Table 1
Sociodemographic characteristics of the sample

Variable	Category	Baseline assessment (n = 34)
Age	–	M = 79.9 (SD = 8.4; R = 60,
98) Gender	Male	6 (17.6%)
	Female	28 (82.4%)
Race/ethnicity	White, non-hispanic	10 (29.4%)
	Black, non-hispanic	3 (8.8%)
	Hispanic	21 (61.7%)
Education	Up to high school	23 (67.6%)
	Some post high school training	3 (8.8%)
	College graduate	4 (11.8%)
	Master's degree or higher	4 (11.8%)
Marital status	Never married	2 (5.9%)
	Married	15 (44.1%)
	Widowed	13 (38.2%)
	Divorced	4 (11.7%)
Years diagnosed with Alzheimer's disease	–	M = 3.2 (SD = 2.0; R = 1, 11)

M, mean; *SD*, standard deviation; *R*, range.

37], and the initial success of the aforementioned pilot study, additional examination of the oligosaccharide-based formula is justified. Thus, we investigated the effect of a 12 month course of an oligosaccharide-based multinutrient formula on cognitive and immune functioning in a sample of persons with AD. Because of the known links between chronic brain and systemic inflammation and the neuropathology of AD (i.e., cognitive impairment due to cytokine-mediated interactions between neurons and glial cells) [38–43], we evaluated a panel of cytokines and lymphocyte and monocyte subsets in response to our intervention.

MATERIALS AND METHODS

Study participants

Participants (n = 34) were recruited from referrals to the Miami Jewish Health Systems outpatient facility from 2008 to 2011. The study was conducted with the approval of the Stein Gerontological Institute Institutional Review Board for human subjects research, which operates within the standards set forth by the Helsinki Declaration of 1975, and each subject (and/or the primary caregiver) signed informed consent before participating in the study. The sample comprised of
82% females (n = 28) and 18% males (n = 6) with a mean age of 79.9 years (SD = 8.4; range = 60–98 years). The racial/ethnic distribution of the subjects was as follows: 62% Hispanic (n = 21), 29% white, non-Hispanic (n = 10), and 9% black, non-Hispanic (n = 3). See Table 1 for all sociodemographic charac- teristics of the sample. Subjects were not required to stop or change their medication regimen for entry into the study and continued taking their drugs as ordered by the treating physician. Additionally, subjects had to be diagnosed with moderate-to-severe AD for at least 1 year prior to entering the study. Our participants were typically not eligible for other trials due to the severity of their condition and/or other co-morbid conditions. Each participant was evaluated by the study psychiatrist prior to enrollment in the study to verify the diagnosis of AD.

Intervention

The oligosaccharide-based multinutrient formula used in this study is a nutritional supplement that has been sold by several commercial entities for over 15 years. The formula used in the study is an aloe polymannose multi-nutrient complex (APMC) composed of the following constituents in a fixed combination by weight, including: aloe powder containing more than 15% acetylated polymannose, stabilized rice bran, larch tree fiber, larch tree soluble extract, cysteine, soy lecithin, UltraTerra® calcium alumino silicate, cherry tart powder, inositol hexaphosphate, dioscorea (yam) powder, omega 3 spherules, citric acid, and glucosamine. The final product is a pow- der, packaged in 300 gram containers, which dissolves readily in any liquid. All participants consumed 1 teaspoon orally of the APMC four times per day (with 3 meals and before bedtime). The primary caregiver was shown how to administer the APMC at the baseline assessment, and the first dose was given to the participant at our facility to ensure compliance with