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A brief behavioral intervention targeting mental health risk factors for vascular disease: A pilot study

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Keywords

Acceptance and Commitment Therapy (ACT); Illness Management; Depression; Anxiety; Vascular Disease; Treatment Outcome

Psychological distress, often manifesting as depression and anxiety, is a risk factor for vascular disease [1]. These states also contribute to withdrawal and avoidance behaviors, which impede health promotion [2]. Effective treatments that target these syndromes and related health behaviors are needed for this broad group of distressed patients at risk of vascular disease, who comprise a considerable portion of clinic visits [3]. Acceptance and Commitment Therapy (ACT) is an empirically-supported behavioral therapy that aims to enhance psychological flexibility through use of acceptance, mindfulness, and behavioral change strategies. When presented as a brief intervention, ACT has produced positive long-term outcomes in those with co-morbidity [4, 5].

We developed a one-day ACT plus education (ACT-IM) group workshop and compared it to treatment as usual (TAU) for individuals at risk of vascular disease with clinically significant anxiety or depressive symptoms. We hypothesized this one-day intervention would improve quality of life, depression, and anxiety over six months.

Individuals, ages 18–75, at risk of vascular disease (hypertension, diabetes mellitus or impaired fasting glucose, dyslipidemia, or obesity) were screened as outlined in the CONSORT Diagram (Figure 1). Of 142/827 screened scored ≥10 on either the Patient

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Health Questionnaire-8 or the GAD-7 without exclusion criteria: 1) brain injury; 2) past month medication changes; 3) schizophrenia or bipolar disorder, 4) current substance abuse; and 5) active suicidal ideation. Of those consented for this IRB-approved study at the University of Iowa, 30 were randomly assigned (2:1) to ACT-IM and 14 to TAU.

As a general measure of well-being, our *a priori* primary outcome was Quality of Life as measured with the World Health Organization Quality of Life-BREF (WHOQOL-BREF) [6]. Our *a priori* secondary outcomes included the clinician-rated Hamilton Rating Scale for Depression (HRSD) and Hamilton Anxiety Rating Scale (HRSA). We also explored self-report measures with relevant Inventory of Depression and Anxiety Symptoms (IDAS) subscales [7]. An 11-item subscale of the Experiencing Questionnaire (EQ) measured psychological flexibility/decentering [8].

Each 6-hour ACT-IM workshop involved 7–10 participants and emphasized three topics: education (cardiovascular risk factors, diet and lifestyle recommendations, and self-monitoring), acceptance (new ways of managing troubling thoughts, feelings, and sensations), and behavioral change (how to recognize ineffective patterns, set goals, and commit to action). The intervention was manualized and participants received a corresponding workbook. The TAU group received any treatment in the community rather than through the protocol.

Linear mixed models for a treatment-by-time interaction assessed the effect of treatment on primary and secondary outcomes for all randomized participants (intention-to-treat). The fixed effects were treatment status (ACT-IM versus TAU) and time (baseline, 12-, and 24 weeks). In analogous models, psychological flexibility (EQ) was assessed as a potential mediator on HRSD.

Twenty six participants completed the ACT-IM intervention and 14 completed TAU. The mean age in both groups was 45. A majority of the participants were female (69% ACT-IM, 64% TAU), Caucasian (69% ACT-IM, 86% TAU), had completed college (69% ACT-IM, 71% TAU), and were working (85% ACT-IM, 71% TAU). Nearly half of those assigned to ACT-IM and 64% of those in the TAU condition were taking antidepressant medications at intake. There were no significant differences between the ACT-IM and TAU groups on any variables. All four WHOQOL-BREF (physical, social, psychological, environment) domains significantly changed from baseline through the 24-week follow-up with ACT-IM, but only for the psychological domain with TAU. The treatment-by-time interactions were not significant (Physical p=0.17; Psychological p=0.67; Social p =0.18; Environmental p=0.33).

A significant overall group-by-time interaction on HRSD was observed (p<0.0001, Figure 2). The mean decrease in HRSD in the ACT-IM condition was 7.1 (95% C.I.: −12.1, −2.2) greater than TAU at 12 weeks and 10.8 (95% C.I.: −15.9, −5.7, effect size=1.4) greater at 24 weeks. More participants treated with ACT-IM responded (≥50% HRSD reduction) at the 24-week follow-up (ACT-IM: 20/26, 77%; TAU: 3/14, 21%; χ^2=11.5, df=1, p<0.01). The self-report IDAS General Depression scale similarly revealed a significant group-by-time interaction (p=0.0005, effect size=0.9 at 24 weeks).

The HRSA also demonstrated a significant group-by-time interaction ($p<0.0001$). The mean decrease in HRSA in the ACT-IM condition was 9.4 (95% C.I.: −14.9, −3.8) greater than TAU at 12 weeks and 12.7 (95% C.I.: −18.5, −6.9, effect size=1.5) greater at 24 weeks. More participants treated with ACT-IM responded to treatment at 24 weeks (ACT-IM: 17/26, 65%; TAU: 1/14, 7%; $\chi^2=12.5$, $p<0.01$). The self-reported IDAS Social Anxiety had a corresponding group-by-time interaction ($p=0.049$).

The intervention yielded significant improvements in EQ ($p=0.03$), improvements in EQ predicted improvements in HRSD ($p<0.0001$), and after controlling for changes in EQ, the group-by-time interaction on HRSD remained significant although the standardized parameter estimate was attenuated (−1.14 ($p=0.0005$) to −0.87 ($p=0.002$)), while a significant relationship with improvements in EQ persisted ($p=0.0002$).

In this pilot study, we found significant improvements in WHOQOL-BREF in the intervention group, which did not significantly differ from TAU. The ACT intervention yielded larger effects on both secondary outcomes, HRSD and HRSA, suggesting that this brief one-day intervention may be effective in treating psychological distress in this broad at-risk population with durable effects. A 1-day workshop is a feasible and acceptable alternative to weekly treatments. This brief intervention was designed for ease of implementation in primary care settings, accessibility, and cost-effectiveness.

The effects of the intervention qualitatively improved at each follow-up visit akin to other ACT treatment trials [5, 9]. Participants are taught new ways to approach their thoughts and emotions and to engage more meaningfully in their lives. As participants practice these skills, they may develop more flexible patterns of behavior which positively impact well-being. Consistent with this, improvements in psychological flexibility partial mediated the benefits of our intervention on depression. The substantial improvements in depression and anxiety did not translate efficiently to that measured by the WHOQOL-BREF, which incorporates facets less amenable to intervention (e.g., mobility, work capacity, physical environment, financial resources, and access to health care and transportation).

There is a striking paucity of clinical studies addressing psychological distress with comorbid vascular risk factors. Our small sample limited our ability to detect but large effects on outcome, which were observed for anxiety and depression. Evaluators of our secondary outcomes were not blind to treatment assignment; however, self-report measures showed similarly positive results. Social desirability and effort justification bias could differentially impact the treatment group. Strengths of the study include random assignment, a high participation rate, and a high retention rate. After randomization, more TAU participants were taking antidepressants, which might bias findings opposite the direction observed. Our generalizable sample included individuals with various vascular risk factors and manifestations of psychological distress as might be commonly encountered in primary care settings. The promise of our preliminary findings for a novel intervention, which could be feasibly disseminated to a neglected at-risk group for vascular disease, warrants replication in a larger clinical trial.

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References

1. Smoller JW, Pollack MH, Wassertheil-Smoller S, Jackson RD, Oberman A, Wong ND, Sheps D. Panic attacks and risk of incident cardiovascular events among postmenopausal women in the women's health initiative observational study. Arch Gen Psychiatry. 2007; 64:1153–1160. [PubMed: 17909127]
2. Bauer LK, Caro MA, Beach SR, Mastromauro CA, Lenihan E, Januzzi JL, Huffman JC. Effects of depression and anxiety improvement on adherence to medication and health behaviors in recently hospitalized cardiac patients. The American journal of cardiology. 2012; 109:1266–1271. [PubMed: 22325974]
3. Kroenke K, Spitzer RL, Williams JB, Monahan PO, Lowe B. Anxiety disorders in primary care: Prevalence, impairment, comorbidity, and detection. Ann Intern Med. 2007; 146:317–325. [PubMed: 17339617]
4. Dindo L, Recober A, Marchman J, O'Hara MW, Turvey C. One-day behavioral intervention in depressed migraine patients: Effects on headache. Headache. 2014; 54:528–538. [PubMed: 24741688]
5. Dindo L, Recober A, Marchman JN, Turvey C, O'Hara MW. One-day behavioral treatment for patients with comorbid depression and migraine: A pilot study. Behav Res Ther. 2012; 50:537–543. [PubMed: 22728646]
6. Skevington SM, Lotfy M, O'Connell KA. The world health organization's whoqol-bref quality of life assessment: Psychometric properties and results of the international field trial. A report from the whoqol group. Qual Life Res. 2004; 13:299–310. [PubMed: 15085902]
7. Watson D, O'Hara MW, Simms LJ, Kotov R, Chmielewski M, McDade-Montez EA, Gamez W, Stuart S. Development and validation of the inventory of depression and anxiety symptoms (idas). Psychol Assess. 2007; 19:253–268. [PubMed: 17845118]
8. Fresco DM, Moore MT, van Dulman MHM, Segal ZV, Ma SH, Teasdale JD, Williams JMG. Initial psychometric properties of the experiences questionnaire: Validation of a self-report measure of decentering. Behav Ther. 2007; 38:234–246. [PubMed: 17697849]
9. Luoma JB, Kohlenberg BS, Hayes SC, Fletcher L. Slow and steady wins the race: A randomized clinical trial of acceptance and commitment therapy targeting shame in substance use disorders. J Consult Clin Psychol. 2012; 80:43–53. [PubMed: 22040285]

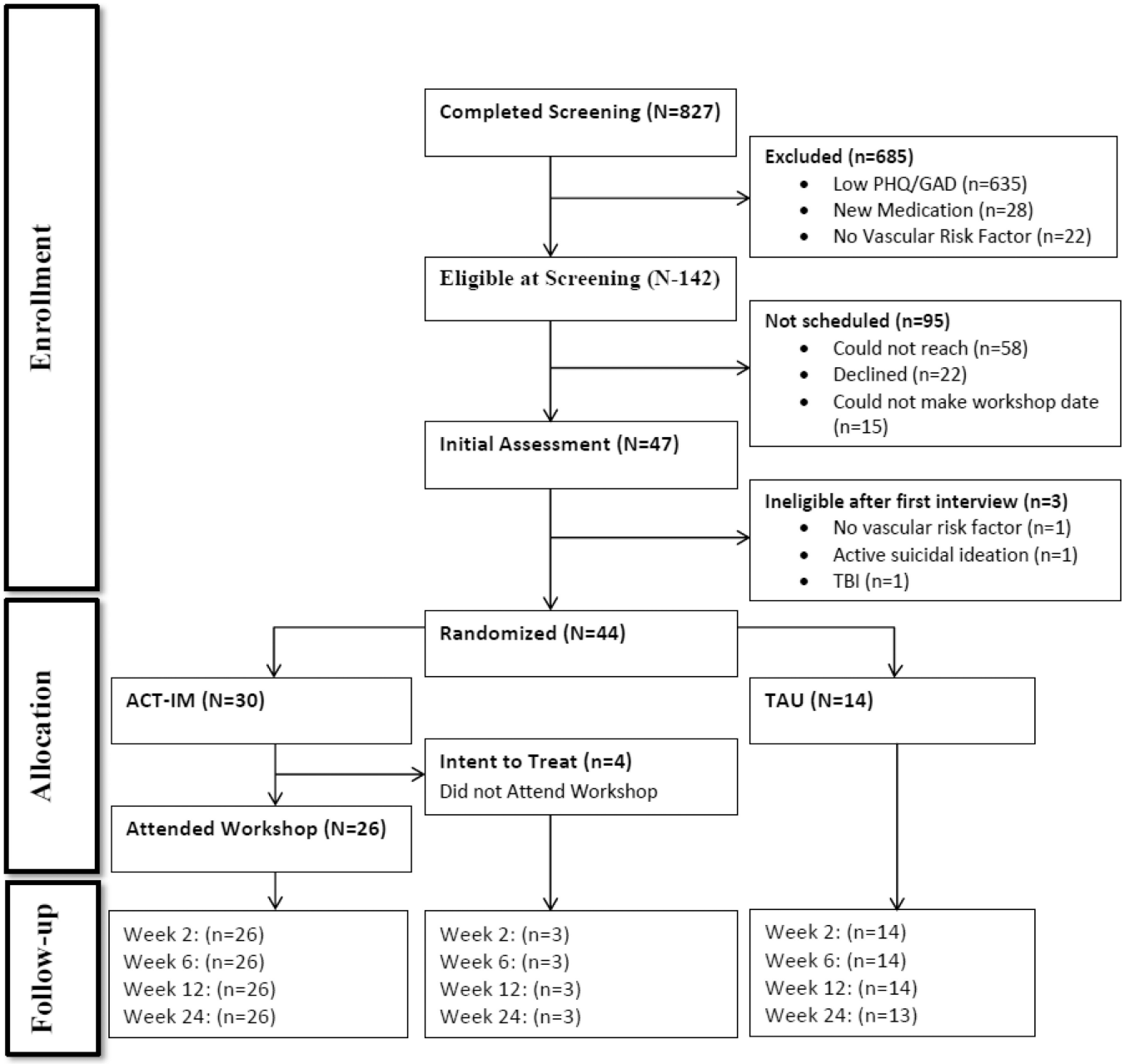

Figure 1.
Participant flow chart for the treatment trial.

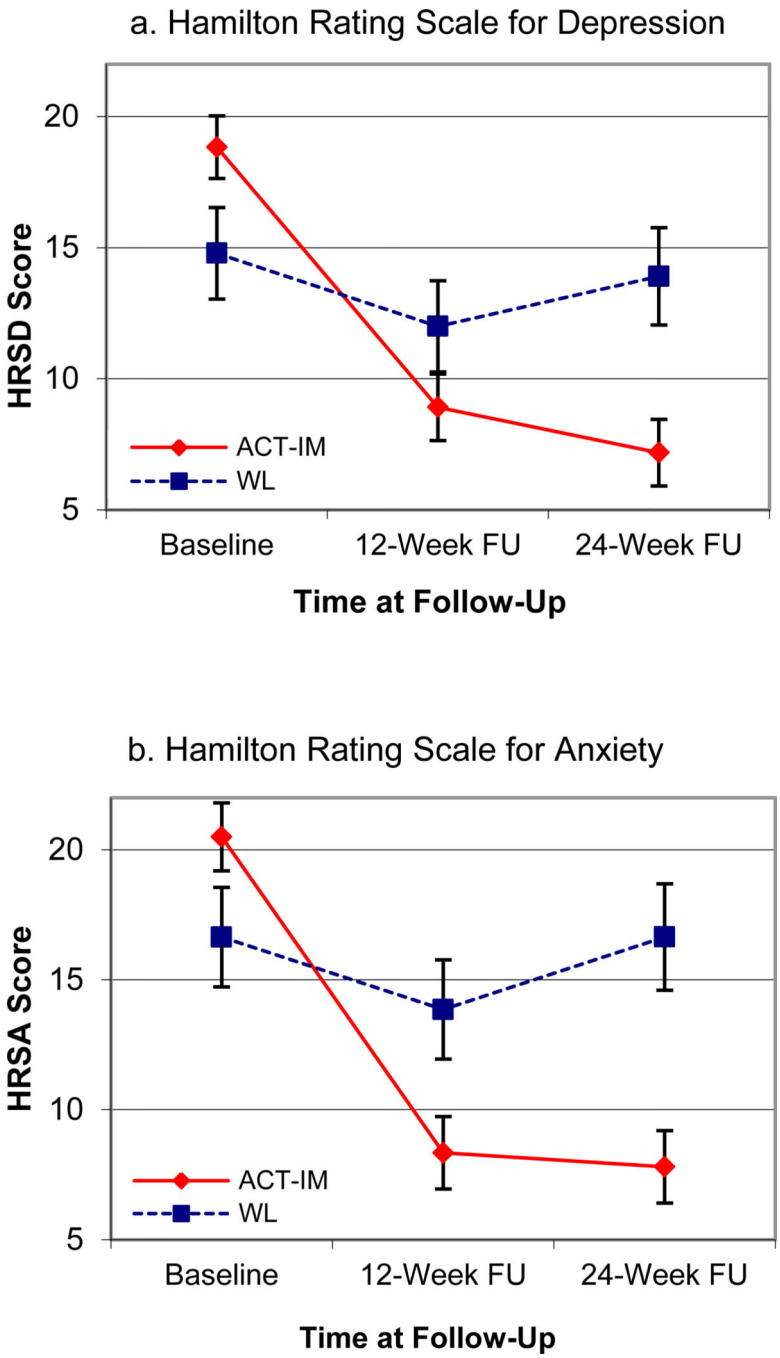

Figure 2.
Depression and Anxiety