primary studies - published RCT

Randomized clinical trial of behavioral and nutrition treatment to improve energy intake and growth in toddlers and preschoolers with cystic fibrosis.

Code: PM16322169 **Year:** 2005 **Date:** 2005 **Author:** Powers SW

Study design (if review, criteria of inclusion for studies)

Parallel RCT.

Participants

Population of interest N = 21 with n = 14 meeting criteria. Four withdrew or lost to follow-up. Thus, n = 10 participants included aged 18 - 48 months with confirmed diagnosis of CF with pancreatic insufficiency

Interventions

Comparing behavioral and nutrition treatment (BEH) with usual standard care (CTL). Crossover from CTL to BEH offered after stage 1 of trial finished with 3- and 12-month follow-up. Hypotheses: 1. BEH would improve child's energy intake relative to CTL 2. improvements would be maintained for 12 months. a. increasing calorie and fat intake b. dosage and timing of pancreatic enzymes c. teaching parent management skills. Treatment over 8-week period with baseline at week 1 and 6; intervention sessions during weeks 3 - 6. 2. CTL (n = 6) scheduled clinic visits every 3 months and dietitian consulted whenever diet and growth issues were identified. 1. BEH (n = 4) nutritional counselling - targeted at 1 meal each week. 3 focus areas

Outcome measures

Change in average energy intake % fat intake measured with 7-day diet diaries 1 week before intervention and 1 week after intervention (8 weeks apart).

Main results

BEH led to greater increases in energy intake pre- to posttreatment than CTL as measured by calories per day (842 kcal/day vs -131 kcal/day change). On receiving BEH, the change in energy intake was replicated with the CTL group (892 kcal/day change). At 3- and 12-month follow-up, energy intake was maintained (672 kcal/day increase from baseline and 750 kcal/day increase from baseline, respectively). Children in this study met or exceeded normal weight and height velocities from pretreatment to the 3-month follow-up (mean weight: 1.4 kg/6 months; mean height: 5.1 cm/6 months) and from posttreatment to the 12-month follow-up (mean weight: 2.5 kg/12 months; mean height: 8.3 cm/12 months).

Authors' conclusions

Toddlers and preschoolers who have CF and received BEH were able to meet the energy intake recommendations for this disease and maintain these gains up to 12 months after treatment. In addition, these children demonstrated weight and height velocities from pretreatment to 12-month follow-up, consistent with the goal of normal growth. BEH is a promising, evidence-based, early nutritional intervention for children with CF. An upcoming multisite clinical trial will test BEH versus an attention control condition using a larger sample (N = 100), providing additional evidence about the efficacy of this treatment for energy intake and growth in young children with CF.

http://dx.doi.org/10.1542/peds.2004-2823

See also

Pediatrics. 2005 Dec;116(6):1442-50.

Keywords

Caloric Intake; Child; Infant; non pharmacological intervention - diet; non pharmacological intervention - psyco-soc-edu-org;

Supplementation; Behavioural interventions;