



## Randomized Controlled Trial of a Facilitated Online Positive Emotion Regulation Intervention for Dementia Caregivers

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### Abstract

**Objective:** To test the effects of LEAF (Life Enhancing Activities for Family caregivers), a 6-week positive emotion regulation intervention, on outcomes of positive emotion, depression, anxiety, and physical health as measured by PROMIS.

**Methods:** A randomized controlled trial (N = 170) comparing LEAF (N=86) to an emotion reporting/waitlist condition (N = 84) in dementia caregivers. LEAF was individually delivered online by trained facilitators. Participants in the control condition completed daily online emotion reports then crossed over into the intervention condition after 6 weeks. The study was registered with [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT01825681) and funded by R01NR014435.

**Results:** Analyses of difference in change from baseline to 6 weeks demonstrated significantly greater decreases in PROMIS depression, ( $d = -.25$ ;  $p = .02$ ) and NeuroQOL anxiety ( $d = -.33$ ;  $p < .01$ ), and improvements in PROMIS physical health ( $d = .24$ ;  $p = .02$ ) in the intervention condition compared to the emotion reporting/waitlist control. The intervention also showed greater improvements in positive emotion ( $d = .58$ ;  $p < .01$ ) and positive aspects of caregiving ( $d = .36$ ;  $p < .01$ ). Increases in positive emotion significantly mediated the effect of LEAF on depression over time.

**Conclusions:** This randomized controlled trial of the online facilitated positive emotion regulation intervention in dementia caregivers demonstrated small to medium effect sizes on caregiver well being and shows promise for remotely delivered programs to improve psychological well-being in caregivers of people with dementia and other chronic illnesses.

### Keywords

Caregivers; stress; randomized controlled trial; positive emotion; patient reported outcomes

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The prevalence of Alzheimer's Disease and other dementias is steadily climbing and predicted to affect as many as 16 million Americans by 2050 (Alzheimer's Association,

2017). If the current trend continues, more than 90% of those with dementia will receive care from a family member or friend (Kasper, Freedman, Spillman, & Wolff, 2015). In a nationwide poll in 2016, 59% of dementia caregivers reported experiencing high levels of emotional and physical stress (Association, 2017) and the chronic stress of dementia caregiving is associated with a range of deleterious physical and mental health consequences (Chattillion et al., 2012; Gouin, Glaser, Malarkey, Beversdorf, & Kiecolt-Glaser, 2012; Kiecolt-Glaser, Dura, Speicher, Trask, & Glaser, 1991; Kiecolt-Glaser, Marucha, Mercado, Malarkey, & Glaser, 1995; Mausbach et al., 2012; Roepke et al., 2012; Schulz & Beach, 1999; Von Känel et al., 2006; von Känel et al., 2012). In addition, caregiving stress and burden negatively impact quality of care and lead to poorer quality of life in the care recipient (Hébert, Dubois, Wolfson, Chambers, & Cohen, 2001; Mittelman, Haley, Clay, & Roth, 2006).

Interventions designed to reduce burden for dementia caregivers have primarily consisted of education or training in caregiving skills, (e.g., Chu, Edwards, Levin, & Thomson, 2000; McCallion, Toseland, & Freeman, 1999; Quayhagen & Quayhagen, 1989), social support (e.g., McCurry, Logsdon, Vitiello, & Teri, 1998; Mittelman, Ferris, Shulman, Steinberg, & Levin, 1996), or stress management, (e.g., Morris, Woods, Davies, Berry, & Morris, 1992; Zarit, Anthony, & Boutselis, 1987) with a primary focus on reducing negative emotion and stress. However, over the past few decades, it has become clear that positive affect or positive emotions, defined as subjective positively valenced feelings that range from happy, calm, and satisfied, to excited and thrilled, are uniquely related to better psychological and physical well-being, independent of the effects of negative emotion (Folkman, 1997; Folkman & Moskowitz, 2000; Fredrickson, 1998; Fredrickson, Cohn, Coffey, Pek, & Finkel, 2008; Tice, Baumeister, Shmueli, & Muraven, 2007; Wichers et al., 2007; Zautra, Johnson, & Davis, 2005). Positive emotion is associated with a host of beneficial outcomes including better relationships, more creativity, better quality of work, higher likelihood of prosocial behavior (Lyubomirsky, King, & Diener, 2005), better physical health (Pressman & Cohen, 2005), and even a lower risk of mortality in healthy as well as chronically ill samples (Chida & Steptoe, 2008; Liu et al., 2016; Moskowitz, 2003; Moskowitz, Epel, & Acree, 2008; Steptoe & Wardle, 2011).

Among caregivers, positive emotion predicts lower frailty over a two-year follow-up (Park-Lee, Fredman, Hochberg, & Faulkner, 2009) and engagement in pleasant activities is associated with higher positive emotion and lower negative emotion (Mausbach, Coon, Patterson, & Grant, 2008; Mausbach, Roepke, Depp, Patterson, & Grant, 2009). Positive caregiver resources such as optimism, resilience, and a sense of coherence are associated with lower levels of burden and higher quality of life (Fianco et al., 2015; Trapp et al., 2015), suggesting that an intervention that specifically targets positive emotion holds promise for improving caregiver well-being, reducing burden, and, ultimately, improving quality of care for the individual living with dementia. Indeed, interventions that specifically target positive emotion are showing efficacy across a range of stressful health conditions such as diabetes (Cohn, Pietrucha, Saslow, Hult, & Moskowitz, 2014; Huffman, DuBois, Millstein, Celano, & Wexler, 2015) heart disease (Huffman et al., 2011; Peterson et al., 2012), hypertension (Boutin-Foster et al., 2016; Ogedegbe et al., 2012), substance use (Carrico et al., 2015; Krentzman et al., 2015), schizophrenia (Caponigro, Moran, Kring, &

Moskowitz, 2013), depression (Seligman, Steen, Park, & Peterson, 2005), and HIV (Moskowitz et al., 2017).

Grounded in theory and building on empirical findings of a link between positive emotion and adaptive outcomes for people coping with significant stress, we developed a multi-component intervention that focuses on skills for increasing the frequency of positive emotion to better cope with stress (Cheung et al., 2016; Cohn et al., 2014; Dowling et al., 2014; Moskowitz et al., 2014; Moskowitz et al., 2017; Moskowitz et al., 2012) The intervention is based on revised Stress and Coping Theory (Folkman, 1997) and the Broaden-and-Build Theory of positive emotion (Fredrickson, 1998). These theories describe ways positive emotion supports coping and well-being, such as providing a psychological “time-out” from stressful experiences and motivating and sustaining ongoing efforts to cope. Repeated experiences of positive emotion build social, intellectual, and physical resources that may ultimately benefit psychological well-being and physical health. The rapidly growing body of literature on the social, cognitive, psychological, and health benefits of positive emotion argue strongly for programs targeted at increasing positive emotions and positive experiences as a mechanism for mitigating depression, stress, and burden, and subsequently increasing the likelihood of higher quality care, improved self-care, and improved physical and psychological well-being for dementia caregivers. A feasibility pilot test of a positive emotion regulation intervention in a small sample of caregivers of dementia patients demonstrated increases in positive emotion and decreases in negative emotion, burden, and stress compared to an active control condition (Dowling et al., 2014).

As in other areas of research on health-related stress, the literature on dementia caregiving has suffered from a lack of precision and standardization of measures used to assess important constructs such as stress, depression, health and well-being. Given the variety of measures used across different research teams, it has become difficult to compare these scores in dementia caregiver samples with the general population or other chronically-stressed samples. Moreover, the lack of standardized measures used across research teams has made it difficult to compare the effects of different behavioral or psychological interventions.

The Patient Reported Outcomes Measurement Information System (PROMIS) is a collection of highly flexible, precise, and responsive self-report measures of physical, mental, and social well-being that aims to address the lack of precision, standardization, and comparability of measures that plague the dementia caregiving literature as well as the literature in health and medicine more broadly (Cella et al., 2007). PROMIS is part of the larger person centered HealthMeasures system that includes a number of self-report measures of well-being and functioning ([www.healthmeasures.net](http://www.healthmeasures.net).) The National Institutes of Health funded a team of leading experts in clinical and patient-reported outcomes research to develop state of the art, psychometrically robust systems to measure patient-centered (or person-centered) outcomes efficiently in patients with a wide range of chronic diseases as well as the general population. Within domains, these person-centered measures have been created through the use of qualitative and quantitative methods that have leveraged both classical test theory and item response theory approaches. Moreover, these measures have been rigorously reviewed and tested for reliability and validity and can be

compared across domains and diseases using standardized metrics. There are now more than 800 published studies with PROMIS measures alone, in a number of different chronically ill and general population samples. The majority of the studies are cross sectional, however, with fewer studies reporting longitudinal change or responsiveness to behavioral or psychological interventions. Although there have been a few studies that used PROMIS measures in caregivers (e.g., Daly, Douglas, Lipson, & Foley, 2009; Romero, Flood, Gasiewicz, Rovin, & Conklin, 2015), none have examined change in these outcomes over time or in response to interventions and none have been in dementia caregivers. In the present paper, we report results from an emotion regulation intervention for caregivers of dementia patients and, as part of a set of self-report measures, examine PROMIS and related HealthMeasures constructs (depression, physical health, and anxiety) as outcomes.

In the present study we address a number of concerns in the burgeoning field of positive emotion regulation interventions. Many of the studies thus far suffer from methodological weaknesses including small sample sizes, lack of randomized trials, failure to report intent-to-treat analyses (Bolier et al., 2013), and imprecise measurement of outcomes (Moskowitz et al., 2017). In addition, few studies of positive interventions address questions of whether improvements in the targeted positive psychological construct mediate the effects of the intervention on more distal outcomes. We present results from a randomized controlled trial of a theory based positive emotion regulation intervention, delivered online by trained facilitators, for caregivers of people with dementia. The intervention, Life Enhancing Activities for Family caregivers (LEAF) was delivered remotely, via the internet which allowed us to reach a wide range of caregivers from all over the country, many of whom would not otherwise have been able to participate.

We examine outcomes of depression, anxiety, and physical health as measured by PROMIS (and related HealthMeasures systems), precise and responsive measures that facilitate meaningful comparisons across studies and to other populations, and test whether positive emotion, the proximal target of the intervention, mediated effects on outcomes of depression and burden. We hypothesized that the participants in the LEAF condition would show increases in our primary outcome of interest, positive emotion, compared to the control condition. In addition, we hypothesized that intervention participants would show significantly greater improvements in our secondary outcomes of interest, namely: depression, mental and physical health, anxiety, stress, and caregiving burden relative to controls, and that these improvements would be mediated by increases in positive emotion.

## Methods

We conducted a randomized controlled trial of a 6-session positive emotion regulation intervention (LEAF) compared to an emotion-reporting waitlist control. All sessions were delivered live by trained facilitators via the internet on study-supplied tablet computers. Assessments were completed online.

### Participants, recruitment, screening, and randomization.

In order to be eligible, participants had to 1) be a primary family caregiver of a person diagnosed with a degenerative dementia condition; 2) live with the care recipient or visit

daily; 3) be able to speak and read English; and 4) have reliable WiFi internet at home or access from another location (e.g., a library) convenient for them. Exclusion criteria were active psychosis or significant cognitive impairment as evidenced in the screening phone call. All study procedures were approved by the University of California San Francisco and Northwestern University IRBs, all participants provided verbal and online informed consent, and the study was registered with [Clinicaltrials.gov](https://clinicaltrials.gov) (NCT01825681).

Participants were recruited in person through brochures in clinic waiting rooms and at caregiver events, and online through caregiver support groups, bulletin boards, and other internet postings such as clinical trial matching sites and Facebook. Recruitment started in August, 2014 and was completed in November, 2016. Follow up data collection was completed in June, 2017. Interested participants filled out a brief contact form on the study website. The project coordinator then followed up with a phone call to ask additional screening questions and provide a more detailed description of study procedures. Eligible participants were sent a link to the online consent form and subsequent baseline questionnaire.

Once the baseline questionnaire was completed, participants were randomized 1:1 to either receive the LEAF content immediately (LEAF condition) or to complete daily emotion reports for 6 weeks followed by the LEAF content (emotion reporting-waitlist control.) Randomization was stratified by gender and by three categories of population density: rural (1–999 persons per mi<sup>2</sup>), suburban (1000–3000 persons per mi<sup>2</sup>), and urban (>3000 persons per mi<sup>2</sup>). The study statistician devised the randomization table and participants were automatically randomized upon completing their baseline assessment via a FileMaker database that contained their demographic information and population classification.

Prior to beginning LEAF sessions, the participants were sent a package that contained study materials and an 8” tablet computer. Before scheduling LEAF sessions, the study coordinator had a tech setup meeting by phone with each participant to walk them through the steps of joining a WebEx meeting and to familiarize them with the other uses of the tablet. Each participant was invited to keep their tablet for their own personal use at the end of study participation, when all follow-up data had been collected. Participants who withdrew from the study early were given instructions and mailing supplies to return the tablet and study workbook to the study office.

We minimized attrition by reaching out to the participants often and taking extra time to thoroughly explain study procedures, answer questions, and attend to concerns. The coordinator helped each participant assess whether or not they could successfully integrate the study activities into their schedules and gave each caregiver time to decide to enroll without pressure. If a participant did not complete a study activity, the coordinator made multiple attempts to reach out and connect, making room for the participant to skip that activity but remain in the study.

### **Intervention sessions**

The intervention condition consisted of 6 sessions in which a facilitator taught participants a set of 8 emotion regulation skills intended to increase positive emotion. The intervention has

demonstrated feasibility, acceptability, and preliminary efficacy in pilot tests and randomized trials in a number of different samples (Caponigro et al., 2013; Carrico et al., 2015; Cheung et al., 2016; Cohn et al., 2014; Moskowitz et al., 2017), including dementia caregivers (Glenna A Dowling et al., 2014). We briefly review the rationale for inclusion of each of the skills here. Details on development of the intervention are published elsewhere (Dowling et al., 2014; Moskowitz et al., 2014; Moskowitz et al., 2012; Verstaen, Moskowitz, Snowberg, Merrilees, & Dowling, 2018).

In session 1, the facilitators presented the first three skills: *noticing positive events*, *capitalizing* on them, and *gratitude*. Positive life events are associated with increases in positive emotion and intentionally scheduling positive activities is a central part of behavioral activation, an activity commonly used in depression treatment (Cuijpers, Muñoz, Clarke, & Lewinsohn, 2009). Capitalizing, otherwise known as savoring, is an expressive response to a positive event that strengthens the association between positive events and positive emotion (Langston, 1994). Capitalizing includes telling others about it, marking the occurrence in some way, or even thinking about the event again later on (Langston, 1994). The association between intentionally noting things for which one is grateful and increased well-being is supported empirically in a number of different samples (Emmons, 2007; Emmons & McCullough, 2003).

Session 2 focused on the skill of *mindfulness*. Mindfulness is defined as the ability to intentionally pay attention to and maintain nonjudgmental awareness of thoughts, feelings, and physical sensations in the present moment (Kabat-Zinn, 2003) and mindfulness-based interventions have been demonstrated to improve a number of aspects of psychological and physical well-being, including higher positive emotion (Grossman, Tiefenthaler-Gilmer, Raysz, & Kesper, 2007; Shapiro, Brown, & Biegel, 2007). The LEAF intervention focused specifically on the attention and non-judgment aspects of mindfulness.

In session 3, facilitators presented the skill of *positive reappraisal*. Positive reappraisal is a reinterpretation of the significance of a potentially stressful event in a more positive, and ultimately less stress-inducing way. For example, seeing the “silver lining” in a stressful event is a common form of positive reappraisal. Positive reappraisal is one of the few ways of coping that is consistently associated with increased positive emotion (Carver & Scheier, 1994; Folkman, 1997; Sears, Stanton, & Danoff-Burg, 2003).

Session 4 contained two skills: *personal strengths* and *attainable goal setting*. Focusing on one’s strengths is a form of self-affirmation that can be used as a coping strategy to increase positive emotion and noting one’s strengths is associated with better psychological adjustment to illness (Taylor, Lerner, Sage, & McDowell, 2003; Taylor & Lobel, 1989). Pursuit of attainable goals (vs. more diffuse distant goals) is associated with higher subjective well-being (Emmons, 1986; Emmons, 1992) and an extensive body of research shows that perceptions of goal progress are associated with greater positive emotion. Interventions that encourage attainable goal-setting in students demonstrate greater increases in the ratio of positive to negative emotion over the course of several weeks (Sheldon & Houser-Marko, 2001).

In session 5, the focus was on *acts of kindness*. Volunteerism and other altruistic behaviors are associated with lower risk of mortality, lower risk of serious illness (Musick & Wilson, 2003; Oman, Thoresen, & McMahon, 1999) and increased positive emotion (Dunn, Aknin, & Norton, 2008; Moen, Dempster-McCain, & Williams, 1993). In this session participants were encouraged to find opportunities to engage in acts of kindness.

In session 6, the final session of the intervention, facilitators worked with participants to plan continued practice of the skills and they provided suggestions for making engagement in the skills an ongoing habit.

### **Emotion Reporting/Wait list control condition.**

In order to control for daily attention to emotional experience, control group participants were asked to complete a daily emotion survey for six weeks (comparable to the time for the LEAF intervention). After 6 weeks, they completed assessment 2, then crossed over into the intervention condition and proceeded as described above.

### **Assessments.**

All participants completed assessments at baseline, immediately following the intervention (approximately 6 weeks later), and at three follow up time points: 1 month, 3 months and 6 months post intervention. Emotion reporting/waitlist control participants were assessed at the same intervals: baseline, after an initial wait period of six weeks (equal to the length of the intervention), then at 1-, 3-, and 6-months post intervention. Here we present the data from the first two assessments, prior to the waitlist crossing over to the active LEAF condition. See Figure 1 for CONSORT participant flow diagram.

## **Measures**

### **Positive and negative emotion.**

A modified version of the Differential Emotions Scale (Fredrickson, Tugade, Waugh, & Larkin, 2003) was used to assess positive and negative emotion. The scale includes positive items such as interest, enjoyment, awe, gratitude, hope, and love and negative items such as sadness, anger, disgust, fear, and guilt. In this caregiver sample, the modified DES shows acceptable reliability for both positive emotion ( $\alpha = .91$ ) and the negative emotion ( $\alpha = .85$ ).

### **Depression.**

Emotional Distress – Depression, Patient Reported Outcomes Measurement Information System Item Bank, v. 1.0 (PROMIS; Cella et al., 2010) was used to assess depression. Participants rated 28 items ( $\alpha = .95$ ) focused on depressive symptoms over the past 7 days.

### **Anxiety.**

The NeuroQOL (Cella et al., 2012) anxiety measure contains 29 items ( $\alpha = .95$ ) to tap anxiety over the past 7 days. NeuroQOL is one of the HealthMeasures systems, similar to PROMIS.

**Global Health.**

Participant perceptions of overall physical and mental health were assessed with the Global Health Scale, PROMIS v.1.0/1.1 (Cella et al., 2010) which contains 10 items that are rated on Likert scales reflecting frequency or severity of symptoms and functioning (physical health,  $\alpha = .68$ ; mental health,  $\alpha = .77$ ).

**Perceived Stress.**

The Perceived Stress Scale (PSS;Cohen, 1988) was used to assess stress. The 10 items ( $\alpha = .88$ ) are designed to identify how unpredictable, uncontrollable and overloaded respondents find their lives.

**Dementia Severity.**

The Dementia Severity Rating Scale (DSRS; Clark & Ewbank, 1996) was used to characterize the level of functional abilities of the care recipient. The DSRS is comprised of 12 items ( $\alpha = .90$ ), and scores can range from no impairment (a total score of 0) to extreme impairment for each category assessed (a total score of 54).

**Caregiver Burden, Strain, and Positive Aspects of Caregiving.**

The Zarit Burden Interview (Zarit, Reever, & Bach-Peterson, 1980) was used to assess caregiver burden. This 22-item inventory ( $\alpha = .91$ ) assesses caregivers' subjective feelings of the impact of caregiving on emotional and physical health functioning, social life, and financial status. Caregiver Strain Index (CSI; Robinson, 1983) was used to assess perceived strain. The CSI is a 13-item measure ( $\alpha = .74$ ) of both objective and subjective elements of caregiver strain. Positive aspects of caregiving was measured with the Positive Aspects of Caregiving scale (Boerner, Schulz, & Horowitz, 2004) an 11-item scale ( $\alpha = .91$ ) that identifies positive consequences of caregiving such as feeling more useful, feeling appreciated, and strengthening relationships with others.

**Analysis**

We first examined whether the LEAF and control conditions were comparable at baseline on demographics and outcome variables using t-tests. Next, we conducted intention to treat analyses using multilevel modeling (MLM; Singer & Willett, 2003). MLM offers an approach that accommodates missing data and non-independence in observations. We used MLM to examine whether there were differences in the magnitude of change from the baseline assessment to the post-intervention assessment as a function of intervention condition (LEAF intervention vs. control) as evidenced by a Condition x Time interaction. Specifically, we modeled the fixed effects of time at Level 1 (dummy coded: baseline = 0, post = 1) and intervention condition (dummy coded: control = 0, LEAF intervention = 1) at Level 2. The only random effect that was included in our multilevel models was for the intercept.

Given the LEAF intervention was specifically designed to target positive emotion as the proposed theoretical mechanism, we conducted multilevel moderated mediation analyses (Bauer, Preacher, & Gil, 2006) using a multilevel SEM framework (Preacher, Zyphur, &



Zhang, 2010) to examine changes in positive emotion as a mechanism of change. Specifically, we examined whether increases in positive emotion mediated the effects of the intervention for each of the outcome variables that were significantly different between intervention and control conditions. We estimated the specific indirect effects, and conducted Monte Carlo simulations with 20,000 replications to obtain confidence intervals around the indirect effects (MacKinnon, Lockwood, & Williams, 2004; Preacher & Selig, 2012).

Assuming a two-sided alpha of .05 and power of .80, a constant correlation between the repeated assessments of .4, and an overall attrition of 19%, we estimated we would be able to detect a medium effect of  $d = .5$  with a sample size of  $N = 170$ .

## Results

One hundred and seventy caregivers were randomized to the intervention ( $N = 86$ ) or the waitlist control ( $N = 84$ ). Table 1 has the baseline demographics. Participants were aged 34–87 ( $M = 62.91$ ), 84% were female, and 88% were White. The mean duration of caregiving was 4.2 years with 67% of caregivers being the spouse of the person with dementia. As evidenced in Table 2, correlations of PROMIS and related HealthMeasures outcomes and other indicators of burden, stress, and psychological well-being were highly intercorrelated. Compared to general population norms, baseline scores on depression, anxiety, and perceived stress were significantly higher and global health (both physical and mental health subscales) was significantly lower (Dowling, Verstaen, Snowberg, Merrilees, & Moskowitz, 2017) indicating that caregiving is having a deleterious impact in this sample.

Caregivers in the intervention and control conditions did not differ on any of the outcome measures at baseline. Retention in the study from baseline to the post-intervention assessment was excellent and did not differ by condition: 89% (77 of 86) of participants in the LEAF condition and 92.8% (78 of 84) of the control completed the second assessment,  $\chi^2 = 0.58, p = .44$ .

In Table 3, we present the estimates and the significance tests for the Condition  $\times$  Time interactions for all outcome measures of interest. These estimates represent the differences in the magnitude of change between the LEAF group relative to the emotion-reporting/waitlist control group, as modeled by the differences in slopes between the LEAF group relative to the control group. As predicted, analyses of difference in change from baseline to the post intervention assessment demonstrated significantly greater increases in our primary outcome of interest: positive emotion ( $d = .58; p < .01$ ).

In addition, the intervention also showed greater improvements in secondary outcomes including greater decreases in depression, ( $d = -.25; p = .02$ ) in the LEAF condition compared to the emotion-reporting/waitlist control. The LEAF group showed a 10.67 point decrease, a full standard deviation, on PROMIS depression. In other words, participants in the intervention group decreased from showing moderate symptoms of depression relative to the population norm, to falling within the normal range of depressive symptoms by the post-intervention assessment. In contrast, participants in the control condition showed a smaller

decrease in depression scores ( $M = 6.97$  point decrease), which corresponds to a 0.5  $SD$  decrease, remaining within the mild to moderate range (scores between 55–60).

Participants in the LEAF condition also showed significantly greater decreases in anxiety ( $d = -.33$ ;  $p < .01$ ) from baseline to the post intervention assessment, compared to the emotion-reporting/waitlist control. In the current sample, participants in both the intervention and control groups began the study with levels of anxiety that were comparable to the population norm of 50 ( $M_{LEAF} = 52.15$  and  $M_{Control} = 51.38$ ). Nevertheless, participants in LEAF showed a 7.51 point decrease in their NeuroQOL anxiety T-scores from baseline to post, which corresponds to a 0.75  $SD$  decrease.

Participants in the LEAF condition showed greater improvements in physical health ( $d = .24$ ;  $p = .02$ ) from baseline to the post intervention assessment, compared to the emotion-reporting/waitlist control. In addition, the intervention also showed greater improvements in positive aspects of caregiving ( $d = .36$ ;  $p < .01$ ). Of note, effects on caregiving burden ( $d = -.16$ ;  $p = .07$ ) and perceived stress ( $d = -.20$ ;  $p = .10$ ) were in the hypothesized direction but did not reach statistical significance, and LEAF appeared to have negligible effects on caregiver strain, negative emotion, and reports of dementia severity.

Multilevel moderated mediation analyses demonstrated that increased positive emotion significantly mediated the effect of LEAF on depression over time (See Table 4). As reported above, there was a significant direct effect of LEAF on change in depression from baseline to post intervention as well as a significant direct effect of the intervention on change in positive emotion. The change in positive emotion significantly predicted change in depression,  $b = 2.05$ ,  $Z = 3.08$ ,  $p = .002$ , and when change in positive emotion was entered into the model simultaneously with intervention condition, the total direct effect of the intervention on depression was reduced to non-significance,  $b = -2.34$ ,  $Z = -1.08$ ,  $p = .28$ . The indirect effect for increased positive emotion mediating the effect of the intervention on depression was significant, 1.71 95% CI [0.63, 2.79],  $p = .009$ . As seen in Table 4, the indirect effects for the remaining outcomes were not significant,  $ps > .24$ .

## Discussion

The stress of dementia caregiving is associated with a range of physical and psychological health problems and has a deleterious impact on caregiving quality as well as quality of life for the care recipient. Interventions for dementia caregivers have primarily focused on education and skills training with the goal of reducing negative emotions and burden. However, over the past few decades, it has become clear that positive emotions are uniquely related to better psychological and physical well-being, independent of the effects of negative emotion, suggesting that an intervention that specifically targets positive emotion holds promise for improving caregiver well-being and, ultimately, quality of care for the individual living with dementia.

The present randomized controlled trial in dementia caregivers showed that, compared to an emotion reporting control condition, the LEAF positive emotion regulation intervention led to significantly greater increases in the primary outcome of interest, positive emotion, as well as improvements on secondary outcomes including increases in positive aspects of

caregiving, decreases in depression and anxiety, and improvements in self-reported physical health. Effects on caregiving burden and perceived stress approached significance. Consistent with the theoretical foundation of the LEAF intervention (Folkman, 1997; Fredrickson, 1998), increases in positive emotion mediated the effects of the intervention on depression. The study was of high quality meeting five of the six Cochrane collaboration quality criteria (Higgins & Green, 2008): 1) randomization concealment, 2) baseline comparability of groups, 3) power analysis and at least 50 participants in the analysis, 4) loss to follow up < 50%, and 5) the use of intent-to-treat analyses. The 6<sup>th</sup> criteria, blinding of subjects to condition, was not possible once participants started sessions in their assigned condition, although they were blind as to details of the content of the conditions at the time of enrollment and randomization.

Valid and reliable measurement is another important consideration for study quality. The present study included PROMIS and related NeuroQOL self-report measures that follow a systematic and well-documented approach and set of standards for development of new measures. Investigators follow an established protocol that includes guidelines for every step of the process from defining the target concept and conceptual model, composing individual items, constructing and testing the item pool, to determining validity, reliability, interpretability, language translation, and cultural adaptation. The result of this process is a set of valid, highly reliable measures of patient-reported health status for physical, mental, and social well-being. PROMIS measures may be more sensitive to intervention effects than more commonly used caregiving burden/strain measures, and inclusion of highly reliable PROMIS assessments yielded meaningful reports of change. An additional strength of PROMIS is in the scoring metrics that yield easily interpretable T-scores anchored to the distribution of scores in the US general population. This provides meaningful information for our data, because it allows us to have a useful comparison group and to identify the clinical significance of scores.

Overall, the findings of the present study, combined with the growing body of research supporting the efficacy of interventions that focus on positive emotion (e.g., Bolier et al., 2013; Charlson et al., 2007; Charlson et al., 2014; Cheung et al., 2016; Cohn et al., 2014; Moskowitz et al., 2017; Sin & Lyubomirsky, 2009), indicate that such interventions may produce key benefits for individuals coping with health related or other types of life stress. Few randomized trials, however, have examined whether increases in the theorized positive affect target of the intervention actually mediate effects on more distal outcomes such as adherence to recommended health behaviors or depression. For example, Charlson and colleagues tested a positive affect intervention in samples of people with chronic illness and hypothesized that the intervention would have beneficial effects on health behaviors (Boutin-Foster et al., 2016; Mancuso et al., 2012; Ogedegbe et al., 2012; Peterson et al., 2012). Although the intervention was associated with improvements in distal outcomes of achieving exercise recommendations (Peterson et al., 2012) and medication adherence (Ogedegbe et al., 2012), it was not clear whether the intervention influenced positive affect or whether intervention effects were mediated through increased (or maintained) positive affect (Peterson et al., 2013). Moskowitz and colleagues (2017) found that the same positive emotion regulation intervention tested here was associated with improved positive affect, decreased intrusive and avoidant thoughts, and decreased antidepressant use in people newly

diagnosed with HIV. However, increased positive emotion did not mediate intervention effects on these outcomes. In contrast, increased positive emotion was a statistically significant mediator of intervention effects on PROMIS depression in the present study.

There are a number of differences between the present sample where positive emotion appears to mediate intervention effects on depression and our previous work where there was no evidence of mediation. First, there are differences in the nature of the stress that may influence the likelihood of the intervention influencing positive emotion, i.e., caregiving is chronic and deteriorating; HIV diagnosis is acute with some chronic elements, and generally improving. There may have been more opportunity for the intervention to influence positive emotion in the caregiving situation that was generally deteriorating compared to HIV diagnosis where the majority of participants show a normative trend toward increased positive emotion as time passes after the diagnosis. A second important difference is in the measures of depression. In the Moskowitz et al (2017) study, in which there was no effect on depression, we used the CES-D. In the present study, we used the PROMIS depression measure and had stronger effects on depression, possible attributable to which may be more precise measurement afforded by the PROMIS measure.

Given that the LEAF intervention was specifically designed to target positive emotion as the proposed theoretical mechanism, we examined changes in positive emotion as a mechanism of change. However, despite finding evidence that positive emotion was a statistically-significant mediator of intervention effects on PROMIS depression, we are limited in the ability to draw causal conclusions about positive emotion as the mechanism of change in this study. Given that we only have data from two assessments collected in the present research (baseline and post), we cannot definitively conclude whether changes in positive emotion temporally preceded changes in depression, or whether changes in depression may have preceded changes in positive emotion (see Winer, Cervone, Bryant, McKinney, Liu, & Nadorff, 2016 for a discussion). Future research that demonstrates change in positive emotion temporally preceding subsequent change in depression would provide a more convincing demonstration of positive emotion as a causal mechanism of change.

To our knowledge, this is the first test of a positive affect regulation intervention in dementia caregivers. The results clearly show that the intervention is acceptable and feasible and holds promise as an efficacious intervention for people in the midst of the stress of caring for a loved one with dementia. Future work should extend to other caregiving groups (e.g. cancer caregivers; (Kent et al., 2016) and explore ways to tailor the intervention content to the individual to potentially increase the strength of the intervention. Furthermore, researchers should consider the possibility of integrating positive emotion skills with other established health behavior interventions to maximize effects on psychological and physical health.

The study had a number of weaknesses. First, the intervention was delivered individually by trained facilitators. Although this individual attention likely contributed to the high levels of retention, such an approach is expensive and may be challenging to implement with fidelity on a wide scale. Future studies should address the question of whether self-guided versions of the intervention have a similar impact on caregiver outcomes and explore ways to

incorporate LEAF into clinical care, which would enable more cost efficient and wide-spread implementation. In addition, the present study only had the immediate post-intervention follow-up (6 weeks post baseline) before the control condition crossed over into the intervention so we were unable to examine durability of effects. Instead of a waitlist design, researchers should consider other designs in which it is possible to compare differences of effects between intervention and control arms for a longer period of time.

Finally, a weakness that applies to all interventions with a positive focus, is that proclaiming the importance of positive affect in the stress and coping process may appear to minimize the pain and serious individual and societal consequences associated with major stressful events. We are not advocating a simplistic “don’t worry-be happy” approach, nor do we believe that simply increasing positive emotion will prove to be a cure-all for the very real and complex issues facing dementia caregivers. Such a stance could easily degenerate into blaming the victim for not thinking the positive thoughts that may prevent depression or other negative consequence of enduring stress. However, the present study demonstrates that an intervention that targets positive emotions in caregivers sets the stage for a cascade of adaptive consequences, including reduced depression. Ultimately, given the high levels of stress and depression documented in dementia caregivers, we consider increasing positive emotion to be an inherently worthwhile intervention goal.

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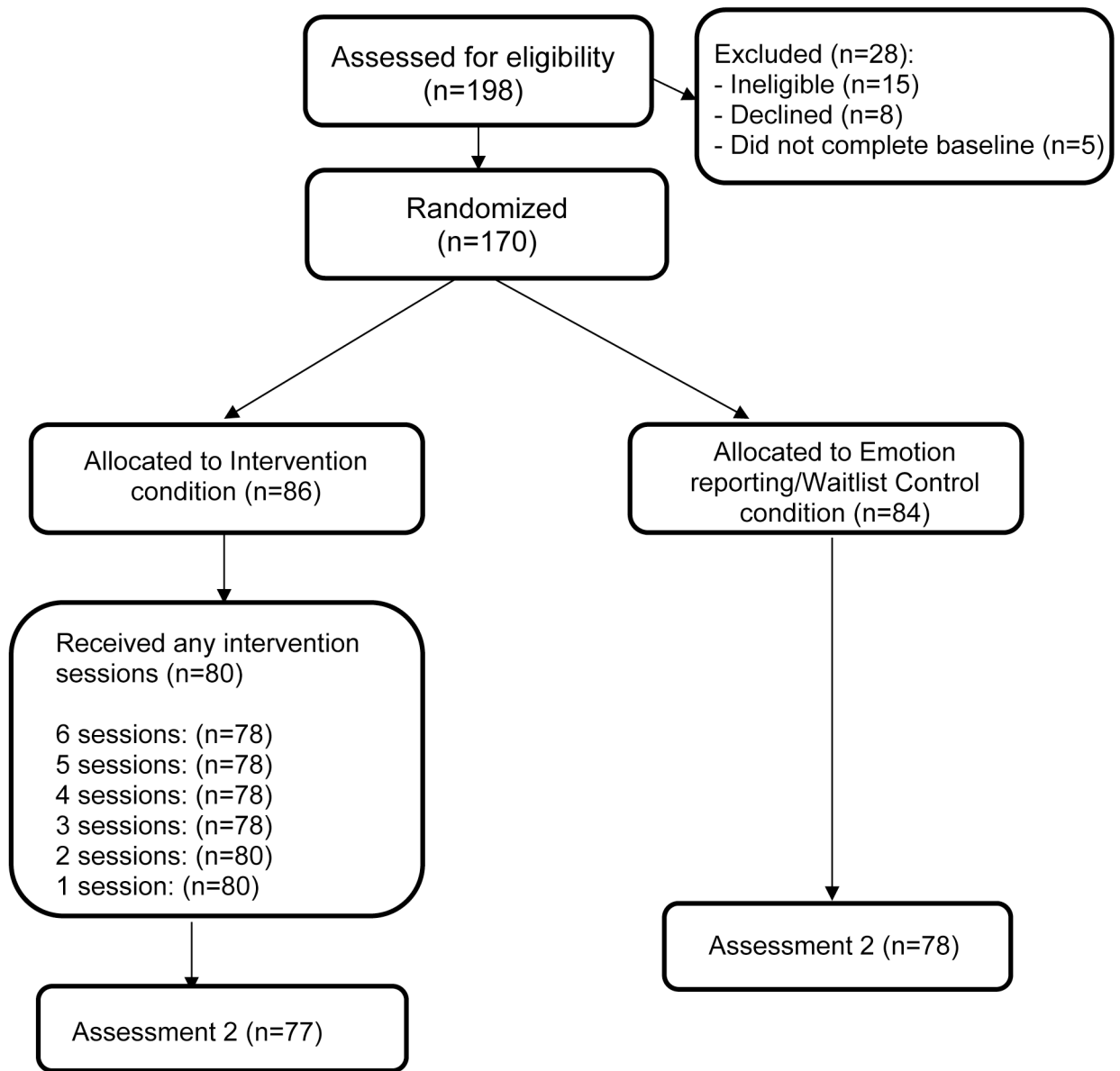
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**Figure 1.**  
CONSORT Participant Flow Diagram.

**Table 1**  
Demographics and Caregiving Characteristics by Condition

	Total Sample	LEAF	Control
N	170	86	84
Age Mean (SD)	62.91 (9.69)	63.03 (9.36)	62.77 (10.09)
Patient Dementia Severity at Baseline Mean (SD)	22.81 (9.51)	23.12 (9.84)	22.49 (9.21)
Length of caregiver in years Mean (SD)	4.21 (4.18)	4.53 (4.31)	3.89 (3.91)
Gender (% Female)	84.1	84.9	83.3
Race Ethnicity			
Black/African American (%)	2.4	0	4.8
White/European (%)	88.2	91.9	84.5
Asian/Asian-American/Pacific Islander (%)	7.1	5.8	8.3
American Indian/Eskimo (%)	.6	1.2	0
Mixed/Other (%)	1.8	1.2	2.4
Care Recipient Diagnosis (%)			
Alzheimer's	30.0	25.6	34.5
Frontotemporal Dementia	11.2	12.8	9.5
Lewy Body Disease	8.2	12.8	3.6
Parkinson's	15.3	15.1	15.5
Other	35.3	33.7	36.9
Rurality (%)			
Urban	50.6	48.8	52.4
Suburban	32.4	32.6	32.1
Rural	17.1	18.6	15.5
Relationship to care recipient (%)			
Spouse/sig other	67.1	72.1	61.9
Parent (Child?)	27.1	26.7	27.4
Other Family member	4.7	1.2	8.3
Friend	1.2	0	2.4
Education (%)			
< High School	.6	1.2	0
High School	5.9	8.1	3.6
Some College	14.7	18.6	10.7
College Graduate	25.3	20.9	29.8
Associate Degree	9.4	5.8	13.1
Some graduate school	10.0	11.6	8.3
Masters	20.0	19.8	20.2
Some post Masters work	3.5	5.8	1.2
PhD, MD, JD Other	10.6	8.1	13.1

*Note.* No group differences were found for any of the demographic variables above.

Table 2

## Baseline Correlations Among Measures

	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.
1. PROMIS Depression	-										
2. PROMIS Mental Health	-.71**	-									
3. PROMIS Physical Health	-.57**	.68**	-								
4. NeuroQOL Anxiety	.71**	-.59**	-.55**	-							
5. Caregiver Burden	.62**	-.59**	-.49**	.60**	-						
6. Caregiver Strain	.48**	-.49**	-.50**	.39**	.64**	-					
7. Dementia Severity	.19*	-.27**	-.21**	.05	.30**	.43**	-				
8. DES Positive	-.57**	.56**	.33**	-.43**	-.41**	-.30**	-.16*	-			
9. DES Negative	.79**	-.61**	-.44**	.65**	.63**	.42**	.16*	-.48**	-		
10. Positive Aspects of Caregiving	-.38**	.31**	.20**	-.27**	-.48**	-.26**	-.16*	.53**	.37**	-	
11. Perceived Stress	.71**	-.64**	-.53**	.69**	.67**	.50**	.10	-.49**	.64**	-.43**	-

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

Table 3

## Intervention Outcomes

		Baseline <i>M (SE)</i>	Post intervention <i>M (SE)</i>	Overall Effect: Condition × Time Interaction ( $\beta_{11}$ )	Cohen's <i>d</i> (CI)
PROMIS depression					
	LEAF	65.85 (2.02)	55.18 (2.08)	$\beta_{11} = -4.70, t(141) = -2.28, p = .02$	-.25 (-.55,.06)
	Control	65.62 (2.04)	59.65 (2.15)		
PROMIS Mental Health					
	LEAF	37.4 (4.10)	39.8 (4.10)	$\beta_{11} = -.08, t(160) = -0.70, p = .49$	.21 (-.09,.52)
	Control	39.8 (4.10)	39.8 (4.10)		
PROMIS Physical Health					
	LEAF	42.3 (4.20)	44.9 (4.30)	$\beta_{11} = 0.59, t(146) = 2.24, p = .03$	.24 (-.07,.54)
	Control	44.9 (4.30)	44.9 (4.30)		
NeuroQOL Anxiety					
	LEAF	52.15 (1.63)	44.64 (1.68)	$\beta_{11} = -5.04, t(145) = -2.63, p = .009$	-.32 (-.63,-.02)
	Control	51.38 (1.65)	48.91 (1.76)		
Zarit Caregiver Burden					
	LEAF	42.19 (1.58)	38.18 (1.60)	$\beta_{11} = -2.38, t(142) = -1.86, p = .066$	-.16 (-.46,.14)
	Control	42.18 (1.59)	41.13 (1.65)		
Caregiver Strain					
	LEAF	8.40 (0.33)	8.46 (0.33)	$\beta_{11} = .05, t(160) = 0.33, p = .74$	.01 (-.30,.30)
	Control	8.061 (0.35)	8.55 (0.33)		
Dementia Scale					
	LEAF	23.12 (1.07)	23.42 (1.09)	$\beta_{11} = -0.27, t(154) = -0.37, p = .71$	-0.03 (-.33, .27)
	Control	22.49 (1.09)	23.06 (1.10)		
DES Positive					
	LEAF	4.64 (0.16)	4.86 (0.16)	$\beta_{11} = .84, t(148) = 4.03, p < .001$	.58 (.27,.88)
	Control	4.92 (0.17)	4.31 (0.17)		
DES Negative					
	LEAF	3.66 (0.13)	2.6 (0.13)	$\beta_{11} = -.27, t(148) = -1.51, p = .13$	-.22 (-.52,.08)
	Control	3.70 (0.13)	2.91 (0.14)		
Positive Aspects of Caregiving					
	LEAF	35.92 (1.09)	39.04 (1.12)	$\beta_{11} = 3.59, t(140) = 4.42, p = .001$	.35 (.05,.66)
	Control	26.88 (1.11)	36.41 (1.16)		
Perceived Stress					
	LEAF	30.64 (0.71)	27.48 (0.72)	$\beta_{11} = -1.32, t(145) = -1.66, p = .10$	-.20 (-.50,.11)
	Control	31.08 (0.73)	29.24 (0.76)		

Notes. Baseline sample size=170, post-intervention sample size=155.

**Table 4**

Results of the Multilevel Moderated Mediation Analyses Examining Whether Increased Positive Emotion Mediates the Intervention Effects

<b>Outcome</b>	<b>Indirect Effect (SE)</b>	<b>95% CI</b>	<b>Z</b>	<b>p</b>
PROMIS Depression	1.71 (0.66)	[0.63, 2.79]	2.60	.009
PROMIS Physical Health	0.01 (0.09)	[-0.13, 0.16]	0.17	.86
NeuroQOL Anxiety	0.75 (0.64)	[-0.30, 1.80]	1.18	.24
Zarit Burden Interview	-0.23 (0.42)	[-0.92, 0.46]	-0.54	.59
Positive Aspects of Caregiving	-0.32 (0.38)	[-0.95, 0.30]	-0.85	.40

Note.

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