

Clinical Trials Update

Telehealth Reduces Excess Weight Gain in Pregnancy

A telehealth lifestyle intervention substantially decreased excess gestational weight gain (GWG) among pregnant women who were overweight or obese and improved insulin resistance markers, a [trial](#) in *The Lancet Diabetes & Endocrinology* reported.

The study's 398 women, who were at 8 to 15 weeks' gestation, were randomly assigned to receive the lifestyle intervention or usual antenatal care. The intervention consisted of 2 in-person and 11 telephone sessions on strategies to improve weight, diet, physical activity, and stress management. Usual care included an average 8 antenatal visits and newsletters on GWG guidelines, healthful eating, and physical activity during pregnancy.

Forty-eight percent of women in the intervention group and 69% in the usual care group exceeded the Institute of Medicine's guidelines for weekly GWG. In the intervention group, women gained an average of 260.82 g (9.2 oz) per week compared with an average weekly gain of 320.35 g (11.3 oz) in the usual care group. The intervention group also reduced total caloric intake, sedentary behaviors, and insulin resistance markers. There were no differences in perinatal complications between the groups.

Rivaroxaban Reduces Complications of PAD Revascularization

Daily rivaroxaban and aspirin significantly reduced major limb and cardiovascular events among patients with peripheral artery disease (PAD) who had undergone lower-extremity revascularization, a [trial](#) in the *New England Journal of Medicine* reported.

The study's 6564 participants were randomly assigned to receive twice-daily rivaroxaban plus aspirin or placebo plus aspirin. The primary efficacy outcome—a composite of acute limb ischemia, major amputation for vascular causes, myocardial infarction, ischemic stroke, or death from cardiovascular causes—occurred among 508 patients in the rivaroxaban group and 584 in the placebo group.

The 3-year incidence of these outcomes was 17.3% in the rivaroxaban group and 19.9% in the placebo group. Major bleeding incidence depended on the definition. There was no significant difference in Thrombolysis in Myocardial Infarction-defined major bleeding between the groups. But the incidence of major bleeding as defined by the International Society on Thrombosis and Hemostasis was significantly higher in the rivaroxaban group than in the placebo group.

Intervention Improves Kids' Attitudes About Mental Disorders

A school-based intervention reduced mental health stigma among preadolescent students and resulted in more children seeking treatment, according to a [trial](#) in *Pediatrics*.

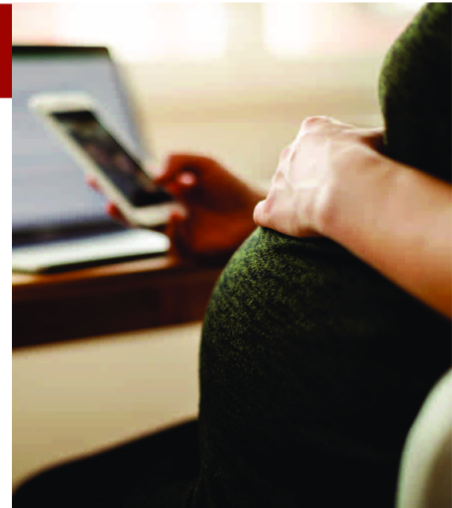
Conducted in ethnically diverse sixth-grade classes in 14 Texas schools, the trial compared the Eliminating the Stigma of Differences (ESD) course with a control group and with 2 other interventions: a discussion with 2 young adults with mental illness or antistigma materials displayed in the classroom. ESD is a 3-hour curriculum covering mental health disorders, consequences of stigma, and ways to end it. About 300 students participated in 2 years of follow-up.

The youth assigned to ESD reported greater knowledge and positive attitudes about mental disorders and were more inclusive to peers with mental illness than students in the other groups. Children with mental health symptoms in the ESD group also were more likely to seek treatment than those in the other groups.

Novel Therapy Eradicates *H pylori*

Antimicrobial resistance to existing therapies has made *Helicobacter pylori* infection increasingly difficult to treat. In a phase 3 [trial](#) published in the *Annals of Internal Medicine*, a 3-drug combination of amoxicillin, omeprazole, and rifabutin in 1 capsule achieved high eradication rates of *H pylori* infection.

The study's 455 treatment-naive adults with confirmed *H pylori* infection were ran-



A telehealth intervention helped pregnant women control excess weight gain, a recent clinical trial reported.

domly assigned to receive the novel study drug or high-dose amoxicillin and omeprazole dual therapy for 14 days.

Four weeks after the treatment ended, *H pylori* was eradicated in 83.8% of patients who received the rifabutin-based triple therapy compared with 57.7% in the omeprazole and amoxicillin group. The microbe's resistance to clarithromycin or metronidazole did not affect eradication rates, and no rifabutin resistance was detected.

Wellness Program Failed to Improve Employee Health

A comprehensive workplace wellness program did not improve health outcomes, a [trial](#) in *JAMA Internal Medicine* reported.

The 4834 employees of a large US university were randomly assigned to take part in a 2-year workplace wellness program or to a no-intervention control group. The intervention group received paid time off to attend wellness sessions and got cash rewards for completing annual onsite biometric screenings and other wellness activities.

After 12 and 24 months, the wellness program had no significant effects on 16 biometric outcomes or medical diagnoses. — Anita Slomski

Note: Source references are available through embedded hyperlinks in the article text online.