Oral Nutritional Supplement Provided During Dialysis is Not Superior to Dietary Counseling Provided by Registered Dietitians in Improving Serum Albumin

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DaVita Clinical Research
Advancing Kidney Care

In the management of hypoalbuminemia

- Is oral nutritional supplementation provided during dialysis more effective than nutritional counseling alone?

Study Design

- Randomized, controlled, open-label, Phase 4
- Intervention
  - Treatment: 1 serving of ONS during each dialysis, plus nutritional counseling
  - Control: nutritional counseling alone
- Primary endpoint
  - Change in serum albumin from baseline

Patient Selection

- Inclusion
  - In-Center Hemodialysis
  - Prevalent (≥90 days on dialysis at center)
  - Malnourished (serum albumin ≤3.5 g/dl)
  - Adequately dialyzed (Kt/V ≥1.4)
- Exclusion
  - Use of appetite stimulants
  - Regular supplement use (>7 supplements/mo)
  - Significant medical disease

Treatment Intervention

- Renal-specific ONS provided to patients on hemodialysis 3x/week
  - 475 kcal per serving
  - 16 g protein per serving
- Nutritional counseling

Standard-of-Care Nutritional Counseling

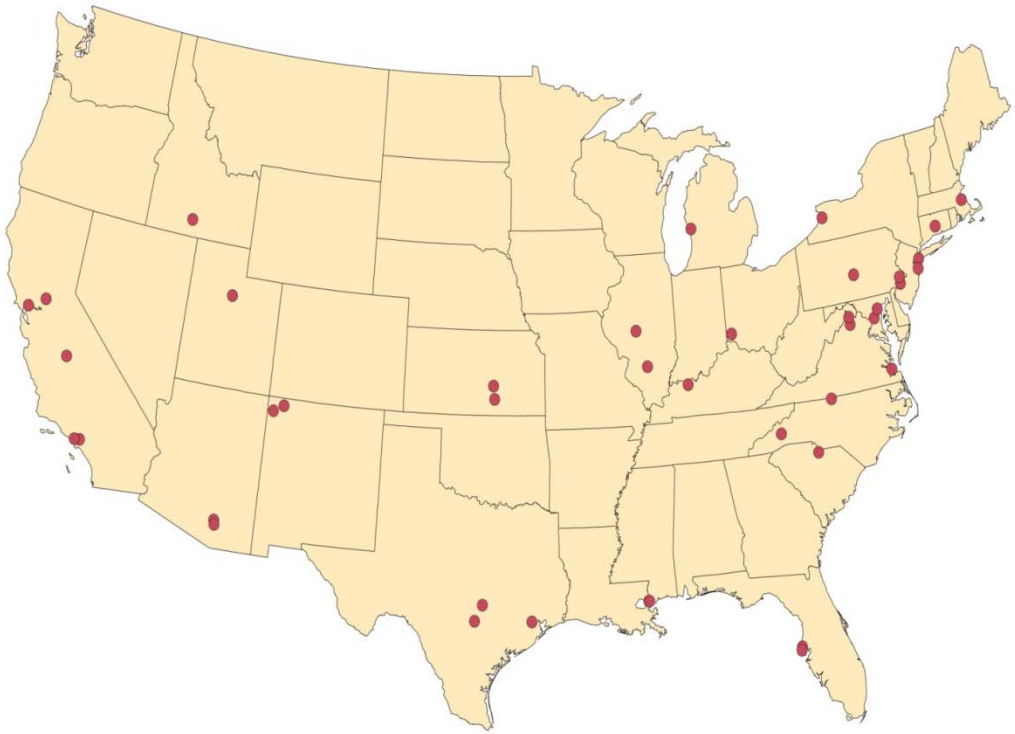
- Nutrition counseling was standardized and provided monthly by dietitian sub-investigators.
- Topics included
  - Protein and kcal intake goals
  - Sources of HBV protein and role
  - Menu ideas
  - Recipes
  - Strategies to address poor appetite, altered taste and early satiety

Standard of Care Nutritional Counseling, cont'd.

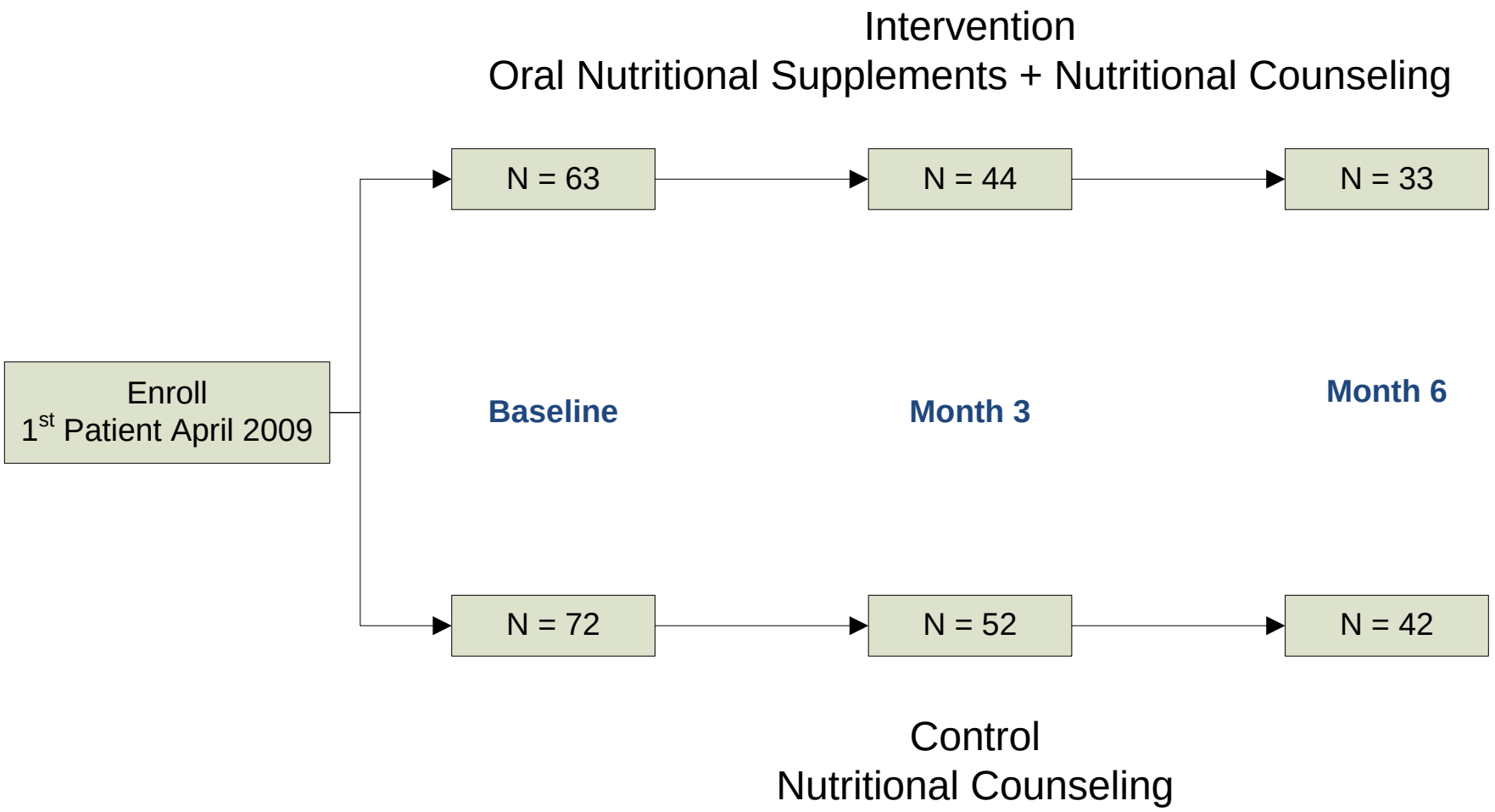
- Standardized monthly nutritional interview using "Deep Dive" Albumin tool to identify and address barriers to protein intake:
  - Difficulty shopping, cooking, and preparing foods
  - Altered taste for high protein foods
  - Chewing and swallowing problems
  - Early satiety, nausea, vomiting
  - Cost
  - Poor appetite

Facility Enrollment

- 42 dialysis facilities with 46 facility dietitians
- Study design allowed for study participant diversity



Patient Enrollment



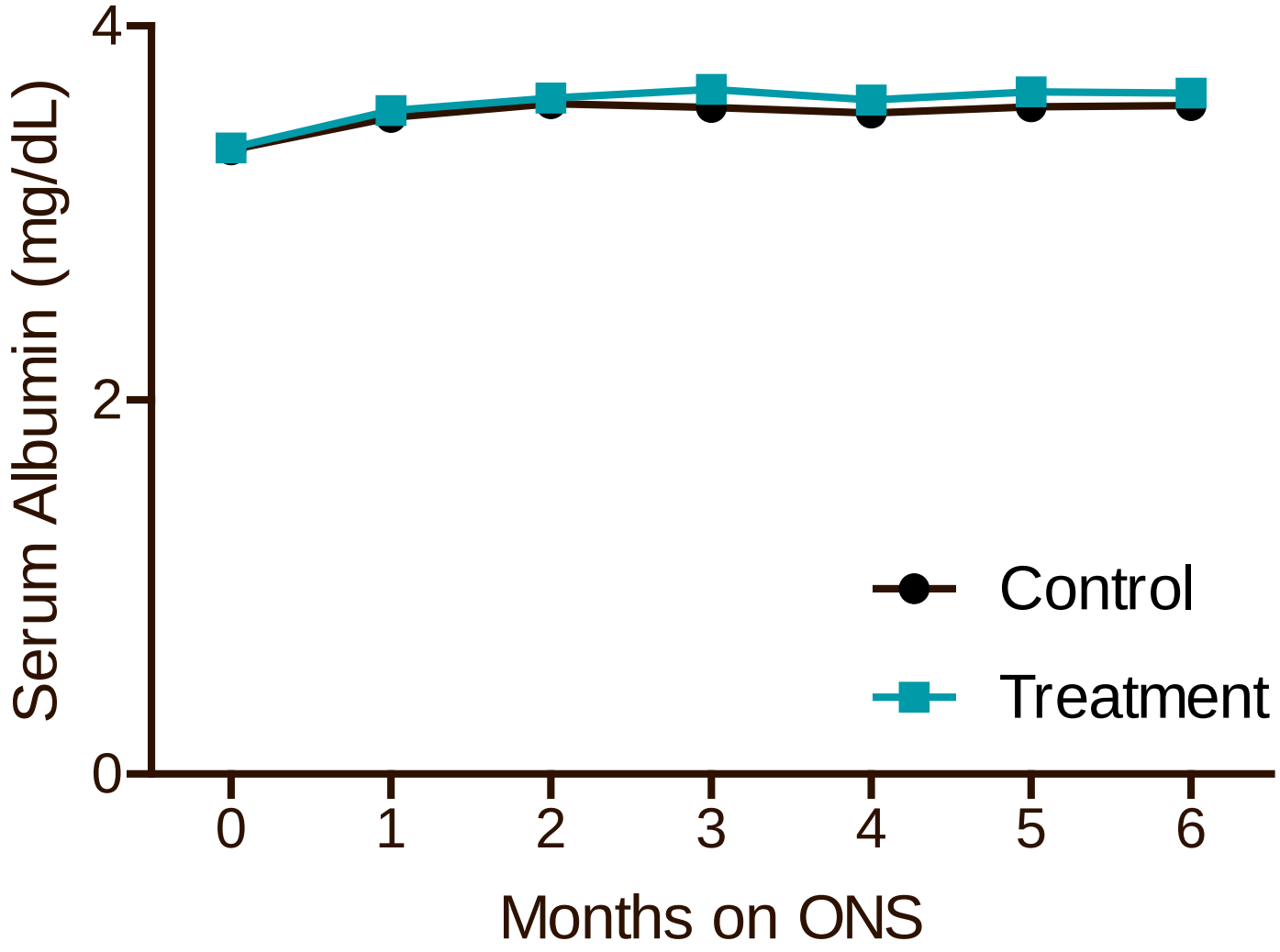
Patient Demographics

	Mean ± SD
N	127
Age (yr)	62.4±12.4
% Male	43.4%
% African American	26.8%
% Hispanic	8.7%
% Asian, Pacific Islander	0.0%
% Native American	5.5%
% Unknown	0.0%
% Diabetic	78.7%
Vintage (yr)	3.5±3.8
BMI	29.4±8.3

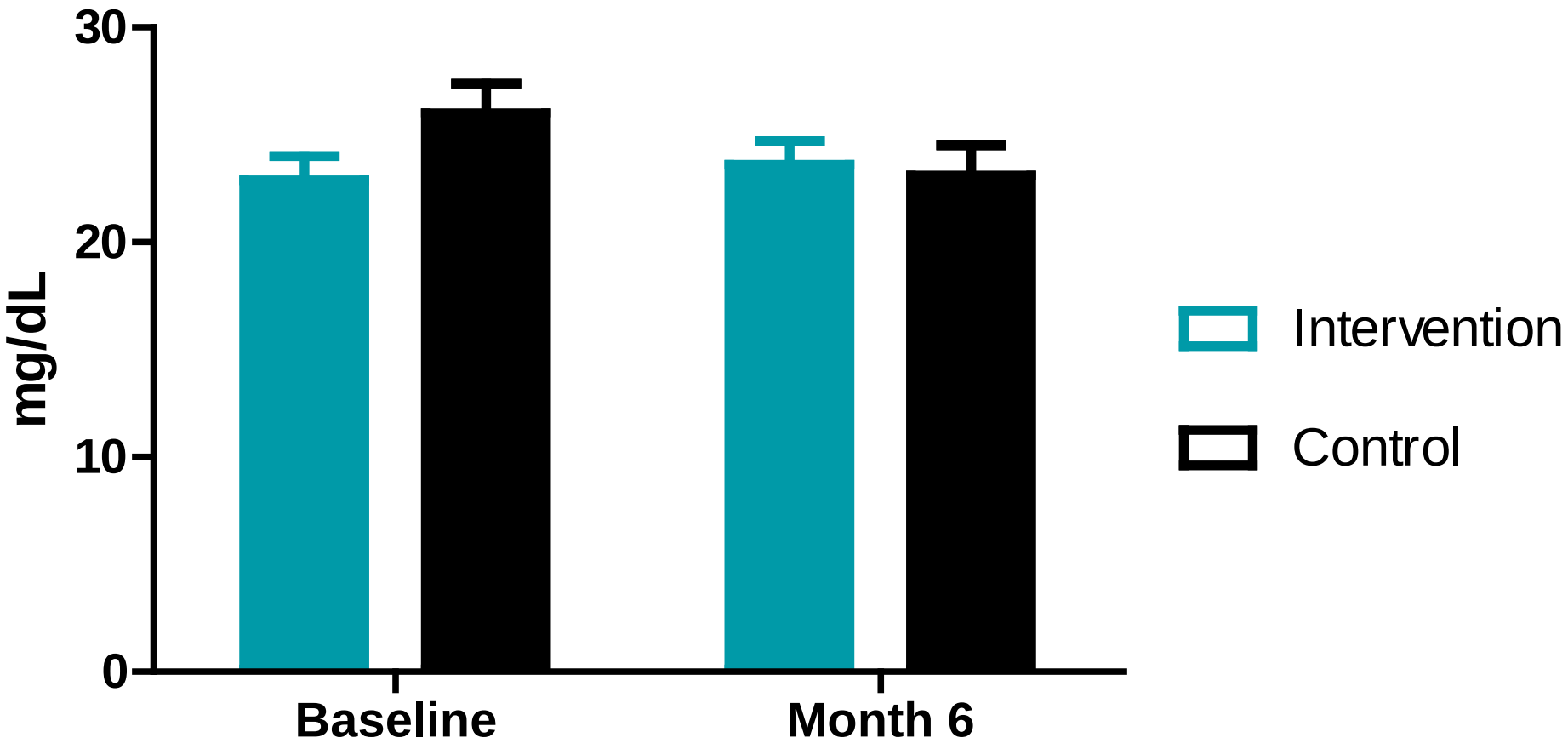
Results: Serum Albumin

- Increased with time in both treatment and control groups
- Did not differ between groups

Serum Albumin by Treatment Group



Prealbumin: Between-group differences were not significant



Strengths and Weaknesses

- Strengths
  - Randomized controlled trial
  - Standardized nutritional counseling for both groups
  - Geographical diversity
- Limitations
  - Frequency of ONS administration limited to TIW
  - High drop out rate in ONS group
  - Enrollment challenges
    - Significant number of patients already on regular supplements
    - Investigators reluctant to enroll patients if possibility to be randomized to control

Conclusion

- Adding oral nutritional supplementation during dialysis affords no discernable benefit over nutritional counseling alone

- Our results confirm the importance of the dietitian's role in modifying patient behavior to improve nutritional biomarkers

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