GOOD EVIDENCE MATTERS

GEMs of the Week

SPOTLIGHT

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FPIN
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One Shot: Single Dose of HPV Vaccine Noninferior for Preventing HPV16 and HPV18

Noninferiority of One HPV Vaccine Dose to Two Doses
Kreimer AR, Porras C, Liu D, et al. Noninferiority of One HPV Vaccine Dose to Two Doses. *N Engl J Med*. 2025;393(24):2421-2433. doi:10.1056/NEJMoa2506765

KEY TAKEAWAY: A single dose of human papillomavirus (HPV) vaccine is non-inferior to two doses for the prevention of infection with HPV16 & HPV18 in adolescent females for up to five years.

STUDY DESIGN: Randomized controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: HPV subtypes 16 & 18 are responsible for most cervical cancer, and HPV vaccination has been shown to be effective in preventing cervical cancer. However, fewer than one in three adolescent girls worldwide are vaccinated. This study aimed to evaluate whether a single dose of HPV vaccine was non-inferior to two doses for preventing infection with HPV subtypes 16 & 18.

PATIENTS: Adolescent girls never immunized against HPV

INTERVENTION: One dose of bivalent or nonavalent HPV vaccine

CONTROL: Two doses of bivalent or nonavalent HPV vaccine

PRIMARY OUTCOME: Incident infection with HPV 16 or 18

Secondary Outcome: Infection with subtypes 16, 18, 31, 33, 45, 52 or 58; vaccine effectiveness

METHODS (BRIEF DESCRIPTION):

- Girls 12–16 years old were recruited from more than 200 districts in Costa Rica.
- Potential participants who were not in good health or who had received an HPV vaccination were excluded.
- No more than 35% of eligible girls in any district could be included to prevent herd immunity effects.
- Participants were randomized 1:1:1:1 to receive either one or two doses of either bivalent or nonavalent vaccine. Participants randomized to receive one vaccine received a dose of control vaccine.
- Participants were tested at enrollment and every six months by self-collected cervicovaginal specimen.
- The primary outcome was HPV16 or HPV18 infection which persisted for six months.
- Noninferiority analysis was measured based on a margin of 1.3 infections per 100 participants, demonstrating >80% efficacy for one dose.
- Secondary endpoints measured infection with HPV subtype 16, 18, 31, 33, 45, 52 or 58.
- Vaccine effectiveness of both protocols was measured using a comparator group of similar but unvaccinated females 16–21 years old.

INTERVENTION (# IN THE GROUP): One vaccine dose: 8,177 (4,068 bivalent; 4,109 nonavalent)

COMPARISON (# IN THE GROUP): Two vaccine doses: 8,123 (4,040 bivalent; 4,083 nonavalent)

FOLLOW-UP PERIOD: Five years

RESULTS:

Primary Outcome –

- There was no significant difference in infection rate between one and two doses of bivalent vaccine (–0.13 infections per 100 participants; 95% CI, –0.45 to 0.15).
- There was no significant difference in infection rate between one and two doses of nonavalent vaccine (0.21 infections per 100 participants; 95% CI, –0.09 to 0.51).
- One dose of either bivalent or nonavalent HPV vaccine was noninferior to two doses for preventing infection with HPV 16 and 18.

LIMITATIONS:

- The study was done only in Costa Rica, potentially limiting generalizability.
- The study only lasted five years, so there may be differences in efficacy between one and two doses of the vaccine over a longer time.
- Estimates of vaccine effectiveness depended on a non-randomized comparator group.

Robert Brennan McKay, MD
Eisenhower Army Medical Center FMR
Ft. Gordon, GA

The opinions and assertions contained herein are those of the authors and are not to be construed as official or as reflecting the views of the US Army Medical Department, the Army at large, or the Department of Defense.

A Change of Heart: The Evolving Role of Beta-Blockers in Post MI Care

Beta-Blockers after Myocardial Infarction without Reduced Ejection Fraction

Ibanez B, Latini R, Rossello X, et al. Beta-Blockers after Myocardial Infarction without Reduced Ejection Fraction. *N Engl J Med*. 2025;393(19):1889-1900. doi:10.1056/NEJMoa2504735

KEY TAKEAWAY: For patients with a myocardial infarction (MI) and a left ventricular ejection fraction (LEVF) of >40%, beta-blocker therapy does not reduce the incidence of all-cause death, reinfarction, or hospitalization for heart failure (HF).

STUDY DESIGN: Prospective, randomized, open-label trial with blinded outcome evaluation (PROBE design)

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Current guidelines recommend beta-blocker therapy for all patients following a MI. However, these recommendations were established before the widespread use of modern reperfusion and pharmacological therapies. Recent evidence suggests that beta-blockers may not benefit patients who have a preserved ejection fraction after an MI.

PATIENTS: Adults post-MI with an EF >40%

INTERVENTION: Beta-blocker therapy

CONTROL: No beta-blocker therapy

PRIMARY OUTCOME: Composite of death from any cause, reinfarction, or hospitalization for HF

Secondary Outcome: Individual components of the primary outcome, safety, other cardiac events

METHODS (BRIEF DESCRIPTION):

- The study enrolled adults from 109 centers in Spain and Italy who had a MI (with or without ST-segment elevation), a LVEF >40%, and received coronary angiography during the hospitalization.
- Patients were excluded if they had a history of HF, a contraindication to beta-blockers, or another indication for beta-blockers.
- The average participant age was 61 years old and 19% of participants were women.
- Participants were randomized 1:1 to receive either beta-blocker therapy (at the discretion of the treating physician) or no beta-blocker therapy (control), with randomization occurring at the time of discharge or within 14 days after discharge.
- The primary outcome was the composite of death from any cause, reinfarction, or hospitalization for HF.
- Secondary outcomes included the individual components of the primary outcome, death from cardiac causes, sustained ventricular tachycardia, ventricular fibrillation, resuscitated cardiac arrest, and safety outcomes.
- A per-protocol and intention-to-treat analyses were performed, with outcomes centrally adjudicated by a committee blinded to treatment assignment.

INTERVENTION (# IN THE GROUP): 4,207

COMPARISON (# IN THE GROUP): 4,231

FOLLOW-UP PERIOD: 48 months

RESULTS:

Primary Outcome –

- Beta-blocker therapy did not reduce the composite incidence of all-cause death, reinfarction, or hospitalization for HF compared to no beta-blocker therapy (hazard ratio [HR] 1.0; 95% C,I 0.89–1.2).

Secondary Outcome –

- No significant differences were observed between the two groups for any of the secondary outcomes, including all-cause death, reinfarction, hospitalization for HF, or safety.

LIMITATIONS:

- The open-label design meant patients and physicians were aware of the treatment, which could introduce bias.
- A lower-than-expected event rate was observed, which may have reduced the study's statistical power.
- The lack of adjustment for multiplicity in secondary outcomes increase the risk of false-positive findings
- The choice and dosage of beta-blocker were left to physician discretion, which may have obscured dose-dependent effects.
- Most patients were prescribed bisoprolol, which may limit generalizability to other countries where carvedilol and metoprolol are more commonly used.

- Heart rate monitoring was not obtained at follow-up visits, limiting the study's ability to correlate heart rate changes to clinical outcomes.

Nathan Snyder, DO
Naval Hospital (Camp Lejeune) Program
Jacksonville, NC

The views expressed herein are those of the author and do not necessarily reflect the official policy of the Department of the Navy, Defense Health Agency, Department of Defense, or the U.S. Government.

Post-Delivery, Labetalol Doesn't Deliver

Risk of Postpartum Readmission after Hypertensive Disorder of Pregnancy and Variation by Discharge Antihypertensive Medication Prescription

Mitro SD, Hedderson M, Xu F, et al. Risk of Postpartum Readmission after Hypertensive Disorder of Pregnancy and Variation by Discharge Antihypertensive Medication Prescription. *Am J Obstet Gynecol*. 2024;231(4):456.e1-456.e13. doi:10.1016/j.ajog.2024.01.015

KEY TAKEAWAY: In postpartum patients with hypertensive disorders of pregnancy (HDP), labetalol monotherapy is associated with the highest readmission rate, even compared to no treatment. Nifedipine monotherapy or a combination of ≥2 medications is associated with a lower rate compared with no treatment.

STUDY DESIGN: Retrospective cohort study

LEVEL OF EVIDENCE: STEP 3

BRIEF BACKGROUND INFORMATION: HDPs are a significant predictor of postpartum readmissions. HDPs are most often treated with labetalol, nifedipine, and hydralazine and less commonly with methyldopa and thiazide diuretics. Previous studies have shown mixed results regarding the effectiveness of the most prescribed medications in reducing readmission rates. This study explored the effectiveness of these antihypertensive medications in preventing readmissions among a diverse patient population, considering demographic and clinical factors.

PATIENTS: Pregnant patients with hypertension

INTERVENTION: Labetalol, nifedipine, or multiple medications

CONTROL: No medication

PRIMARY OUTCOME: Postpartum readmission rate

METHODS (BRIEF DESCRIPTION):

- The study examined records for 57,254 pregnant patients who had an HDP diagnosis and delivered between 2012 and 2018 at a Kaiser Northern California facility.
    - Hypertensive diagnosis and severity were determined by inpatient coding, ACOG criteria, vitals, and laboratory values during delivery hospitalization.
- The primary outcome was readmission within six weeks of delivery.
- Higher readmission rates are associated with factors such as older age, higher parity, Black race, earlier gestational age at delivery, and greater HDP severity.
- The intervention groups consisted of nifedipine alone (4.2%), labetalol alone (7.5%), or multiple antihypertensive medications (2.2%) vs no medication (86%).
    - Medication dosage was not assessed.
    - Discharge instructions were used to determine prescription information.
    - Patients prescribed multiple antihypertensives were more likely to have severe pre-eclampsia, be of Black race, have earlier gestational age at delivery, and have had a C-section compared to other intervention groups.
- Researchers used Cox proportional hazards regression models to assess the link between medication prescribed at discharge and readmission rate.
- Models were adjusted for hypertensive diagnosis, last blood pressure, age, body mass index (BMI), mode of delivery, insurance, race and ethnicity, facility, smoking, preterm delivery, parity, Neighborhood Deprivation Index (NDI), delivery year, and comorbidities at admission.
    - NDI, based on maternal zip code, combines factors like census tract-level poverty, employment, education, and housing, with zero set as the mean and higher values indicating greater deprivation.
- The analysis was repeated with labetalol monotherapy as a reference group and again excluding patients with chronic hypertension.

INTERVENTION (# IN THE GROUP):

- Labetalol: 4,288
- Nifedipine: 2,426
- ≥2 medications: 1,245

COMPARISON (# IN THE GROUP): 49,295

FOLLOW-UP PERIOD: Six weeks after date of hospitalization for delivery

RESULTS:

Primary Outcome –

- Labetalol monotherapy group increased the risk of postpartum readmission compared to the no antihypertensives group (adjusted hazard ratio [aHR] 1.6; 95% CI, 1.4–1.9).
- Nifedipine monotherapy decreased the risk of postpartum readmission compared to no antihypertensives (aHR 0.74; 95% CI, 0.59–0.93).
- ≥2 antihypertensive medications at discharge decreased the risk of postpartum readmission compared to no antihypertensives (aHR 0.53; 95% CI, 0.38–0.74).

LIMITATIONS:

- Demographic parameters could not be standardized between exposure groups.
- Reasons for readmission not examined.
- Medication dosage or titration not assessed.
- Prescriptions for antihypertensive medication after discharge not examined.
- Medication adherence not measured.

Elena Sharma, MD
St Peter Hospital (Olympia) Program
Olympia, WA

Oral or IM Naltrexone? Either Works for Alcohol Use Disorder

Oral vs Extended-Release Injectable Naltrexone for Hospitalized Patients with Alcohol Use Disorder: A Randomized Clinical Trial

Magane KM, Dukes KA, Fielman S, et al. Oral vs Extended-Release Injectable Naltrexone for Hospitalized Patients with Alcohol Use Disorder: A Randomized Clinical Trial. *JAMA Intern Med*. 2025;185(6):635-645. doi:10.1001/jamainternmed.2025.0522

KEY TAKEAWAY: Oral or injectable naltrexone at hospital discharge reduces heavy drinking days (HDDs) in patients with alcohol use disorder (AUD), with no significant difference in efficacy between the groups.

STUDY DESIGN: Single-center, open-label randomized controlled trial

LEVEL OF EVIDENCE: STEP 3 (downgraded due to small size and lack of blinding)

BRIEF BACKGROUND INFORMATION: AUD is common among hospitalized patients, yet pharmacologic treatment is underutilized. Naltrexone, available in oral and injectable formulations, is effective for AUD, but no prior study has compared formulations head-to-head at hospital discharge.

PATIENTS: Hospitalized adults with AUD

INTERVENTION: Injectable naltrexone

CONTROL: Oral naltrexone

PRIMARY OUTCOME: HDDs in the past 30 days

Secondary Outcome: Hospitalization or emergency department (ED) use in the past 90 days

METHODS (BRIEF DESCRIPTION):

- This study was a single site open-label randomized controlled trial conducted at an urban academic hospital in New Haven, Connecticut.
- Participants were adults ≥18 years old referred to the study by their hospital physicians, hospitalized for any reason, with AUD and ≥1 HDD (defined as ≥5 drinks for men and ≥4 four drinks for women) in the 30 days preceding hospitalization, and had to name ≥2contacts who could assist with study follow-up.
- Participants were recruited primarily through review of inpatient medical records (87%) and through referral by the medical team or Addiction Consult Service (13%). An AUD screening assessment with a validated instrument was performed to confirm the diagnosis.
- Participants were excluded if they were requiring or using opioids, were pregnant or breastfeeding, or had laboratory evidence of hepatic disease, contraindications to naltrexone (hypersensitivity or habitus incompatible with IM injection), or an unstable psychiatric condition or cognitive impairment.
- Of 248 participants, 199 (80%) were male, and the mean (SD) age was 49 (±10) years. The baseline percentage of HDDs in the past 30 days was 80%.
- Participants were randomized 1:1 to oral or injectable naltrexone at hospital discharge.
    - Participants in the oral group were instructed to take naltrexone 25 mg daily for three days, then naltrexone 50 mg daily. Based on tolerability and not reaching goals, the dosage was increased to 100 mg per day.
    - The injectable group received one 380 mg injection on the day of discharge, and at one- and two-month follow-up visits.
- All participants received brief medical management counseling from addiction-trained nurses.
- The primary outcome was assessed via self-report on a participant questionnaire at 30 days and three-month follow-up: Percent change of HDDs (past 30 days) between baseline prior to randomization and at three months.
- Secondary outcomes were assessed via self-reported questionnaire of any alcohol-related hospital readmission or ED use in 90 days post-discharge.

INTERVENTION (# IN THE GROUP): 124

COMPARISON (# IN THE GROUP): 124

FOLLOW-UP PERIOD: Three months

RESULTS:

Primary Outcome –

- Both groups had similar reductions in HDDs from baseline to three-month follow-up:
    - Oral naltrexone (67% to 27%, respectively; difference –38%; 95% CI, –125 to 48)
    - Injectable naltrexone (71% to 24%, respectively; difference –46%; 95% CI, –123 to 31)

- There was no significant difference in HDDs between oral naltrexone and injectable naltrexone (adjusted between-group difference −8.2; 95% CI, −19 to 2.6).

Secondary Outcome –

- There was no significant difference in hospitalization or ED use for oral naltrexone and injectable naltrexone after three months.

LIMITATIONS:

- Open-label design may introduce performance and reporting bias.
- The study was conducted at a single urban center, which limits generalizability.
- Self-reported alcohol use may be subject to underreporting, despite biomarker collection.
- Relatively short follow-up period (3 months) may not capture long-term differences in outcomes.
- The study did not compare naltrexone to placebo or no treatment.

Daniel Brown, MD
Northern Light Eastern Maine FMR
Bangor, ME

Two for One Immunity: Effectiveness of Influenza Vaccination During Pregnancy

Influenza Vaccination During Pregnancy and Infant Influenza in the First 6 Months of Life

Zerbo O, Modaressi S, Goddard K, Fireman B, Klein NP. Influenza Vaccination During Pregnancy and Infant Influenza in the First 6 Months of Life. *Obstet Gynecol*. 2025;146(2):e36-e42. Published 2025 Jun 26. doi:10.1097/AOG.0000000000005986

KEY TAKEAWAY: Influenza vaccination during pregnancy can decrease the risk of infant influenza during the first six months of life compared to no influenza vaccination during pregnancy.

STUDY DESIGN: Retrospective cohort study

LEVEL OF EVIDENCE: STEP 3

BRIEF BACKGROUND INFORMATION: It is understood that vaccination against influenza is the most effective way to prevent contracting influenza and its subsequent complications. Infants under six months old are not eligible to receive the influenza vaccination. Prior data has demonstrated that influenza vaccination during pregnancy, especially in the latter half of pregnancy, can reduce the risk of infant influenza by 30–60% in the first six months of life.

PATIENTS: Pregnant individuals

INTERVENTION: Influenza vaccination during pregnancy

CONTROL: No influenza vaccination during pregnancy

PRIMARY OUTCOME: Influenza diagnosis in infants during the first six months of life

Secondary Outcome: Hospitalization, vaccine effectiveness by trimester, vaccine effectiveness by infant age

METHODS (BRIEF DESCRIPTION):

- The population of this study included pregnant individuals 15–45 years old in the Kaiser Permanente Northern California (KPNC) health system, with at least one prenatal visit and a liveborn infant with pregnancy onset between January 1, 2011, and December 31, 2022.
- Exclusion criteria included pregnant individuals <15 years old, >45 years old, those with <30 days of KPNC membership prior to initial prenatal visit, non-singleton pregnancies, or a pregnancy not resulting in a live birth were also excluded.
- The exposure in this study was one dose of inactivated influenza vaccine given during pregnancy between timeframe of conception and 14 days prior to delivery, stratified by trimester.
- The comparison group received no influenza vaccination.
- Of those enrolled, 36% identified as White, 27% as Hispanic, 26% as Asian, 5.8% as Black, 4.4% as multiracial or unknown, 0.8% as Pacific Islander, and 0.4% as Native American.
- In total, 7% of infants in this study were born before 37 weeks' gestation (6% of infants in the vaccinated group and 7.6% in the unvaccinated group).
- Of the individuals who received influenza vaccination, 26% were vaccinated during the first trimester, 42% in the second trimester, and 32% in the third trimester.
- Infant influenza diagnosis in the first six months of life was determined by a positive PCR test result.
- The secondary outcomes for this study included vaccine effectiveness by trimester administered, risk of infant influenza diagnosis, and risk of infant hospitalization for influenza.
- The results were adjusted based on time of year (month) the infant was born, maternal age, maternal medical comorbidities, race, and ethnicity.

INTERVENTION (# IN THE GROUP): 112,896

COMPARISON (# IN THE GROUP): 132,602

FOLLOW-UP PERIOD: Six months

RESULTS:

Primary Outcome –

- Maternal influenza vaccination during pregnancy was associated with a decreased risk of infant influenza diagnosis vs no influenza vaccination during pregnancy (0.12% vs 0.3%, adjusted vaccine effectiveness [AVE] 44%; 95% CI, 31–55).

Secondary Outcome –

- Maternal influenza vaccination during the second and third trimesters was associated with a decreased risk of infant influenza diagnosis vs no influenza vaccination during pregnancy.
  - 2nd trimester (AVE 52%; 95% CI, 26–68)
  - 3rd trimester (AVE 59%; 95% CI, 45–70)

- Maternal influenza vaccination during the first trimester of pregnancy was not associated with a significant decreased risk of infant influenza diagnosis or infant hospitalization.
- Vaccine effectiveness varied by infant age and effectiveness was greatest for infants in the first 120 days of life.
    - 0–60 days of life (DOL) (AVE 51%; 95% CI, 28–67)
    - 61–120 DOL (AVE 56%; 95% CI, 34–70)
    - 121–180 DOL (AVE 29%; 95% CI, 2.8–47)

LIMITATIONS:

- The study cohort did not include patients without insurance or those outside of the limited geographical area of Northern California.
- Overall, the rate of hospitalization was too low to perform adjusted modeling or to detect a significant difference.
- If patients received influenza vaccination outside the KPNC system, they were potentially misclassified as non-vaccinated.
- Infants from multi-gestational pregnancies were not included.
- Some influenza cases may have been missed if the sick infant was not tested or was incorrectly diagnosed.

Mikayla Sargent, DO
Northern Light Eastern Maine Medical Center
Bangor, ME

Running it Back: Assessing Running as Exercise for Patients with Chronic Low Back Pain

Running is Acceptable and Efficacious in Adults with Non-Specific Chronic Low Back Pain: The ASTEROID Randomized Controlled Trial

Neason C, Samanna CL, Tagliaferri SD, et al. Running is Acceptable and Efficacious in Adults with Non-specific Chronic Low Back Pain: The ASTEROID Randomized Controlled Trial. *Br J Sports Med*. 2025;59(2):99-108. Published 2025 Jan 2. doi:10.1136/bjsports-2024-108245

KEY TAKEAWAY: For patients with chronic low-back pain, a run-walk interval training program reduces pain intensity and disability after 12 weeks compared to usual care.

STUDY DESIGN: Two-arm parallel randomized controlled trial

LEVEL OF EVIDENCE: STEP 3 (downgraded due to small sample size)

BRIEF BACKGROUND INFORMATION: Low back pain is one of the most common healthcare concerns, affecting over 7% of people worldwide. Recreational running is associated with lower rates of low back pain and healthier spinal tissue, but studies have not clearly shown if running is effective for individuals with pre-existing low back pain. This study examined running as an acceptable intervention for individuals with chronic low back pain.

PATIENTS: Individuals 18–45 years old with non-specific chronic low back pain

INTERVENTION: Run-walk interval program

CONTROL: Usual care

PRIMARY OUTCOME: Pain intensity and disability
Secondary Outcome: Acceptability (adherence and attrition), adverse events

METHODS (BRIEF DESCRIPTION):

- Participants were recruited from the Melbourne, AU metropolitan region via web-based advertising.
- Exclusion criteria:
  - Individuals with a history of spinal surgery, spine trauma, cauda equina symptoms, known structural scoliosis, symptomatic radiculopathy, inflammatory spondyloarthropathies, or non-musculoskeletal causes of LBP
  - Inability to communicate in English
  - Are pregnant, lactating, or <1 year postnatal
  - Are current or prior elite athletes
  - Have a contraindication to MRI
  - Participate in running or involved in a sport with running in the last three months
  - Have experienced a lower extremity injury in the last six weeks
  - Have absolute contraindications for exercise training (high risk for adverse events
  - Unable to access a smartphone with internet connection
  - Individuals that participate in running/sports
- Patients were randomized 1:1 to run-walk interval program or usual care.
- Patients randomized to exercise received three 30-minute training sessions per week by an accredited exercise physiologist and consisted of a progressive interval-based run-walk training program (short running intervals interspersed with rest periods of walking). Participants also received weekly (weeks 1–4) and bi-weekly (weeks 6–12) meetings with regular support, guidance and education.
- Patients randomized to the control group received usual care and were instructed to manage their low back pain as usual (e.g., PCP management, OTC pharmacotherapy) and to avoid starting a running program.
- Primary outcomes were measured at baseline, six weeks, and 12 weeks using online questionnaires.
- Pain intensity was measured on a 100-point Visual Analogue Scale (VAS). Scores range from 0–100, with higher scores indicating worse pain. Patients were asked to answer questions regarding current, average, and worst pain experienced in the last seven days.
- Disability was measured with the Oswestry Disability Index. Questions are rated on a scale of 0–5, with increasing score correlating to worsening back pain. These scores were added together and doubled to get a total number on a scale of 2–100.
- Secondary outcomes were measured using the following:
  - Acceptability data was documented throughout the study using an online questionnaire. Data regarding recruitment, attrition, adherence, and

utilization of a running tracker were monitored throughout the study.
    - Adverse events were self-reported by participants. They were categorized as serious (resulting in death, life-threatening, or requiring hospitalization) or non-serious (increased pain/injury that resulted in missed training sessions).

INTERVENTION (# IN THE GROUP): 20

COMPARISON (# IN THE GROUP): 20

FOLLOW-UP PERIOD: 12 weeks

RESULTS:

Primary Outcome –

- The run-walk interval program decreased low-back pain compared to usual care at six and 12 weeks:
    - Six weeks (between-group difference –10; 95% CI, –20 to –0.05)
    - 12 weeks (between-group difference –15; 95% CI, –25 to –5.3)
- The run-walk program did not significantly affect disability compared to usual care at six weeks (between-group difference –5.2; 95% CI, –16 to 5.7).
- The run-walk interval program decreased disability compared to usual care at 12 weeks (between-group difference –5.2; 95% CI, –10 to –0.24).

Secondary Outcome –

- Acceptability: There was no attrition. The mean (SD) training adherence was 70% (2.1 of 3 sessions per week).
- There were nine adverse events that were likely deemed study-related in the intervention group, all of which were non-serious. These adverse events accounted for a total of 20 missed training session.

LIMITATIONS:

- Participants in this study had an average pain intensity rated as “mild pain,” potentially limiting generalizability to those with moderate-to-severe low back pain.
- Unlike the intervention group that met with an exercise physiologist, the control group did not have regular contact with researchers, which could affect performance bias.
- Patients were self-referred, increasing the risk of selection bias.
- Participants knew this study involved running, which may have influenced their willingness/ability to participate, resulting in recruitment bias.
- Participants are 18–45 years old, and results may not be generalizable to those outside of this range.
- The participants in this study have non-specific chronic low back pain, so this study cannot reliably advise interventions for individuals with acute low back pain.

Alexander Kures, DO
PeaceHealth Southwest Family Medicine
Vancouver, WA