

Prevention (nonpharmacological) / Other

Behavioral RCT using internet-based social interactions: Why some gain and some do not

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Abstract

Background: Increasing social interaction could be a promising intervention for improving the cognitive well-being of socially isolated older adults. However, we expect that the efficacy of a social intervention can differ across subjects due to personality traits, preference for specific activities, and different pathological stages, even within the same clinical diagnosis. For most behavioral intervention studies, the priority of randomized controlled trials is not necessarily to gain a statistically significant intervention effect, but to find which subjects benefit from the specific intervention. Factoring this potential heterogeneity into the efficacy analysis of randomized controlled trials (RCT) will be discussed.

Methods: Building upon our previously completed NIH-funded project (ClinicalTrials.gov #: NCT01571427), we developed a multi-site RCT to examine whether conversation-based cognitive stimulation has a positive effect on domain-specific cognitive functions and higher-order objectively measured IADL (Instrumental Activities of Daily Living). We target socially isolated older adults with either normal cognition or mild cognitive impairment (Internet-Based Conversational Engagement Clinical Trial (I-CONNECT), ClinicalTrials.gov # NCT02871921). The experimental group engages in semi-structured video-chat conversation with trained conversational staff 4 times per week for 6 months (high dose) and twice per week for additional 6 months (maintenance dose). In addition to the main outcomes of neuropsychological test scores, we aim to determine factors which lead to heterogeneities in efficacy including: baseline brain atrophy and connectivity using MRI/fMRI, personality, Apoe genotype, mood and nature of social isolation (emotional vs. structural).

Results: While recruiting socially isolated subjects is challenging, as of January, 2020, our study has reached out 26,000 subjects, screened 195 subjects, and 131 subjects were ultimately randomized with 40% of those being eligible for MRI assessment. Baseline recruitment will continue until March of 2021. Carefully considered outcomes, covariates and mediating factors are being collected in this RCT. This

presentation will examine some of the key heterogeneities observed in our ongoing baseline sample, and discuss potential implications these differences may have on our future efficacy analysis.

Conclusions: Our project serves as a reference for developing individualized, targeted community intervention strategies with high adherence with maintainable life style modifications.