

MEETING NUTRITIONAL NEEDS WITH REFORMULATED FIBER-CONTAINING ADULT TUBE FEEDING FORMULAS

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BACKGROUND & OBJECTIVES

Background

- Enteral nutrition (EN) therapy is essential for individuals unable to meet daily energy and protein needs orally
- Enteral formulas should meet updated recommendations by experts, new clinical practice, and individual patient needs
- Two standard fiber-containing formulas were recently renovated to improve the vitamin and mineral content and update to a blend of insoluble (pea hull fiber) and soluble (fructooligosaccharides, inulin, and acacia gum) fiber

Objectives

- The primary objective is to assess the ability to meet energy goals in a clinically stable, tube fed population. Secondary objectives included the ability to meet protein goals and understand symptoms of intolerance and frequency and nature of adverse events

METHODS

- Clinically stable, tube-fed adults (>18 years) with established enteral access, currently tolerating EN, and anticipated to require EN to provide at least 90% of their nutritional needs for 21 days were recruited
- Consented subjects were observed on their pre-study formula for 3 days (days -3 to -1)

Table 1. Study Formula Nutrition Composition

	Formula A	Formula B
kcal/mL	1.2	1.5
Protein (% kcals)	18	18
Carbohydrate (% kcals)	53	47
Fiber (g/L)	15.2	15.2
Fat (% kcal)	29	35
Protein Source	Soy protein isolate, sodium caseinate (milk), calcium caseinate (milk)	Soy protein isolate, sodium caseinate (milk), calcium caseinate (milk)
Fiber Source	50% pea fiber, 20% FOS, 10% inulin, 20% gum acacia	50% pea fiber, 20% FOS, 10% inulin, 20% gum acacia

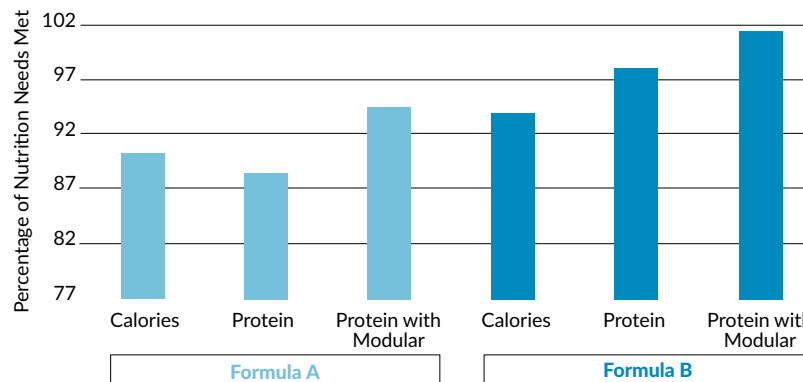
METHODS

- At study Day 0, study formula Fibersource® HN (Formula A) and Isosource® 1.5 (Formula B) (Nestlé Health Science, Florham Park, NJ) were initiated
- Each subject was fed for 14 to 21 days
- Study formula prescribed, actual intake, and daily percentage of calorie and protein goals achieved was recorded daily
- Gastrointestinal tolerance measures included abdominal distension, vomiting, nausea, abdominal pain, increased irritability, and stool frequency/consistency and were assessed on days -3 to -1, 1-3, 10-12, and 19-21
- This study was registered on clinicaltrials.gov (NCT02312271)

RESULTS

- Eighteen subjects were initially enrolled on each study arm, with 17 subjects completing the study on Formula A (mean age 51.6 years, 72% male) and 18 subjects completing the study on Formula B (mean age 48.7 years, 83% male)
- The average daily percentage of caloric goal achieved was 90.2% and 94.3% for formulas A and B, respectively (see Figure 1)
- The average daily percentage of protein goal achieved was 88.5% and 97.9% for formulas A and B, respectively (see Figure 1)
- Stool data is presented in Figures 2 and 3. There was no difference between time points in frequency, number, or consistency of stool in either formula
- Two subjects on Formula A and 5 on Formula B experienced gastrointestinal symptoms, none were withdrawn from the study

Figure 1. Daily Percentage of Nutritional Goals Met



RESULTS

- No product-related serious adverse events were reported for either formula nor were any differences reported in tolerance between the open 250mL format or ready-to-hang closed system 1500mL format for both formulations

Figure 2. Stool Characteristics Formula A

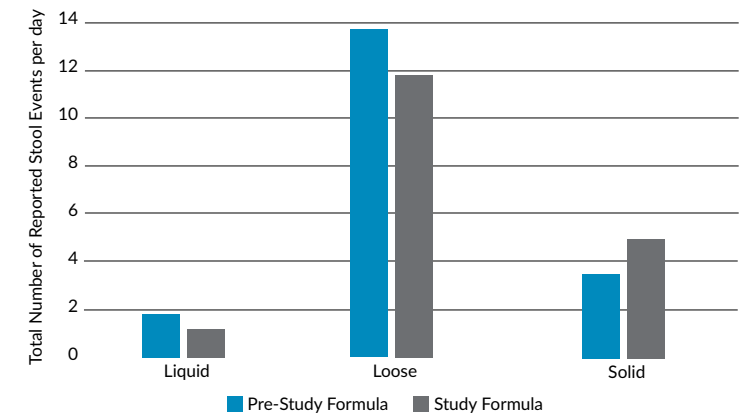
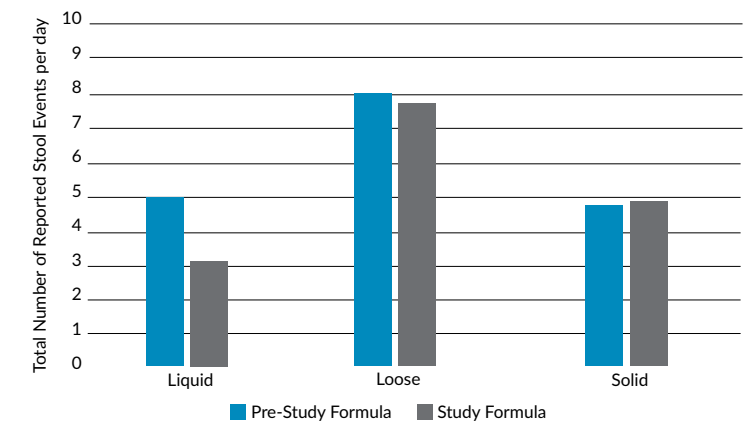


Figure 3. Stool Characteristics Formula B



CONCLUSION

Subjects consuming both reformulated products including a blend of soluble and insoluble fibers, in open and closed system, were able to meet over 90% of prescribed calories and over 88% of prescribed protein and were shown to be well tolerated by stable tube-fed subjects.