



TITLE: Efficacy of the Nutritional Supplement, EvenFlo, in the Management of Sickle Cell Disease: A Randomized Controlled Trial.

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Background: This study aimed to assess the combined efficacy of the nutraceutical supplement EvenFlo and folic acid in comparison to the standard use of folic acid alone in individuals with sickle cell disease (SCD).

Methods: We conducted a randomized, double-blind, active-controlled clinical trial, enrolling 70 subjects aged 5-12 years with SCD. Of these, 35 were assigned to the intervention group receiving EvenFlo and folic acid, and 35 to the control group receiving only folic acid. A total of 61 participants completed the trial, with 32 in the intervention group and 29 in the control group.

Results: Participants in the intervention group were significantly less prone to crises compared to the control group. Notably, none of the intervention group subjects experienced vasoocclusive crisis (VOC), whereas 93.1% of subjects in the control group did. Moreover, the intervention group demonstrated a substantially higher increase in hemoglobin concentration from baseline (2.92 g/dL, 95% CI [2.33, 3.51]) compared to the control group (1.77 g/dL, 95% CI [1.00, 2.54]). Additionally, the intervention group showed a significant increase in mean weight from baseline (4.47 Kg, 95% CI [4.02, 4.92]), while the control group experienced a decrease (-1.05 Kg, 95% CI [-1.60, -0.51]).

Conclusions: The study findings indicate that EvenFlo, when combined with folic acid, is an effective nutritional supplement for managing SCD. Its positive impact on hemoglobin concentration and weight indices in individuals with SCD, along with its ability to reduce crises, emphasizes its potential as a valuable intervention for this population.

Keywords: Sickle cell anemia, sickle cell disease, SCD, EvenFlo, nutraceutical supplement, randomized controlled trial, RCT.

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