POEMs

Patient-Oriented Evidence That Matters

Telephone-Based Cognitive Behavior Therapy for Insomnia Is Effective

Clinical Question

Can cognitive behavior therapy (CBT) for insomnia in patients with chronic pain be effectively delivered via telephone?

Bottom Line

In patients with clinical insomnia and chronic pain, CBT for insomnia delivered via telephone over six sessions leads to relief of sleeplessness that is sustained for at least one year. In this study, general education also provided insomnia relief to many patients. (Level of Evidence = 1b–)

Synopsis

The researchers recruited 327 participants with moderate to severe osteoarthritis and clinical insomnia identified via telephone screening. The patients had not sought care but had a positive screen for insomnia with an average score on the Insomnia Severity Index of 15.5 out of a possible 28. Most participants were women (75%) and White (96%), and almost one-half (48%) were college graduates. The patients were randomized (allocation concealment unknown) to receive telephone-based CBT for insomnia (focused on in-bed restriction, cognitive strategies to reduce hyperarousal, and setting realistic sleep expectations) or an education-only intervention. All participants were contacted six times by telephone over eight weeks. Two months after the end of the treatment period, insomnia scores decreased by 8.1 points in the CBT group and 4.8 points in the education-only group ($P = .001$); 81% of the CBT group had at least a 30% improvement in insomnia scores compared with 49% of the education group ($P < .001$). Differences in scores were maintained 12 months after treatment. Feelings of fatigue improved to a greater extent with CBT.

Study design: Randomized controlled trial (nonblinded)

Funding source: Industry and foundation

Allocation: Uncertain

Setting: Inpatient (any location)

Reference: *McCurry SM, Zhu W, Von Korff M, et al. Effect of telephone cognitive behavioral therapy for insomnia in older adults with osteoarthritis pain: a randomized clinical trial.* JAMA Intern Med. *2021;181(4):530-538.*

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Amoxicillin Does Not Improve Outcomes for Nonpneumonia Lower Respiratory Tract Infection in Children

Clinical Question

Is amoxicillin beneficial for children six months to 12 years of age with a lower respiratory tract infection that is not pneumonia?

Bottom Line

A high dosage of amoxicillin (50 mg per kg per day, in three divided doses) did not significantly improve outcomes for children with a lower respiratory tract infection that is not pneumonia. (Level of Evidence = 1b)

Synopsis

The investigators identified 432 children six months to 12 years of age who presented to their primary care physician in the United Kingdom with lower respiratory tract infection symptoms for less than 21 days, but with no clinical signs indicating possible pneumonia. All of the patients had acute cough with signs and symptoms that localized the infection to the lower respiratory tract, such as shortness of breath, sputum production, or pain. The children were randomized (concealed allocation) to receive amoxicillin, 50 mg per kg per day in three divided doses, or matching placebo. Nasal swabs were taken to look for common respiratory pathogens, and parents kept symptom diaries for 28 days or until symptoms had resolved. The median age of participants was 3.2 years, 54% were boys, 13% had a comorbidity, and only 28% had received the influenza vaccine in the past year. The authors had complete follow-up data for 73% of the patients,

and they imputed missing data where possible. The primary outcome was the duration of moderately bad or worse respiratory symptoms and did not differ between groups (five days for antibiotics; six days for placebo; hazard ratio = 1.13; 95% CI, 0.90 to 1.42). There was also no difference in secondary outcomes, such as the likelihood of hospitalization, returning with new or worsening symptoms, symptom severity, or the duration until the symptoms were reported to be mild . There were no differences between groups in adverse events. A high dose of amoxicillin is recommended for pathogens with intermediate levels of resistance. Only two patients in the placebo group and five in the antibiotics group had atypical bacterial pathogens, such as *Chlamydia pneumoniae, Mycoplasma pneumoniae, Bordetella pertussis, Streptococcus pyogenes*, or *Fusobacterium necrophorum*, that would not be expected to respond to amoxicillin.

Study design: Randomized controlled trial (double-blinded)

Funding source: Government

Allocation: Concealed

Setting: Outpatient (primary care)

Reference: *Little P, Francis NA, Stuart B, et al. Antibiotics for lower respiratory tract infection in children presenting in primary care in England (ARTIC PC): a double-blind, randomised, placebo-controlled trial.* Lancet. *2021;398(10309):1417-1426.*

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Every-Other-Year FIT Is at Least as Effective as a Single Sigmoidoscopy to Detect Colorectal Cancer

Clinical Question

Is fecal immunochemical testing (FIT) an effective method of screening for colorectal cancer?

Bottom Line

FIT every other year, over at least six years, identified fewer cancers and advanced adenomas initially, but surpassed a single sigmoidoscopy in detection after three rounds of testing. The increased detection may be because of greater participation in FIT than in sigmoidoscopy. (Level of Evidence = 1b)

Synopsis

Using a national patient registry in two geographic areas of southeast Norway, the investigators randomly invited individuals 50 to 74 years of age (N = 139,291) for either a once-only screening with flexible sigmoidoscopy or FIT every other year for a maximum of four rounds. None of the patients who received an invitation to this study had ever undergone any colorectal cancer screening. Positive findings with either screening were confirmed by colonoscopy. More patients accepted the invitation for screening via FIT (58.4% in the first round and 68.4% after three cumulative rounds) compared with sigmoidoscopy (52.1%). Patients with a 10-mm or larger polyp or at least three adenomas with dysplasia or villous architecture were referred for colonoscopy. Sigmoidoscopy identified more stage I colorectal cancer than FIT (odds ratio = 0.72; 95% CI, 0.55 to 0.95), although overall identification of colorectal cancer was similar between the two means of screening. Colorectal cancer detection rates were higher after three cumulative rounds of FIT (0.49% vs. 0.27%), and the difference was particularly pronounced for lesions located in the proximal colon. Advanced adenoma detection rates were higher with sigmoidoscopy for the first two rounds of FIT but were better with FIT after three rounds. False positives cannot be calculated because not all screened participants had a colonoscopy. FIT may result in a higher diagnostic yield because patients were solicited up to four times whereas patients assigned to sigmoidoscopy were solicited just once, and more patients (68%) who were offered FIT received at least one screening compared with only 52% for sigmoidoscopy.

Study design: Randomized controlled trial (nonblinded)

Funding source: Government

Allocation: Concealed

Setting: Population-based

Reference: *Randel KR, Schult AL, Botteri E, et al. Colorectal cancer screening with repeated fecal immunochemical test versus sigmoidoscopy: baseline results from a randomized trial.* Gastroenterology. *2021;160(4):1085-1096.e5.*

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Clopidogrel Monotherapy More Effective Than Aspirin to Prevent Coronary Events After PCI With Drug-Eluting Stents

Clinical Question

In people needing chronic antiplatelet therapy after completing dual antiplatelet therapy following percutaneous coronary interventions (PCIs) with drug-eluting stents, is clopidogrel (Plavix) monotherapy safer and more effective than aspirin monotherapy in preventing future coronary events?

Bottom Line

In this study, clopidogrel monotherapy caused fewer subsequent events compared with aspirin monotherapy in stable

patients who completed dual antiplatelet therapy after PCI with drug-eluting stents. (Level of Evidence = 2b)

Synopsis

This open-label study took place in 37 sites in South Korea. Adults who had completed six to 18 months of dual antiplatelet therapy after PCI with drug-eluting stents were randomized to receive clopidogrel, 75 mg daily (n = 2,719), or aspirin, 100 mg daily (n = 2,278), for two years. The included patients had no events during the period of dual antiplatelet therapy. The research team evaluated the participants 12 months and 24 months after randomization. They used intention-to-treat analysis for the main outcome (a composite of all-cause mortality, nonfatal myocardial infarction, stroke, hospitalization for acute coronary syndrome, and major bleeding complications). The authors had several other planned analyses, but did not include statistical adjustments to guard against type 1 errors (i.e., finding differences by chance). The primary outcome occurred in 5.6% of clopidogrel-treated patients and 7.6% of aspirin-treated patients (number needed to treat [NNT] = 51; 95% CI, 31 to 152). Compared with those taking aspirin, patients taking clopidogrel had fewer strokes (NNT = 110; 95% CI, 67 to 282), fewer hospitalizations (NNT = 65; 95% CI, 40 to 161), and less major bleeding (NNT = 138; 95% CI, 71 to 1,703). There were no significant differences in all-cause mortality or nonfatal myocardial infarction. A statistical adjustment for multiple analyses indicates that it is possible there was no difference in the rate of major bleeding.

Study design: Randomized controlled trial (nonblinded)

Funding source: Industry and government

Allocation: Concealed

Setting: Outpatient (specialty)

Reference: *Koo B, Kang J, Park KW, et al.; HOST-EXAM investigators. Aspirin versus clopidogrel for chronic maintenance monotherapy after percutaneous coronary intervention (HOST-EXAM): an investigator-initiated, prospective, randomised, open-label, multicentre trial.* Lancet. *2021;397(10293):2487-2496.*

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