RCT (N=27) Treatment= Instruction in exercise program and goals for Cg to complete with PWD Control = home safety visits and recording of activity	Community (US)	Home based exercise program delivered by family Cg with aerobic (walking), strength (resistance bands and ankle weights), balance and flexibility. - Exercise Physiologist - Cg given exercise goals for PWD to equal 5 activities per week
Teri, et al., 2003	RCT (N=153) Treatment=RDAD Control = usual care	Community (US)	Reducing Disability in Alzheimer's Disease (RDAD) - exercise component included aerobic/endurance, strength training, balance, and flexibility with goal of 30min/day. Behavior management component included ABCs, education, and pleasant events. - Healthcare Professionals experienced in Dementia care - 1 hour sessions, 2x weekly for 3 weeks, weekly for 4 week, EoW for 4 weeks, with follow-up visits monthly after
Williams & Tappen, 2008	Repeated measures quasi-experimental with random assignment (N=45) A=comprehensive exercise program B=supervised walking C=equivalent time conversation	SNF (US)	Comprehensive individual exercise with strength, balance, and flexibility exercises, walking. - Graduate Nursing or PT students - 30 min 5x weekly for 16 weeks

Table 3. Studies of Moderators in Dementia

Citation	Independent Variable	Moderating Variable	Dependent Variable	Significant Moderation
Pruchno, et al. 1989	Stressors of Caregiving	Coping Style	Caregiver Burden	No - Mediation
Pot, et al. 2000	Appraisal of Caregiving	Resources Coping Style	Caregiver Psychological Well-being	No
DiBartolo & Soeken 2003	Stressors of Caregiving	Hardiness	Caregiver Self-Perceived Health	Yes
Coon, et al. 2003	Interventions targeting Depression & Anger	Elevated Depression Expression of Anger	Caregiver Depression and Anger	Yes
Gilliam & Steffen 2006	Severity of PWD	Self-Efficacy	Caregiver Depressive Symptoms	No
Rabinowitz, et al. 2006	Skill Building Intervention	Low baseline Self-Efficacy	Caregiver Depression	Yes
Rabinowitz, et al. 2009	BPSD	Self-Efficacy	Caregiver Depression	Yes
Hilgeman, et al. 2007	REACH intervention	Postive Aspects of Caregiving	Caregiver Burden and Depression	Yes
Hilgeman, et al. 2009	Available resources	Race	Caregiver Strain	Yes
Pioli 2010	Demands of Caregiving	Mastery	Caregiver Depression and Anxiety	Yes
Romero-Moreno, et al. 2011	Caregiving Burden	Self-Efficacy for controlling upsetting thoughts	Caregiver Depression and Anxiety	Yes
Kim, et al. 2011	Use of Adult Day Services	Relationship (sps v. child)	Caregiver Burden	Yes
Romero-Moreno, et al. 2013	Leisure Activities	Guilt	Caregiver Depression	Yes
Zhang, et al. 2014	BPSD Social Support	Self-Efficacy	Caregiver Burden	Yes

Table 4. Sample Descriptives

N=239	PWDs	Caregivers
Gender	50.6% Male 49.4% Female	26.5% Male 73.5% Female
Age	Range 49-97yo Mean 81yo	Range 29-93yo Mean 69yo
Race/Ethnicity	90% Caucasian 3.3% African-American 3.3% Asian 1.3% Native American/Alaskan Native 0.4% Native Hawaiian/Pacific Islander 1.7% other	88.2% Caucasian 4.2% African-American 3.4% Asian 1.3% Native American/Alaskan Native 0.4% Native Hawaiian/Pacific Islander 2.5% other
Hispanic	4.2% Hispanic	4.6% Hispanic
Language	92.5% Native English Speakers 7.5% ESL	95.8% Native English Speakers 4.2% ESL
Years of education	35.1% High School or Less 29.3% with education post-high school 35.6% with a Bachelor's or higher	24.7% High School or Less 32.8% with education post-high school 42.4% with a Bachelor's or higher
Relationship	64% Spouse 29% Adult Child 7% Other relationship	

Table 5.

		Pleasant Events					Behavioral Plans					Physical Activity							
		R^2	MSE	β	SE	t	p	R^2	MSE	β	SE	t	p	Wald χ^2 (23)	p	β	SE	z	p
<i>Model Fit</i>		0.03	1.63					0.04	2.23					100.09 *	<0.01				
<i>Coefficients</i>																			
<i>Block 1 Predictors</i>																			
Intercept			3.28	0.28	11.77 *	<0.01			4.07	0.38	10.79 *	0.00				0.39	0.14	2.82 *	<0.01
Caregiver Gender			0.16	0.28	0.58	0.57			-0.30	0.36	-0.83	0.41				-0.22	0.15	-1.42	0.16
CES-D			-0.01	0.02	-0.71	0.48			0.01	0.02	0.30	0.76				-0.01	0.01	-1.38	0.17
RMBPC Reaction			-0.25	0.29	-0.87	0.39			-0.28	0.42	-0.67	0.50				0.16	0.12	1.31	0.19
<i>Block 2 Predictors</i>																			
Intercept			2.93	0.58	5.10 *	<0.01			3.91	0.75	5.25 *	<0.01				0.65	0.29	2.27 *	<0.05
Caregiver Gender			0.83	0.74	1.12	0.26			-0.32	0.96	-0.33	0.74				0.42	0.53	0.81	0.42
CES-D			0.00	0.03	0.11	0.91			-0.03	0.05	-0.66	0.51				0.05	0.02	1.83	0.07
RMBPC Reaction			0.00	0.61	0.01	0.99			0.50	1.02	0.49	0.62				0.43	0.50	0.85	0.40
Gender by CES-D			-0.01	0.04	-0.33	0.74			-0.01	0.04	-0.23	0.82				-0.11	0.05	-2.11 *	<0.05
Gender by RMBPC-R			-0.83	0.73	-1.14	0.26			-0.05	1.07	-0.04	0.97				-0.05	0.84	-0.06	0.95
CES-D by RMBPC-D			-0.01	0.03	-0.27	0.78			-0.01	0.05	-0.15	0.88				-0.05	0.03	-1.56	0.12
Relationship by Gender			0.46	0.81	0.57	0.57			0.67	1.01	0.67	0.50							
Relationship by CES-D			-0.01	0.03	-0.29	0.77			0.08	0.04	1.85	0.07							
Relationship by RMBPC-R			0.20	0.61	0.04	0.97			-0.95	0.92	-1.04	0.30							
<i>Notes. N=176. CES-D = Center for Epidemiologic Studies Depression scale; RMBPC-R = Revised Memory and Behavior Checklist - Reaction sub-scale.</i>																			

* $p < .05$, ** $p < .01$.

Table 6.																			
<i>Person with Dementia Moderators</i>																			
	Pleasant Events					Behavioral Plans					Physical Activity								
	R^2	MSE	β	SE	t	p	R^2	MSE	β	SE	t	p	Wald χ^2 (df)	p	β	SE	z	p	
<i>Model Fit</i>	0.01	1.63					0.08	2.18					216.57 *	<0.01					
<i>Coefficients</i>																			
<i>Block 1 Predictors</i>																			
Intercept			3.33	0.82	4.05 *	<0.01			3.50	1.14	3.07 *	<0.01			0.11	0.33	0.35	0.73	
Gender			-0.19	0.27	-0.71	0.48			0.33	0.38	0.86	0.39			0.18	0.15	1.22	0.22	
MMSE			0.00	0.02	0.03	0.97			-0.01	0.03	-0.33	0.74			0.00	0.01	-0.30	0.77	
RMBPC			-0.16	0.36	-0.43	0.67			0.13	0.49	0.26	0.79			0.01	0.15	0.05	0.96	
Relationship			0.11	0.27	0.42	0.68			0.14	0.38	0.36	0.72			0.19	0.15	1.31	0.19	
<i>Block 2 Predictors</i>																			
Intercept			3.29	2.18	1.51	0.13			4.03	2.8	1.44	0.15			-4.18	2.61	-1.60	0.11	
Gender			-2.71	2.10	-1.29	0.20			1.10	2.91	0.38	0.71			-15.91	11.67	-1.36	0.17	
MMSE			0.10	0.18	0.86	0.39			-0.19	0.15	-1.25	0.21			-0.42	0.15	-2.78 *	<0.01	
RMBPC			0.03	1.05	0.03	0.98			0.43	1.39	0.31	0.76			-2.34	1.46	-1.61	0.11	
Gender by MMSE			0.02	0.04	0.44	0.66			0.11	0.49	2.26 *	<0.05			0.74	0.56	1.31	0.19	
Gender by RMBPC			0.99	0.80	1.24	0.21			1.24	1.17	1.06	0.29			8.73	6.40	1.37	0.17	
MMSE by RMBPC			-0.06	0.06	-0.99	0.32			0.06	0.08	0.73	0.47			0.21	0.08	2.47 *	<0.05	
Gender by Relationship			0.13	1.56	0.08	0.93			-4.84	2.24	-2.16 *	<0.05			18.57	11.99	1.55	0.12	
Relationship by MMSE			0.00	0.04	0.07	0.94			0.02	0.05	0.43	0.67			0.40	0.21	1.94	0.05	
Relationship by RMBPC			0.17	0.75	0.23	0.82			-2.62	1.07	-2.46 *	<0.05			2.39	1.77	1.35	0.18	
<i>Notes. N=176. MMSE = Mini Mental State Exam; RMBPC = Revised Memory and Behavior Checklist; Relationship = Spouse vs. Non-Spouse</i>																			
<i>* p < .05</i>																			

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