

Long-term benefit of PPOIT on Quality of Life in a Randomised Trial

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Abstract

Background: Few Randomized Controlled Trials (RCTs) have evaluated oral immunotherapy effects on quality of life (QoL). We previously reported that probiotic peanut oral immunotherapy (PPOIT) significantly improved QoL compared with placebo, with improvement linked to achieving sustained unresponsiveness (SU). Objective: We examined whether PPOIT-induced QoL improvement is maintained at 4 years post-treatment. Methods: Subjects in the PPOIT-001 RCT (n=57) completed Food Allergy Quality of Life Questionnaire-Parent Form (FAQLQ-PF) and Food Allergy Independent Measure (FAIM) at pre-treatment, end-of-treatment, and 3-months, 12-months and 4-years post-treatment. Paired group t-test analyses were conducted separately for PPOIT and Placebo groups at each time point. Repeated-measures mixed ANOVAs were used to examine overall changes from pre-treatment to 4-years post-treatment, controlling for potential confounders. Results: N=38 (19 Placebo/19 PPOIT) completed FAQLQ at ALL time-points. PPOIT-treated subjects had significantly improved FAQLQ compared with placebo at 3-months, 12-months and 4-years post-treatment. FAQLQ and FAIM scores improved significantly for PPOIT group from pre-treatment to 4-years post-treatment (both p=0.001). Multivariate analysis (controlling for age, sex, SU) confirmed findings, with a very large effect size [partial eta squared=0.56]. A 'large' amount of peanut ingestion predicted greater improvement in FAQLQ score, compared with avoidance, small or moderate ingestion. No changes from baseline in FAQLQ or FAIM were shown for placebo. Conclusions: PPOIT induced substantial improvement in FAQLQ that persisted to 4-years post-treatment. Greatest benefit was observed in subjects ingesting large amounts of peanut. This is the first study demonstrating long-lasting improvement in QoL with a food allergy treatment.

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