

Review of: "Effectiveness of a novel multi-modal intervention for family caregivers of persons with age-related macular degeneration: a randomised controlled trial"

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Potential competing interests: Ojai Retinal Technologies, LLC: management, equity. Retinal Protection Sciences, LLC: management, equity. Vision Protection Institutes, LLC: management, equity; Replenish, Inc: equity

1. Results were statistically non-significant. Strictly speaking, this means the intervention didn't work, ie, wasn't helpful. The apologetic for non-significant benefits betrays an *a priori* bias for the value of the intervention. Why? Because the authors do CBT and have an interest in finding new indications for it?

1. The fact that CBT did not work suggests that either these caregivers are not in need of help, or the CBT is not the help they need. (ie, These people may need actual help (drivers, caregiver relief, financial help, etc., not talk?).

2. What is the difference between AMD caregivers / roles compared to settings where CBT is significantly effective? By comparing the results of CBT in this group to patients with mental / emotional illness, the authors have defined caregiving as a dysfunction. Is this correct? What if caring for a loved is actually a highly functional and rewarding activity rather than a state of dysfunction? Would CBT be of help to highly functioning people? The lack of statistical benefit from the intervention is likely more than a sample size problem. The premises of this study need to be more clearly examined.

3. 10% acceptance / eligibility rate into study is a significant problem. Why so low? This suggests poor study design (or execution), such as looking for a specific pre envisioned population expected to deliver a desired result. Need to explain in more detail the low eligibility / acceptance rate. This casts the entire study in doubt all by itself.

4. Dropout rate high ($17/94 = 18\%$), almost entirely in intervention group. This is very informative. Are such talking interventions counterproductive – stress-inducing? Intensive lifestyle modification was abandoned for diabetics because the stress imposed by the healthcare hectoring increased mortality compared to a *laissez faire* approach. Here as well?

5. 77% of intervention group were "satisfied or very satisfied" even though it didn't help. 84% would recommend, despite lack of benefit. This suggests they are being nice so as not to offend the earnest questioner.

6. "Lack of adverse effects." Then why an 18% dropout rate? Define adverse effects. One might be having to read, meet, and discuss issues with therapists in addition to the already challenging and time-consuming caregiving tasks.

Disclaimer: I am a retina specialist with a practice heavily devoted to patients with AMD. My bias, possibly reflecting my particular patient population, is that CBT would be greeted by them (and their caregivers) as strange; and that the help they need is practical, not psychological. The folks that may be more in need of CBT may be the family members who do not choose to help with the caregiving, rather than the caregivers themselves. My view may be harsh, but it appears

consistent with the results of this study.