

primary studies - published RCT

Randomised Clinical Trial: Lactobacillus Reuteri ATCC55730 in Cystic Fibrosis.

Code: PM24121143 Year: 2013 Date: 2017

Author: Di Nardo G

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

Multicenter, randomized trial

Participants

14 CF centers, 267 patients, at least 14 years old.

Interventions

An intervention directed toward early detection of pulmonary exacerbations using home spirometry and symptom monitoring (electronically twice per week). Participants in the usual care arm were seen every 3 months and were asked to contact the site if they were concerned about worsening pulmonary symptoms.

Outcome measures

The primary outcome was the 52-week change in FEV1. Secondary outcomes included time to first exacerbation and subsequent exacerbation, quality of life, and change in weight.

Main results

There was no significant difference between study arms in 52-week mean change in FEV1 slope (mean slope difference, 0.00 L, 95% confidence interval, -0.07 to 0.07; P = 0.99). The early intervention arm subjects detected exacerbations more frequently than usual care arm subjects (time to first exacerbation hazard ratio, 1.45; 95% confidence interval, 1.09 to 1.93; P = 0.01). Adverse events were not significantly different between treatment arms.

Authors' conclusions

An intervention of home monitoring among patients with CF was able to detect more exacerbations than usual care, but this did not result in slower decline in lung function.

<http://dx.doi.org/10.1097/MPG.000000000000187>

See also

J Pediatr Gastroenterol Nutr. 2013 Oct 10.

Keywords

Adult; Child; Home Care Services; non pharmacological intervention - psycho-soc-edu-org; Organization;