ORIGINAL RESEARCH

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Can Interpreting Nonsignificant Findings Inform the Lessons Learned From an Intervention?

Abstract: *Reducing Disability in Alzheimer's Disease (RDAD) is an evidenced-based intervention for individuals with dementia and their caregivers aimed at reducing the psychosocial strain of the caregiver and improving functional ability of the individual with dementia. Overall efficacy, acceptability, and feasibility outcomes have been published regarding RDAD; however, no specific outcome information has been published on the objective physical performance measures (PPM) of gait speed, functional reach, and balance. Data from the Replication of RDAD (n = 508) was utilized to test the hypothesis that each PPM would show change for participants who completed the program. No significant changes were identified in 3 PPM: gait speed (*$t = .24$, $P = .81$*), balance (*$t = .23$, $P = .82$*), and functional reach (*$t = -.55$, $P = .58$*). To strengthen the research about exercise interventions for individuals with dementia, discussion and interpretation of nonfindings is important for improving intervention designs and methodologies. In the case of RDAD, the intervention protocol may require a sufficient dosage of exercise with respect to fundamental exercise science principles, or there may be misalignment between the intervention and outcome measures.*

Keywords: physical performance; Alzheimer's disease; exercise; research design; outcomes; intervention

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It was estimated that 35.6 million people (5% to 7% of the population) lived with dementia worldwide in 2010, with numbers expected to almost double every 20 years, to 65.7 million in 2030 and 115.4 million in 2050.[1] Individuals with dementia (IWDs) may experience a variety of difficulties including cognitive decline, functional deficits, and psychological difficulties such as symptoms of depression. Most types of dementia result in slow and steady decline over several years leading to increased dependence on caregivers as well as contributing to health care costs worldwide of $604 billion in 2010.[2]

When compared to cognitively intact older adults, IWDs have higher rates of functional mobility problems and falls, which can be related to gait and motor impairments including balance.[3,4] Significant differences have been identified in standardized assessments of gait (eg, 4-meter walk test) when comparing cognitively impaired individuals to healthy older adults.[5] Deficits in functional mobility, balance, and gait can be partially responsible for declines in functional status, institutionalization, or even the increased risk of falls in this population.[4,6,7] Combating these declines is crucial in

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maximizing a person's independence, and achieving optimal functional participation in daily activities and can potentially delay or prevent the need for a long-term care facility. Gait cadence predicts falls in patients with Alzheimer's disease,[6] while walking speed has been associated with transfer from assisted living residence to a skilled nursing facility.[7] It is possible that improvements in walking speed through exercise could allow an IWD to "age in place" longer.

The current body of literature regarding interventions to improve physical performance in IWDs is conflicting.[8] Some interventions demonstrate positive and efficacious results in functional domains such as gait parameters, balance, and strength,[9-13] while other interventions have identified no significant changes in these same outcomes.[14,15] Conflicting results could lead researchers and practitioners to ignore the entire body of literature or dismiss a potentially efficacious intervention due to nonsignificant findings. One must try to resolve the different findings by carefully dissecting the studies and being critical of the intervention and research design. This includes careful review of the development, implementation, and evaluation of a given intervention.

One of the interventions that addresses the physical performance of IWDs is "Reducing Disability in Alzheimer's Disease" (RDAD),[16] an evidenced-based intervention that engages the IWD and the family caregiver. The aim of RDAD is to reduce the psychosocial strain of the caregiver and improve the functional ability of the IWD. In a randomized controlled trial, IWDs in the RDAD group had reduced depressive symptoms, improved subjective physical functioning scores, increased number of exercise minutes, and reduced number of restricted activity days.[16] However, no significant changes were reported from the randomized controlled trial for the objective physical performance measures (PPM) of gait speed, balance, or functional reach, which are important indicators of physical performance.

Reducing Disability in Alzheimer's Disease

RDAD is a multicomponent intervention developed by Teri and colleagues at the University of Washington.[16,17] Specifically, RDAD trains caregivers and IWDs on an in-home program of exercise for IWDs while providing caregivers with strategies for managing behavioral symptoms. RDAD was developed "to increase flexibility, endurance, and strength with the goal of decreasing the behavioral and physical disability common among persons with dementia,"[17] as well as to potentially "reduce functional dependence and delay institutionalization among patients with Alzheimer's disease."[16] (Additional details about the RDAD components and training of the intervention specialists are available elsewhere.[16-18])

The intervention is composed of 12 one-hour, in-home sessions conducted over a 3-month period.[16] This consisted of twice-weekly sessions for the first 3 weeks, followed by weekly sessions over the next 4 weeks and then biweekly sessions over the remaining 4 weeks. The exercise component includes different types of exercise: strength, balance, and flexibility. Dyads are encouraged to establish a regular exercise regimen, as well as engage in aerobic activities (eg, walking). Exercises were to be performed 3 days weekly lasting approximately 10 to 15 minutes. "Participants were taught exercises initially without weights to a maximum of 1 set of 12 repetitions."[19] Following initial instruction, the caregiver was responsible for monitoring completion of the exercises and recording completion in an exercise log.

A community replication of RDAD was conducted in order to determine whether results similar to the randomized controlled trial would be achieved when the intervention is delivered in a less research-controlled, more diverse, community environment. RDAD was implemented across the state of Ohio by the staff from 7 Alzheimer's Association Chapters. Thirty-eight clinical staff from the Alzheimer's Association Chapters serving Ohio were trained to deliver the RDAD program. The purpose of the current study was to explore changes in the objective physical performance of IWDs who participated in the replication of the RDAD program. It is important to look at these objective physical indicators in addition to the efficacious subjective outcomes,[16] as they can predict important adverse events such as falls or mortality.[20-22] It was hypothesized that positive changes would be observed in PPM of gait speed, balance, and functional reach after 3 months.

Methods

Design

The community replication of RDAD used a pre-post treatment design. There was no control group because the primary goal of the replication project was to test the feasibility of a large-scale community implementation of a program already proven to be efficacious. This design and methodology provided a "real-world" understanding of the implementation process,[23,24] which attempts to address the growing need for translation research with interventions evaluating health-related outcomes.[25]

Sample

The 7 Alzheimer's Association Chapters across the state of Ohio recruited potential participants through their service programs and community presentations. Eight hundred forty-two potential families were referred to the program, of which 72% enrolled. No data are available for nonenrolled families; therefore, it is not possible to determine whether their characteristics differed from those who did enroll. Of the 606 families who enrolled, 98 did not complete a survey at Time 1 (Baseline). This analysis includes the 508 enrolled families who completed a Baseline survey. Of these 508 families, 371 families (73%) completed the 12-week intervention and Time 2 assessment.

Participation in RDAD required IWDs to have a dementia diagnosis or memory problems, reside outside of a nursing home, be ambulatory, have the physical ability to do simple exercises, and have an actively involved family or friend caregiver. Families who met the eligibility criteria for the replication were scheduled for Session 1 during which both the caregiver and IWD completed written informed consent (evaluation protocol approved by the institutional review board of the Benjamin Rose Institute on Aging).

Measures

During Session 1, the Trainer conducted a functional assessment with the IWD, which included gait speed (8-foot walk test), standing balance, and functional reach.[19] Demographic information was based on caregiver reports of IWD age, IWD gender, IWD race, caregiver type (ie, spousal or nonspousal caregiver), and IWD primary dementia diagnosis. Cognitive status of IWDs was based on scores from the Short Blessed Memory-Orientation-Concentration Test (SBT),[26] where a higher score (0-28) indicated more cognitive impairment. In addition to the functional assessment at Baseline (Time 1), the IWD participated in a Time 2 assessment during Session 12 of the program (3 months from Baseline) to reassess the PPM.

Analysis Plan

This study of the RDAD program did not have a control group. The impact of the program on IWD PPM (ie, gait speed, standing balance, functional reach) was based on longitudinal changes from participants' preprogram (Time 1) to postprogram (Time 2) outcomes.[23] Paired *t* tests were used to determine if significant change occurred following completion of the RDAD intervention. A priori hypotheses called for 3 paired *t* tests to be conducted separately for each PPM: gait speed, balance, and functional reach. Two sets of analyses were conducted. First, an "as treated" analysis used a pairwise deletion method for those cases without a Time 2 assessment. Second, an "intent to treat" analysis was done in which baseline values replaced missing information at Time 2. No differences in results for these 2 sets of analyses were found, and the "as treated" results are reported.

Table 1.

Sociodemographic Characteristics of Participants (N = 508).[a]

Participant Characteristic	Mean	*SD*
Age (range = 59-103 years)	82.14	8.13
SBT score (scored: 0–28)	19.10	8.16
	%	
Female	44.8	
Married	62.4	
Caucasian	76.4	
Alzheimer's disease	50.1	

Abbreviation: SBT, Short Blessed Test.
[a]For SBT, higher scores indicate higher number of errors equating to more cognitive impairment. For characteristics reported as percentages, 1 = yes.

Table 2.

Functional Capacity of Participants at Baseline (N = 508).

Participant Characteristic	Mean	SD
8-foot walk test (in seconds)	5.93	7.02
Balance (range = 0-6)	3.53	1.66
Functional reach (range = –0.50 to –33 inches)	8.70	3.97
Minutes walked over past week	127.66	218.75
Restricted bed days over past week	0.83	1.88

Results

Participant Baseline Characteristics

Demographic characteristics of participants are presented in Table 1. The sample ranged in age from 59 to 103 years, with a mean of 82.14 (standard deviation [SD] = 8.13). The Short Blessed Test,[26] measuring cognitive status, had a mean score of 19.10, revealing severe impairment. About half of the sample (50.1%) had Alzheimer's disease while the remaining sample had other forms of dementia (eg, vascular dementia, nonspecific dementia).

Gait speed at baseline was based on results from the 8-foot walk test (see Table 2). Average time to complete the 8-foot walk was 5.93 seconds (SD = 7.02). To allow comparison to normative data, values for the 8-foot walk were converted to meters/second. With this conversion, gait speed ranged from 0.02 to 2.34 meters/second, with a mean of 0.62 meters/second indicating that overall the sample was slower than the age-related norm of approximately 1.3 meters/second.[27] Although the gait speed was slower than the norm for people of similar age, the gait speed of the current sample is comparable to other studies of IWDs.[3,28] Participants had scores ranging

Table 3.

Physical Performance Measures: Paired *t* Tests (N = 371).

	Time 1 Mean	Time 2 Mean	Mean Change	Std. Error Mean	*t*	*df*	*P* Value
8-foot walk test (in seconds)	5.55	5.51	0.04	0.16	0.24	366	.81
Functional reach	8.87	8.97	−0.10	0.19	−0.55	325	.58
Balance	3.71	3.69	0.02	0.07	0.23	357	.82

from 0 to 6 on the balance assessment with a mean score of 3.53. No normative data are available for this balance measure. Another measure of dynamic balance is the functional reach test in which participants had a mean score of 8.7 inches. This is below the established norms for adults aged 70 to 87 years (ie, men = 13.2 inches [SD = 1.6]; women = 10.5 inches [SD = 3.5]), indicating a balance deficit in the current sample,[21] but is similar to that of the baseline data reported for the sample in the RDAD randomized controlled trial.[19]

Pre- and Postintervention Performance

After the 12-week intervention, no significant changes were noted in gait speed, balance, or functional reach measures (Table 3). These results are the same as in the RDAD randomized controlled trial; however, no mean values from the posttest assessment were provided from the initial trial to allow comparison to the current study.[16] Mean change in the 8-foot walk test and the functional reach test showed minimal improvement but were not significant. Collectively these results indicate that while RDAD has been found efficacious in improving subjective physical functioning on the SF-36 measure,[16] no significant changes could be noted in the current sample for objective PPM.

Discussion

RDAD is an evidence-based intervention that has been successfully implemented and found efficacious regarding the psychosocial outcomes and subjective physical functioning of IWDs. Analyses from this replication study parsed out the PPM to better understand the effect of the intervention. No significant change was noted with respect to gait speed, balance, or functional reach, indicating that the RDAD intervention did not change the objective physical performance of participants.

Informed by empirical evidence, the American College of Sports Medicine's (ACSM's) Position Stand on exercise and physical activity for older adults clearly states that strength or resistance training improves muscle strength, and exercise improves walking speed and balance.[29] Considering the range of exercises taught in RDAD and ACSM's position, these nonsignificant findings raise questions. Rather than dismiss the potential in RDAD because of the nonsignificant findings, and in an effort to build and improve this body of literature, it is of benefit to consider what other factors may influence these results. These factors may include development or design considerations with respect to the intervention and/or method of testing. To further investigate these potential issues, a brief review of intervention research is warranted to better understand the process. This review is followed by a discussion of exercise interventions with specific recommendations to strengthen this body of literature and better understand the effects of exercise with IWDs.

Intervention Development and Research

When reviewing any intervention, a cursory understanding of the intervention development and research is helpful. While several frameworks have been used to describe the intervention research process (eg, the 5-phase model), most have common themes to guide researchers through the important process of intervention development and implementation as well as study design to allow for proper evaluation of the intervention.[25,30,31] It is important for researchers to inform the reader that the appropriate steps have been taken during the development, implementation, and evaluation of any intervention. This allows the reader to critically assess the level of rigor used during the process, which is integral in determining whether the results and implications are appropriate and acceptable.

In the early phases of intervention research, theoretical considerations should be identified and highlighted to assist with the design of the intervention components as well as the design of the evaluation study. Theories give a better understanding to how processes interact with one another to produce outcomes within a given timeframe and context.[32] Leeuw and Vaessen[33(p16)] state, "Intervention theory provides an overall framework for making sense of potential processes of change induced by an intervention."

For example, exercise science theory can inform the development, implementation, and evaluation of an exercise intervention. For exercise interventions, critical components of the intervention *development* revolve predominantly around the concept of dosage. Any intervention must be delivered at the appropriate level of intensity, duration, and frequency to ensure that intended changes are induced. The *implementation* of any intervention must ensure fidelity to the developed protocol. Finally, during the *evaluation* of any intervention, attention must be given to the link between intervention and outcomes.[33]

Exercise Interventions in Current Literature

A large amount of heterogeneity exists in the methodologies of many exercise intervention studies with IWDs,[9-13,15] including the RDAD protocol.[16,19] Differences in study and intervention design, implementation, and outcomes used in evaluation of these interventions limit the ability to aggregate or compare studies. However, a noted similarity is that most of these studies, as with RDAD, do not report or identify an explicit theory or framework guiding the research and intervention design. Not articulating or aligning with a specific exercise or physical activity framework is a potential limitation. Including these important principles from exercise science, such as appropriate intensity and dosage of exercise and proper alignment of intervention components with outcomes, allows better understanding of the results achieved in the intervention research.

Intensity and Dosage. First, it is possible that many of the exercise interventions for IWDs may not deliver sufficient levels of intensity to facilitate necessary changes to improve PPM outcomes. Principles of exercise science, including the Physical Stress Theory,[34] govern exercise prescription. This theory states that physical stress must surpass that of maintenance in order to provoke changes in muscle and other tissues; therefore, the concept of *overload* becomes pertinent to ensure appropriate levels of intensity during exercise. Exercise interventions must provide a safe level of overload or resistance (60% to 100% of maximum) to induce the beneficial changes in strength and balance, which are vital to improvements in functional status. According to recommendations from the ACSM and the Center for Disease Control (CDC), moderate-intensity exercise is achieved through different modalities. Strength training at 60% to 80% of individual's one repetition max (1 RM)*[35]; or aerobic training that is hard enough to raise your heart rate (HR; 50% to 70% of maximum age-related HR) and break a sweat. Other modes of physical activity can be measured at a moderate-intensity by being able to talk but not sing[36] or by a rating of 5 to 6 out of 10 on Borg's Rate of Perceived Exertion (RPE) scale.[37,38]

Additionally, the Physical Stress Theory posits that the level of exposure to a physical stressor is defined by multiple components of the applied stress such as magnitude, time, and direction.[34] Time factors include the duration of the stress, the number of repetitions, and the rate at which the stressor is applied to the body. Sufficiently resisted strengthening must be completed at least 2 to 3 times per week over a period of at least 6 weeks to elicit significant changes in muscle hypertrophy.[35]

Many of the exercise interventions that demonstrated nonsignificant effects on PPM do not introduce discussion or support for levels of intensity, frequency, or duration that meet these recommendations.[5,15] In the current study, the stated goal of RDAD was for "patients to engage in a minimum of 30 minutes per day of moderate-intensity exercise,"[16] which meets the CDC recommendations; however, it appears as though the implementation of the exercise principles do not align adequately. The RDAD protocol does not provide an initial strength assessment to ensure that a sufficient overload is placed on the participant to induce strength changes using a moderate-intensity level of training. Therefore, an improvement to interventions such as RDAD could be the addition of a strength assessment, which identifies a training starting point. Using the initial assessment as a guide, the IWD can be challenged sufficiently to induce adaptive changes.

Additionally, in the RDAD intervention, IWDs and caregivers were responsible for completion of proper frequency after the initial 3 weeks. It is possible that adherence to frequency and duration were not adequate to elicit gains. Using a simple and user-friendly intensity measure such as Borg's RPE Scale[39] or the Talk Test[36] can assist with fidelity monitoring to ensure the intended protocol is followed.

Interventions for IWDs that have demonstrated significant efficacy often explicitly outline proper intensity and dosage that are in line with the Physical Stress Theory. For example, the High-Intensity Functional Exercise Program (HIFE)[12] as well as a progressive resistance program by Hauer and colleagues[10] demonstrated positive effects on PPM. These protocols called for intensity of 8 to 12 RM and 70% to 80% of the participants' 1 RM, respectively. Kemoun and colleagues[11] outline endurance training that monitored HR with targets of 60% to 70% of the individual's maximum HR as well as introducing medium levels of resistance through strengthening exercises. Efficacious outcomes included improvements in walking speed and balance. These studies demonstrate that adherence to the principles of exercise science when developing an exercise intervention may assist researchers in maximizing successful physical performance outcomes.

Alignment of Outcomes Measures. Another reason for nonsignificant findings in some of the current research can be attributed to the use of outcome measures that do not align sufficiently with exercise

*A repetition maximum (RM) is determined by measuring the number of times an individual can move a specified amount of weight with good form. This can be used as a single or 1 repetition maximum or for multiple repetitions. This form of assessment has been the gold standard in strength assessment across multiple populations of individuals.

intervention components and may not be valid for use with special populations. For example, if an intervention aims to improve strength and endurance, it is important to specifically measure those constructs using valid assessment tools, such as the chair stand test[40,41] or the 6-minute Walk Test,[41,42] respectively. In the current study, a main purpose of the RDAD exercise component was "to increase flexibility, endurance, and strength"[17]; however, there is a misalignment of the physical outcomes of gait speed, balance, and functional reach with the exercise intervention components. Future implementations of RDAD may benefit from adding assessment tools that can measure the effects of the strengthening component of RDAD. The 30-second chair stand test[41] is a quick and easy test that can measure lower extremity strength in older adults, and has been used to successfully detect exercise effects in IWDs.[13]

Some frequently used PPMs may not prove reliable or valid in a sample of IWDs, and this may lead to conflicting or misleading findings simply due to the selected assessment tool. The functional reach measure used in the current study may not be the best measure for balance in IWDs as Duncan et al[22(pM196)] caution, "[The] functional reach may be difficult to perform in patients with severe dementia." Other measures (eg, the modified Berg Balance Scale[3,7]), which have been validated with IWDs, may provide more accurate information regarding change in performance over time in IWDs.

Implications

As mentioned earlier, the initial phase of any intervention research includes review of current literature along with the formulation and development of hypotheses,[31] and the use of a theoretical framework is imperative.[30] According to the principles of exercise science, in order to effect changes in strength, balance, or aerobic capacity, an exercise program should provide adequate workload. This workload includes between 60% and 100% of an individual's maximal ability and can be achieved through resistance or some other form of challenge to balance and postural stability. Furthermore, sufficient frequency and duration (2 times per week for strengthening and/or 5 days per week for aerobic training for at least 12 weeks)[37] should be met to ensure gains in targeted domains. Finally, while a standardized protocol is needed, flexibility should be considered due to the individual needs of each participant. A program may need to be flexible and allow for slower rates of training initially for more frail or sedentary individuals.[35,43] To achieve successful outcomes, the program must allow progression to continually challenge and properly stress the tissue through overload. Interventions that do not possess these key components may not adequately meet the needs of IWDs, or any older adult, to meet goals of improving physical performance.

Limitations of Current Study

Limitations of the current study should be acknowledged. First, no control group was used in this study. The goal of the larger replication project was to test feasibility of a large-scale community implementation of a program already proven to be efficacious with respect to its primary outcome measures.[19] The aim of the current study was to examine the impact of the intervention on the secondary outcomes of physical performance. A control group is necessary to truly discuss the impact of the intervention, as it is possible that a control group may have declined over time whereas the intervention group did not change significantly. However, it should be noted that a control group is not needed to address the concern that the intervention did not meet its stated goal of increasing physical performance. Finally, the Alzheimer's Association Trainers who conducted the physical performance assessments and implemented the intervention were not experts in exercise and fitness. Therefore, it is possible that fidelity to the protocol was not adequate to provide the intended dosage and intensity of the exercise component of RDAD.

Conclusion

Methodological improvements are needed to strengthen the level of evidence regarding exercise and older adults. More evidence is also needed on the effects of exercise on the physical and functional status, cognition, and well-being outcomes in this population of older adults with dementia. Douglas and colleagues[44] state that it is becoming increasingly recognized that nonpharmacological interventions should be used as an initial intervention with IWDs. Exercise could be an excellent adjunct or alternative to current interventions as it is a nonpharmacological, inexpensive, and accessible approach to potentially modifying the impact of the disease on IWDs.[45]

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