primary studies - published RCT

Chest computed tomography outcomes in a randomized clinical trial in cystic fibrosis: Lessons learned from the first ataluren phase 3 study.

Code: PM33141825 **Year:** 2020 **Date:** **Author:** Tiddens HAWM

Study design (if review, criteria of inclusion for studies)

3-year, multi-site, telehealth-delivered randomized trial

Participants

124 adults with CF and elevated anxiety and/or depressive symptoms were recruited coincident with the first COVID lockdown, from Thomas Jefferson University Hospitals, University of Virginia, Augusta University, Duke University Medical Center, and social media. Participants were young adults (mean age 25 years [SD = 12]), female (75 %), on CFTR modulators (67 %), psychotropic medication(s) (60 %), with previous psychotherapy engagement (72 %).

Interventions

Acceptance and Commitment Therapy (ACT with CF) vs Supportive psychotherapy (SP). Participants were randomized to 6 weeks of either ACT with CF or SP, delivered via Zoom.

Outcome measures

Participants completed measures of psychological functioning: depression (BDI-II), anxiety (BAI), cognitive fusion (CFQ-13), acceptance and committed action (AAQ-II); and barriers to adherence at baseline, post-treatment, and at 3-months follow-up. Biobehavioral outcomes, including CF severity and treatment burden, were gathered using EMR data. Treatment effects were evaluated using analysis of covariance, controlling for baseline levels of respective outcomes, age, biological sex, and FEV(1).

Main results

ACT demonstrated greater improvements in psychological functioning at 6-weeks (mean scoreÂ =Â 57.3 [51.6, 63.0]) relative to SP (mean scoreÂ =Â 67.8 [62.2, 73.5], Cohen's dÂ =Â 0.59, PÂ =Â .017), with largest improvements in cognitive fusion (CFQ-13) and acceptance and committed action (AAQ-II). Treatment improvements in psychological functioning persisted at 3-months (ACT: 59.7 (53.5, 65.9) vs. SP: 69.0 [62.6, 75.4], Cohen's dÂ =Â 0.40, PÂ =Â .041), with ACT demonstrating continued improvements in the CFQ-13 and AAQ-II. Negative affect scores were not consistently improved on our mean-rank composite outcome variable (Cohen's dÂ =Â 0.22, PÂ =Â .170), despite post hoc reductions in BDI-II scores (ACT: -7.4 [-9.4, -5.4] vs. SP: -4.5 [-6.4, -2.6], PÂ =Â .040). Improvements in psychological flexibility (CFQ-13 and AAQ-II) were also robustly associated with reductions in negative affect (BÂ =Â -0.45, PÂ

Authors' conclusions

ACT with CF was superior to SP in improving psychological functioning among adults with CF and elevated psychological distress, with additional benefits in secondary biobehavioral outcomes in a subset of individuals with greater medical burden. Improvements in psychological flexibility strongly associated with reductions in negative affect.

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See also

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Keywords

Adolescent; Adult; Caregivers; Child; non pharmacological intervention - psyco-soc-edu-org; Self-Management; Behavioural interventions;