

primary studies - published RCT

Disrupted intestinal microbiota and intestinal inflammation in children with cystic fibrosis and its restoration with Lactobacillus GG: a randomised clinical trial.

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

Pragmatic, clustered, 2-arm randomized controlled trial

Participants

18 CF Centers. 607 adolescents with CF, ages 11-20years.

Interventions

Centers were randomized to IMPACT (n=9; 300 adolescents), a brief problem-solving + education intervention, or standard care (SC; n=9; 307 adolescents). IMPACT was delivered during a regularly scheduled clinic visit by a member of the clinical care team.

Outcome measures

The primary outcome was composite pulmonary medication possession ratio (cMPR); secondary endpoints were lung function, Body Mass Index percentile, courses of IV antibiotics, and health-related quality of life at 12months.

Main results

Effectiveness of the intervention was tested using mixed models, generalized estimating equations comparing IMPACT to SC. 58% of problem-solving sessions targeted barriers to airway clearance, exercise or nutrition, while 18% addressed pulmonary medications. Average intervention fidelity score was 67% (SD=14%; Range=25-100%). No significant intervention effects were found for cMPR or any of the secondary outcomes compared to SC.

Authors' conclusions

The IMPACT intervention did not improve medication adherence or health outcomes over 12months. Challenges to implementing the intervention as intended during busy clinic visits were identified.

<http://dx.doi.org/10.1371/journal.pone.0087796>

See also

PLoS One. 2014 Feb 19;9(2):e87796. doi: 10.1371/journal.pone.0087796. eCollection 2014.

Keywords

non pharmacological intervention - psycho-soc-edu-org; Self-Management; information; Psychoeducation; Behavioural interventions;