TIME HEALTH PRO

# HOW HAVING ECZEMA AFFECTS MENTAL HEALTH

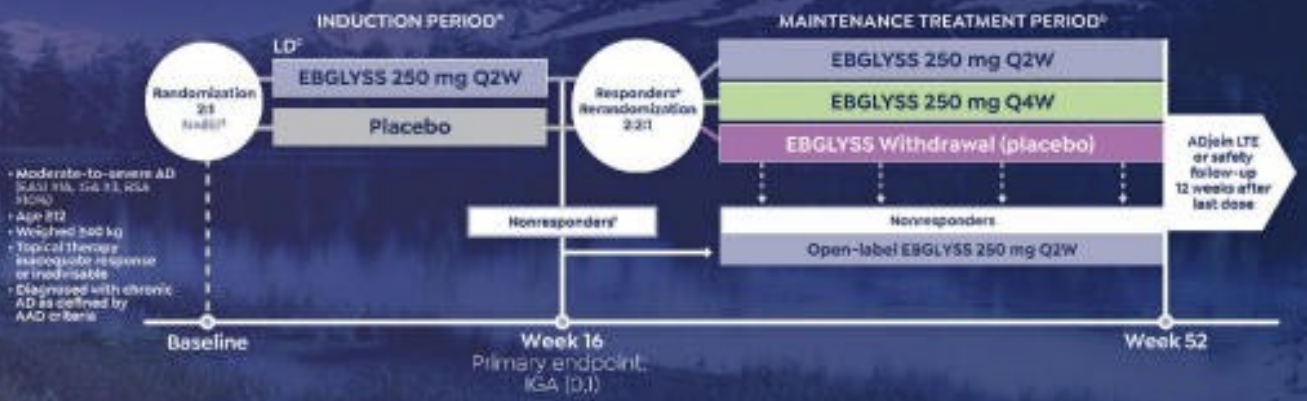
PLUS


Ebglyss®
(lebrikizumab-lbkz)
250mg/2mL injection
A Lilly Medicine
Deliver
CALM TO AD
that can go
ON AND ON[1]
Help give your patients calm skin for the long term with EBGLYSS, a first-line biologic following topical therapy that can provide lasting relief from the burden of the signs and symptoms of moderate-to-severe atopic dermatitis (AD)[1]
INDICATION
EBGLYSS is indicated for the treatment of adults and pediatric patients 12 years of age and older who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. EBGLYSS can be used with or without topical corticosteroids.
SELECT IMPORTANT SAFETY INFORMATION
Contraindication
EBGLYSS is contraindicated in patients with prior serious hypersensitivity to lebrikizumab-lbkz or any excipients of EBGLYSS.
Actor portrayals.

# EBGLYSS MONOTHERAPY

**The efficacy and safety of EBGLYSS were evaluated over the course of 1 year in 2 monotherapy trials with the same design (ADvocate 1, ADvocate 2)[1]**

## ADvocate 1 and ADvocate 2 study design[1,2]




**See Long-Term Efficacy Data on subsequent pages.**

**EXPLORE EBGLYSS BY VISITING**
**ebglyss.lilly.com/hcp**

[a]Use of topical/systemic treatments for atopic dermatitis (AD) was prohibited.[2]
[b]Use of intermittent topical rescue medications for AD was permitted in the maintenance phase.[2]
[c]Two 250-mg injections at week 0 and week 2.[1]
[d]At baseline, there were 424 patients enrolled in ADvocate 1, and 427 patients enrolled in ADvocate 2.[2]
[e]Responders were defined as patients who achieved IGA 0,1 with ≥ 2-point improvement or EASI 75 at week 16 without the use of rescue medication.[2]
[f]Nonresponders were defined as participants who did not achieve IGA 0,1 or EASI 75 at week 16 and participants who required rescue therapy during the first 16 weeks.[2]

AAD=American Academy of Dermatology; BSA=body surface area; EASI=Eczema Area and Severity Index; IGA=Investigator's Global Assessment; LD=loading dose; LTE=long-term extension study; Q2W=every 2 weeks; Q4W=every 4 weeks.

**SELECT IMPORTANT SAFETY INFORMATION**

**Hypersensitivity**

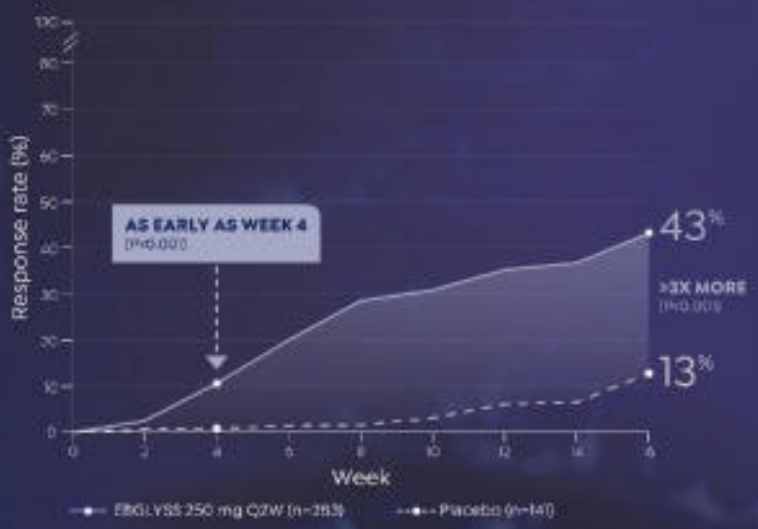
Hypersensitivity reactions, including angioedema and urticaria, have been reported with use of EBGLYSS. If a serious hypersensitivity reaction occurs, discontinue EBGLYSS and institute appropriate therapy.

**See Important Safety Information and Brief Summary of Prescribing Information on subsequent pages.**

# Ebglyss®
(lebrikizumab-lbkz)
250mg/2mL injection

A Lilly Medicine

**Primary endpoint: IGA* (0,1) responders through week 16 in ADvocate 1 (N=424)[1,2,a,b,c]**




**ADvocate 2 (N=427): 33% of patients who received EBGLYSS monotherapy achieved IGA 0 or 1 vs 11% with placebo at week 16 (*P*<0.001).[1,2]**

[a]Responder was defined as a patient with an IGA 0 or 1 ("clear" or "almost clear") and a reduction of ≥2 points on a 0-4 IGA scale.[1]

[b]Patients received 500 mg of EBGLYSS at week 0 and week 2, and 250 mg Q2W through week 16.[1]

[c]Patients who received rescue therapy or discontinued treatment due to lack of efficacy were analyzed as nonresponders. Data after treatment discontinuation due to any other reason were considered missing. Any missing data were imputed using MCMC-MI.[1]

MCMC-MI=Markov chain Monte Carlo multiple imputation.

*IGA: A 5-point clinical assessment measure of atopic dermatitis (AD) severity in which 0="clear," 1="almost clear," 2="mild," 3="moderate," and 4="severe."[3]

Primary endpoint was the proportion of subjects who achieved IGA 0 or 1 with ≥2-point change from baseline at week 16.[1]

**SELECT IMPORTANT SAFETY INFORMATION**

**Conjunctivitis and Keratitis**

Conjunctivitis and keratitis adverse reactions have been reported in clinical trials. Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received EBGLYSS compared to those who received placebo. Conjunctivitis was the most frequently reported eye disorder. Most subjects with conjunctivitis or keratitis recovered during the treatment period. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

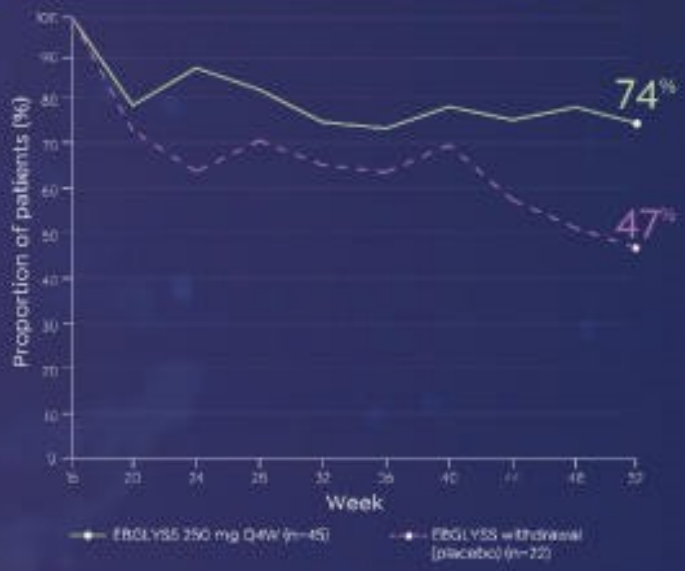

References:

1. EBGLYSS (lebrikizumab-lbkz). Prescribing Information. Lilly USA, LLC.
2. Silverberg JI, Guttman-Yassky E, Thaçi D, et al; for ADvocate1 and ADvocate2 Investigators. Two phase 3 trials of lebrikizumab for moderate-to-severe atopic dermatitis. *N Engl J Med*. 2023;388(21):1080-1091. doi:10.1056/NEJMoa2206714
3. Data on File. Lilly USA, LLC. DOF-LK-US-0010.
4. Data on File. Lilly USA, LLC. DOF-LK-US-0007.
5. Blauvelt A, Thyssen JP, Guttman-Yassky E, et al. Efficacy and safety of lebrikizumab in moderate-to-severe atopic dermatitis: 52-week results of two randomized double-blinded placebo-controlled phase III trials. *Br J Dermatol*. Published online March 30, 2023. doi:10.1093/bjd/ljad022


**See Important Safety Information on next page and Brief Summary of Prescribing Information on subsequent pages.**

Actor portrayal

**Long-lasting clearance: IGA (0,1) responders through week 52 in ADvocate 1[1,5,a]**




**ADvocate 2: 81% of patients who achieved clear or almost-clear skin (IGA 0 or 1) at week 16 and then received EBGLYSS monthly maintained clearance at 1 year (n=32); 50% with EBGLYSS withdrawal (placebo) (n=16).[1]**

Primary endpoint was the proportion of subjects who achieved IGA 0 or 1 with ≥2-point change from baseline at week 16.

The recommended dosage of EBGLYSS is an initial dose of 500 mg (two 250-mg injections) at week 0 and week 2, followed by 250 mg every 2 weeks until week 16 or later, when adequate clinical response is achieved. The maintenance dose is 250 mg every 4 weeks.

[a]Patients who received systemic rescue therapy or discontinued treatment due to lack of efficacy were analyzed as nonresponders. Data after topical rescue medication or treatment discontinuation due to any other reason were considered missing. Any missing data were imputed using MCMC-MI.

## IMPORTANT SAFETY INFORMATION

**CONTRAINDICATION:** EBGLYSS is contraindicated in patients with prior serious hypersensitivity to lebrikizumab-lbkz or any excipients of EBGLYSS.

### WARNINGS AND PRECAUTIONS

**Hypersensitivity**

Hypersensitivity reactions, including angioedema and urticaria, have been reported with use of EBGLYSS. If a serious hypersensitivity reaction occurs, discontinue EBGLYSS and institute appropriate therapy.

**Conjunctivitis and Keratitis**

Conjunctivitis and keratitis adverse reactions have been reported in clinical trials. Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received EBGLYSS compared to those who received placebo. Conjunctivitis was the most frequently reported eye disorder. Most subjects with conjunctivitis or keratitis recovered during the treatment period. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

**Parasitic (Helminth) Infections**

Patients with known helminth infections were excluded from participation in clinical studies. It is unknown if EBGLYSS will influence the immune response against helminth infections by inhibiting IL-13 signaling. Treat patients with pre-existing helminth infections before initiating treatment with EBGLYSS. If patients become infected while receiving EBGLYSS and do not respond to antihelminth treatment, discontinue treatment with EBGLYSS until the infection resolves.

**Vaccinations**

EBGLYSS may alter a patient's immunity and increase the risk of infection following administration of live vaccines. Prior to therapy with EBGLYSS, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines immediately prior to or during treatment with EBGLYSS. No data are available on the response to live vaccines.

### ADVERSE REACTIONS

The most common (≥1%) adverse reactions are conjunctivitis, injection site reactions, and herpes zoster.

EBGLYSS is available as a 250mg/2mL subcutaneous injection prefilled pen or prefilled syringe.

**See Brief Summary of Prescribing Information on subsequent pages.**
**Please see Instructions for Use included with the device.**

LK HCP ISI AD APP

This material may contain images edited with AI.



PP-LK-US-0171-001 03/2025


Lilly
A MEDICINE COMPANY

**EBGLYSS™ (lebrikizumab-lbkz) 250mg/2mL injection for subcutaneous use, available in a prefilled pen or prefilled syringe.**
**Brief Summary:** Consult the Package Insert for complete Prescribing Information.

## INDICATION AND USAGE
EBGLYSS is indicated for the treatment of adults and pediatric patients 12 years of age and older who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. EBGLYSS can be used with or without topical corticosteroids.

## CONTRAINDICATION
EBGLYSS is contraindicated in patients with prior serious hypersensitivity to lebrikizumab-lbkz or any excipients of EBGLYSS (*see Warnings and Precautions*).

## WARNINGS AND PRECAUTIONS

### Hypersensitivity
Hypersensitivity reactions, including angioedema and urticaria, have been reported with use of EBGLYSS. If a serious hypersensitivity reaction occurs, discontinue EBGLYSS and institute appropriate therapy.

### Conjunctivitis and Keratitis
Conjunctivitis and keratitis adverse reactions have been reported in clinical trials. Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received EBGLYSS compared to those who received placebo. Conjunctivitis was the most frequently reported eye disorder. Most subjects with conjunctivitis or keratitis recovered during the treatment period (*see Adverse Reactions*). Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

### Parasitic (Helminth) Infections
Patients with known helminth infections were excluded from participation in clinical studies. It is unknown if EBGLYSS will influence the immune response against helminth infections by inhibiting IL-13 signaling. Treat patients with pre-existing helminth infections before initiating treatment with EBGLYSS. If patients become infected while receiving EBGLYSS and do not respond to antihelminth treatment, discontinue treatment with EBGLYSS until the infection resolves.

### Vaccinations
EBGLYSS may alter a patient's immunity and increase the risk of infection following administration of live vaccines. Prior to therapy with EBGLYSS, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines immediately prior to or during treatment with EBGLYSS. No data are available on the response to live vaccines.

## ADVERSE REACTIONS

### Clinical Trials Experience
Because clinical trials are conducted under widely varying and controlled conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Atopic Dermatitis
The safety of EBGLYSS was evaluated across 4 randomized, double-blind, placebo-controlled, multicenter trials in subjects with moderate-to-severe atopic dermatitis including 3 phase 3 trials (ADvocate 1, ADvocate 2, ADhere) and 1 phase 2 dose ranging trial (KGAF). In these 4 trials, mean age was 37 years; 50% of subjects were male; 62% were White, 13% were Black, and 20% were Asian. In terms of co-morbid conditions, in the phase 3 trials, 30% of the subjects had asthma, 50% had allergic rhinitis, 31% had food allergy, and 14% had allergic conjunctivitis at baseline.

A total of 891 subjects were treated with EBGLYSS for at least 1 year in the atopic dermatitis development program.
ADvocate 1, ADvocate 2, and KGAF compared the safety of EBGLYSS monotherapy to placebo. ADhere compared the safety of EBGLYSS + TCS to placebo + TCS through 16 weeks. All subjects from the phase 3 trials were allowed to enroll in the long-term extension study.

*Weeks 0 to 16*
Table 1 summarizes the adverse reactions that occurred at a rate of at least 1% in the EBGLYSS 250 mg every 2 weeks monotherapy group, or in the EBGLYSS 250 mg every 2 weeks + TCS group, all at a higher rate than placebo during the first 16 weeks of treatment.



**Table 1: Adverse Reactions Occurring in ≥1% of the EBGLYSS Monotherapy Group or the EBGLYSS + TCS Group in the Atopic Dermatitis Trials through Week 16**

| Adverse Reactions | EBGLYSS Monotherapy[a] | | EBGLYSS + TCS[b] | |
|---|---|---|---|---|
| | EBGLYSS 250 mg Q2W[c] N=638 n (%) | Placebo N=338 n (%) | EBGLYSS 250 mg Q2W[c] + TCS N=145 n (%) | Placebo + TCS N=66 n (%) |
| Conjunctivitis[d] | 61 (10) | 10 (3) | 7 (5) | 0 |
| Injection Site Reactions[e] | 16 (3) | 4 (1) | 4 (3) | 1 (2) |
| Herpes Zoster | 3 (<1) | 0 | 2 (1) | 0 |

[a]Integrated analysis of ADvocate 1, ADvocate 2, and the phase 2 dose finding trial (KGAF)
[b]Analysis of TCS concomitant therapy trial ADhere
[c]EBGLYSS 500 mg at Week 0 and Week 2, followed by 250 mg every two weeks
[d]Conjunctivitis cluster includes conjunctivitis, conjunctivitis allergic, and conjunctivitis bacterial
[e]Injection Site Reactions cluster includes injection site-related: pain, erythema, reaction, discomfort, dermatitis, pruritis, swelling and rash

In the monotherapy trials (ADvocate 1, ADvocate 2, and KGAF) through Week 16, the proportion of subjects who discontinued treatment due to adverse events was 2.4% in the EBGLYSS 250 mg every 2 weeks group and 1.8% in the placebo group. In the TCS trial (ADhere) through Week 16, the proportion of subjects who discontinued treatment due to adverse events was 2.1% in the EBGLYSS 250 mg every 2 weeks + TCS group and 0% in the placebo + TCS group. The most common adverse reactions leading to discontinuation of EBGLYSS compared to the placebo group were conjunctivitis and keratitis (0.6% vs. 0.3%), and injection site reactions (0.2% vs. 0) in the monotherapy trials; and conjunctivitis (0.7% vs. 0), and injection site reactions (0.7% vs. 0) in the TCS trial.

*Eosinophilia*
Increased post-baseline blood eosinophils were observed at a higher frequency in EBGLYSS-treated subjects compared to placebo. During the first 16 weeks, eosinophilia (>5000 cells/mcL) was observed in 0.4% in the EBGLYSS-treated subjects and 0% in subjects receiving placebo. Blood eosinophil elevations were generally transient and did not result in discontinuation.

*Safety Weeks 16 to 52*
Among those EBGLYSS-treated subjects who responded at Week 16 and who were re-randomized in the maintenance period of the monotherapy trials ADvocate 1 and ADvocate 2, a total of 113 and 118 subjects received EBGLYSS 250 mg every 2 weeks or every 4 weeks, respectively. The safety profile of EBGLYSS 250 mg every 4 weeks was generally consistent with EBGLYSS every 2 weeks during Weeks 16 to 52. The safety profile of EBGLYSS during maintenance treatment was generally consistent with the safety profile observed through Week 16.

Specific Adverse Drug Reactions
*Conjunctivitis and Keratitis*
Conjunctivitis was the most frequently reported eye disorder. Most cases of conjunctivitis and keratitis were mild or moderate in severity and recovered or resolved without treatment interruption or discontinuation.

During the initial 16-week treatment period of the monotherapy trials, conjunctivitis, including allergic conjunctivitis, was reported by 61 subjects (10%) in the EBGLYSS 250 mg every 2 weeks group and 10 subjects (3%) in the placebo group. In the TCS concomitant therapy trial, conjunctivitis was reported by 7 subjects (5%) in the EBGLYSS 250 mg every 2 weeks + TCS group compared to 0% in the placebo + TCS group. During the 16-week placebo-controlled induction period, 68 subjects reported 73 events of conjunctivitis. All events were nonserious and mild or moderate in severity. Conjunctivitis led to treatment discontinuation in 3 subjects. The exposure adjusted incidence rate of conjunctivitis for subjects treated with EBGLYSS 250 mg every 2 weeks was 30.6 events per 100 patient years through Week 16 (KGAF, ADvocate 1, ADvocate 2, ADhere).

During the maintenance treatment period of the monotherapy trials (ADvocate 1 and ADvocate 2) from 16 to 52 weeks, conjunctivitis, including allergic conjunctivitis, was reported by 2 subjects (1.8%) in the EBGLYSS 250 mg every 2 weeks group and 12 subjects (10.1%) in the EBGLYSS 250 mg every 4 weeks group, compared to 5 subjects (8.3%) in the placebo group. During the maintenance treatment period, 14 subjects treated with EBGLYSS reported 18 events of conjunctivitis.

**See Brief Summary of Prescribing Information continued on adjacent page.**

EBGLYSS™ (lebrikizumab-lbkz) 250mg/2mL
injection for subcutaneous use LK HCP BS AD APP

All events were mild or moderate in severity. Conjunctivitis led to treatment discontinuation in 2 subjects in the EBGLYSS 250 mg every 4 weeks group. The exposure adjusted incidence rate of conjunctivitis for subjects treated with EBGLYSS 250 mg every 2 weeks was 16.3 events per 100 patient years and for those treated with EBGLYSS 250 mg every 4 weeks was 20.6 events per 100 patient years through Week 52 (ADvocate 1, ADvocate 2, ADhere + the long-term extension study).

During the initial 16-week treatment period of the monotherapy trials, keratitis, including atopic and vernal keratoconjunctivitis, was reported by 4 subjects (0.6%) in the EBGLYSS 250 mg every 2 weeks group and 1 subject (0.3%) in the placebo group. In the TCS concomitant therapy trial, vernal keratoconjunctivitis was reported by 1 subject (0.7%) in the EBGLYSS 250 mg every 2 weeks + TCS group, compared to 0% in the placebo + TCS group. During the 16-week placebo-controlled induction period, 5 subjects reported 7 events of keratitis. All events were nonserious and mild or moderate in severity. Keratitis led to treatment discontinuation in 2 subjects. The exposure adjusted incidence rate of keratitis for subjects treated with EBGLYSS 250 mg every 2 weeks was 2.2 events per 100 patient years through Week 16 (KGAF, ADvocate 1, ADvocate 2, ADhere).

During the maintenance treatment period of the monotherapy trials (ADvocate 1 and ADvocate 2) from 16 to 52 weeks, atopic keratoconjunctivitis was reported by 1 subject (0.8%) in the EBGLYSS 250 mg every 4 weeks group, and vernal keratoconjunctivitis was reported by 1 subject (0.9%) in the EBGLYSS 250 mg every 2 weeks group, compared to 0% in the placebo group. One (0.9%) event of severe vernal keratoconjunctivitis in an EBGLYSS 250 mg every 2 weeks subject led to treatment discontinuation. The exposure adjusted incidence rate of keratitis for subjects treated with EBGLYSS 250 mg every 2 weeks was 1.0 event per 100 patient years and for those treated with EBGLYSS 250 mg every 4 weeks was 0.7 events per 100 patient years through Week 52 (ADvocate 1, ADvocate 2, ADhere + the long-term extension study).

*Injection Site Reactions*
Injection site reactions were reported by 3% of the EBGLYSS group and 1% of the placebo group in the first 16 weeks of the monotherapy trials. Incidence of injection site reactions declined with continued treatment. Most events were mild or moderate and recovered without treatment discontinuation.

**DRUG INTERACTION STUDIES**
The effect of lebrikizumab-lbkz on the pharmacokinetics (PK) of co-administered medications has not been studied.

**USE IN SPECIFIC POPULATIONS**
**Pregnancy**
Risk Summary
Available data on lebrikizumab-lbkz use in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Transport of human IgG antibody across the placenta increases as pregnancy progresses and peaks during the third trimester; therefore, lebrikizumab-lbkz may be transmitted from the mother to the developing fetus. In animal reproduction studies, no effects on embryo-fetal development were observed after subcutaneous administration of lebrikizumab-lbkz to cynomolgus monkeys during organogenesis at doses up to 18 times the human exposure at the maximum recommended human dose (MRHD) *(see Data)*. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively. Report pregnancies to Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979).

Data
Animal Data
In an embryofetal development study, no malformations or embryofetal toxicity were observed in fetuses from pregnant cynomolgus monkeys administered lebrikizumab-lbkz during organogenesis at doses up to 150 mg/kg initial dose followed by 50 mg/kg per week by subcutaneous injection, which was associated with plasma exposure ($C_{trough}$) approximately 18 times the human exposure at the MRHD. Lebrikizumab-lbkz crossed the placenta in monkeys.
In a prenatal and postnatal development study, pregnant cynomolgus monkeys were administered lebrikizumab-lbkz during organogenesis to parturition at doses up to 150 mg/kg initial dose followed by 50 mg/kg per week by subcutaneous injection, which was associated with plasma exposure ($C_{trough}$) approximately 18 times the human exposure at the MRHD.
No embryofetal toxicity or malformations, or effects on morphological, functional, or immunological development were observed in the infants from birth through 6 months of age.



**Lactation**
Risk Summary
There are no data on the presence of lebrikizumab-lbkz in human milk, the effects on the breastfed infant, or the effects on milk production. Endogenous IgG and monoclonal antibodies are transferred in human milk. The effects of local gastrointestinal exposure and limited systemic exposure in the breastfed infant to lebrikizumab-lbkz are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EBGLYSS and any potential adverse effects on the breastfed infant from EBGLYSS or from the underlying maternal condition.

**Pediatric Use**
The safety and effectiveness of EBGLYSS have been established in pediatric patients 12 years of age and older who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. A total of 372 pediatric subjects were exposed to EBGLYSS with 270 subjects exposed to EBGLYSS for at least one year. The safety and effectiveness were generally consistent between pediatric and adult subjects *(see Adverse Reactions)*. The safety and effectiveness of EBGLYSS have not been established in pediatric patients younger than 12 years of age and pediatric patients 12 years and older who weigh less than 40 kg.

**Geriatric Use**
Of the 1348 adult subjects with moderate-to-severe atopic dermatitis exposed to EBGLYSS, a total of 123 were 65 years or older, and 29 subjects were 75 years or older. Clinical studies of EBGLYSS did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger adult subjects.

**DOSING**
**Recommended Dosage**
The recommended dosage of EBGLYSS is an initial dose of 500 mg (two 250 mg injections) at Week 0 and Week 2, followed by 250 mg every two weeks until Week 16 or later, when adequate clinical response is achieved. The maintenance dosage is 250 mg every four weeks.

**OVERDOSAGE**
In the event of overdosage, contact Poison Control (1-800-222-1222) for the latest recommendations and monitor the patient for any signs or symptoms of adverse reactions and institute appropriate symptomatic treatment immediately.

**PATIENT COUNSELING INFORMATION**
Advise the patient and/or caregiver to read the FDA-approved patient labeling (Patient Information and Instructions for Use).
Administration Instructions: Provide guidance to patients and caregivers on proper subcutaneous injection technique, including aseptic technique, and how to use the prefilled pen and prefilled syringe correctly. Advise patients to follow sharps disposal recommendations *(see Instructions for Use)*.
Hypersensitivity: Advise patients to discontinue EBGLYSS and to seek immediate medical attention if they experience any symptoms of systemic hypersensitivity reactions *(see Warnings and Precautions)*.
Conjunctivitis and Keratitis: Advise patients to consult their healthcare provider if new onset or worsening eye symptoms develop *(see Warnings and Precautions)*.
Parasitic (Helminth) Infections: Advise patients to notify their healthcare provider if they present with clinical features consistent with helminthic infection (see *Warnings and Precautions)*.
Vaccinations: Advise patients that EBGLYSS may increase the risk of infection following administration of live vaccines and that vaccination with live vaccines is not recommended during EBGLYSS treatment. Instruct patients to inform the healthcare provider that they are taking EBGLYSS prior to a potential vaccination (see *Warnings and Precautions*).
Pregnancy: Inform patients to report their pregnancy to Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979) (see *Use in Specific Populations*).

Additional information can be found at www.ebglyss.lilly.com or by calling 1-800-LillyRx (1-800-545-5979).

**See Instructions for Use accompanying the product device.**

LK HCP BS AD APP

PP-LK-US-0272

EBGLYSS™ (lebrikizumab-lbkz) 250mg/2mL
injection for subcutaneous use LK HCP BS AD APP

TIME HEALTH PRO

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CONTENTS

# Your Patient's Health

FEW PATIENTS OR DOCTORS TALK about eczema's "invisible itch." You can't see it—as its name implies. You can't scratch it. And in many cases you just can't abide it.

The invisible itch is the emotional toll of having eczema. It's the fatigue, distraction, and irritability that results when itching symptoms are so severe they disrupt sleep. It's the mental toll of avoiding dark clothes lest skin flakes appear during a flare. It's the pained self-consciousness of wondering whether other people notice the rash, the raw skin the condition causes, especially when it appears on the face. All of this is part of having eczema—and much of it never gets addressed in hurried appointments with a busy dermatologist who focuses largely on the skin and little or not at all on the mind.

Recognizing the emotional strain often comes indirectly. Says Dr. Jason Miller, a dermatologist in New Jersey: "People don't come in and say, 'I'm anxious' or 'I'm depressed.' They'll say they're not sleeping. Or they'll show you photos from a bad flare and say they're afraid it's coming back."

In this issue of TIME Health Pro we explore the unaddressed emotional load of eczema and explore ways to relieve it. For starters, doctors should be doing more thorough workups, talking with patients about how stress, sleep, and daily habits can show up on the skin. Doctors should also not settle for patients being a little itchy, as long as they're less so than they were on their last visit. "We should be trying to get them to not itching," says Dr. Long Ly, a dermatologist with MetroDerm, a large skin care practice in Atlanta." One New York City-based doctor even offers patients transcranial magnetic stimulation (TMS), a noninvasive way to treat depression and anxiety.

In this issue we also explore the school lunch dilemma—the increasing need to serve kids better, healthier, less-processed food, and the prohibitive cost that puts that goal out of reach for most school districts.

As in every issue of TIME Health Pro, we also survey breakthroughs and developments across the fast-changing field of medicine. New research shows that repeat COVID infections can increase a patient's risk of developing Long COVID. And gene therapy might be effective in slowing Huntington's disease.

**What you learn in these pages can help you stay ahead of developments in your fast-evolving field**

**TIME HEALTH PRO** is created specifically with you, the health care professional, in mind. Keeping up to date with the many changes in your fast-evolving industry can help you stay ahead and better serve patients.

The stories you find in TIME Health Pro are just a sampling of the health reporting you'll find in TIME magazine and on TIME.com. Our journalists have been covering science and medicine for 100 years. Good health is one of the most important aspects to living a full life, and we greatly appreciate your time and trust in allowing us to help you help others reach that goal.

**JEFFREY KLUGER**
*Editor-in-Chief*

# Trendlines

*'THERE MIGHT BE A CUMULATIVE HARMFUL EFFECT OF REPEAT COVID-19 INFECTIONS ON THE BODY.'* —PAGE 12

PRENATAL HEALTH

## Why Syphilis Cases in Newborns Are Rising Even as STIs Decline

BY CHANTELLE LEE

THE NUMBER OF BABIES BEING born with syphilis in the U.S. kept increasing last year, even as the number of cases of sexually transmitted infections (STIs) in the country dropped, according to new government data.

The overall number of reported STI cases fell 9% in 2024 from 2023, the third year in a row that case numbers have declined, provisional data released by the U.S. Centers for Disease Control and Prevention (CDC) this week shows. But cases of congenital syphilis increased for the twelfth straight year. Nearly 4,000 cases were reported in 2024—up almost 700% since 2015, when just under 500 were reported.

The rise in congenital syphilis cases wasn't as steep in 2024 as it has been in previous years—just under 2% from 2023. Dr. Bradley Stoner, the director of the CDC's Division of STD Prevention, says that it's promising that the rate of increase is slowing, but that the rising case numbers are still concerning.

Only a couple decades ago, cases of congenital syphilis were nearly eliminated from the U.S. Congenital syphilis is preventable; syphilis can be cured with treatment, and if it's treated during pregnancy, that can protect the fetus from becoming infected.

But if left untreated, syphilis can be passed on to a fetus during pregnancy or delivery. Syphilis can damage organs such as the heart and brain, and can lead to blindness, deafness, and even death. Congenital syphilis can also lead to miscarriage and stillbirth.

Stoner says that reductions in STI services at the state and local levels, as well as social and economic conditions such as poverty and lack of health insurance, have likely contributed to rising rates of syphilis, which in turn led to increasing rates of congenital syphilis.

Federal funding for STI prevention has seen drastic cuts since the early 2000s. The number of people living in poverty skyrocketed during that period, though it has since declined. And while the percentage of people who are uninsured has fallen since the Affordable Care Act was signed into law in 2010, millions still have no health insurance or are underinsured. Other complications in accessing quality care could impact people with insurance as well.

Elizabeth Finley, interim executive director of the National Coalition of STD Directors, says part of the problem is that pregnant people's access to health care or preventive syphilis care may vary. For instance, some people may not be able to access prenatal care consistently or at all. And some health care providers may be seeing syphilis cases for the first time in their careers.

"You get this perfect storm of people who aren't getting enough prenatal care to begin with for many, many reasons, and then you see providers who haven't had to identify or test for syphilis in the past," Finley says.

There have also been intermittent drug shortages that have affected doctors' ability to quickly treat pregnant people with syphilis, Finley says.

She points out that the overall STI rates have gone up over the past decade or so as well.

"Overall over the past 10 years, we've seen more cases," Finley says. "Any time there are more STI cases in a community or more cases of any infection—and in this case, syphilis—in a community, you have an increased likelihood that pregnant women will be exposed to it and then that their infants or their fetuses will be exposed to it."

The overall prevalence of STIs in the U.S. is still high, with more than 2.2 million reported cases in 2024—up 13% since 2015, according to the CDC. Finley says that part of the reason for that is that the U.S. has "really divested significantly from prevention efforts."

The CDC noted a few areas of progress in addressing the problem: cases of the two most infectious stages of syphilis, known as primary and secondary syphilis, declined nearly 22% for the second year in a row. Stoner says he is hopeful that congenital syphilis will follow. And cases of gonorrhea and chlamydia continued to fall, too. The agency attributed those declines to the impact of public health initiatives, such as increased awareness about STIs and the use of prevention tools. Those tools include self-tests and the antibiotic doxycycline, which can be taken within 72 hours after sex to help reduce the risk of acquiring syphilis, chlamydia, and gonorrhea.

"The data do suggest that we may be turning the corner on STIs," Stoner says. "But the fact that congenital syphilis is still a major problem tells us that we have to accelerate progress to stop the STI epidemic and its most tragic consequences. These are preventable infections, and greater awareness and greater early intervention, I think, will help us get these infections under better control."

**'These are preventable infections, and greater awareness and greater early intervention, I think, will help us get these infections under better control.'**

**— DR. BRADLEY STONER, DIRECTOR OF THE CDC DIVISION OF STD PREVENTION**

The CDC recommends that women get tested for syphilis three times over the course of a pregnancy. Stoner also encourages people of reproductive age to get tested for syphilis, and to have conversations with their partners about STIs.

Finley says that, while it's been encouraging to see public health initiatives try to address this issue, there needs to be a "much more coordinated and intentional effort" to bring various government agencies together to tackle congenital syphilis. She adds that funding for STI prevention efforts has dropped significantly in recent years.

"These syphilis cases in pregnant patients don't happen in a bubble; they happen in a broader context, and right now that broader context is that our overall STI rates are too high," Finley says. "This really does need to be a part of a broader effort to reduce STIs in the U.S."

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RESEARCH

# A Huntington's Disease Treatment Is Closer than Ever

BY ALICE PARK

GENE THERAPY IS BECOMING A POWERFUL WAY TO TREAT challenging diseases that don't respond to traditional treatments, and researchers now report the first success in modifying genes to slow Huntington's disease.

In a study reported by Uniqure, which developed the experimental gene therapy, scientists found that it slowed progression of Huntington's disease by 75% over three years. The study has not yet been published in a scientific journal.

"I went into the trial cautiously optimistic but very anxious, as one does when starting a gene-therapy trial," says Dr. Sarah Tabrizi, director of the University College London Huntington's Disease Center and a lead investigator on the study. "I was blown away when I saw all of the data and it was very, very clear that the gene therapy worked."

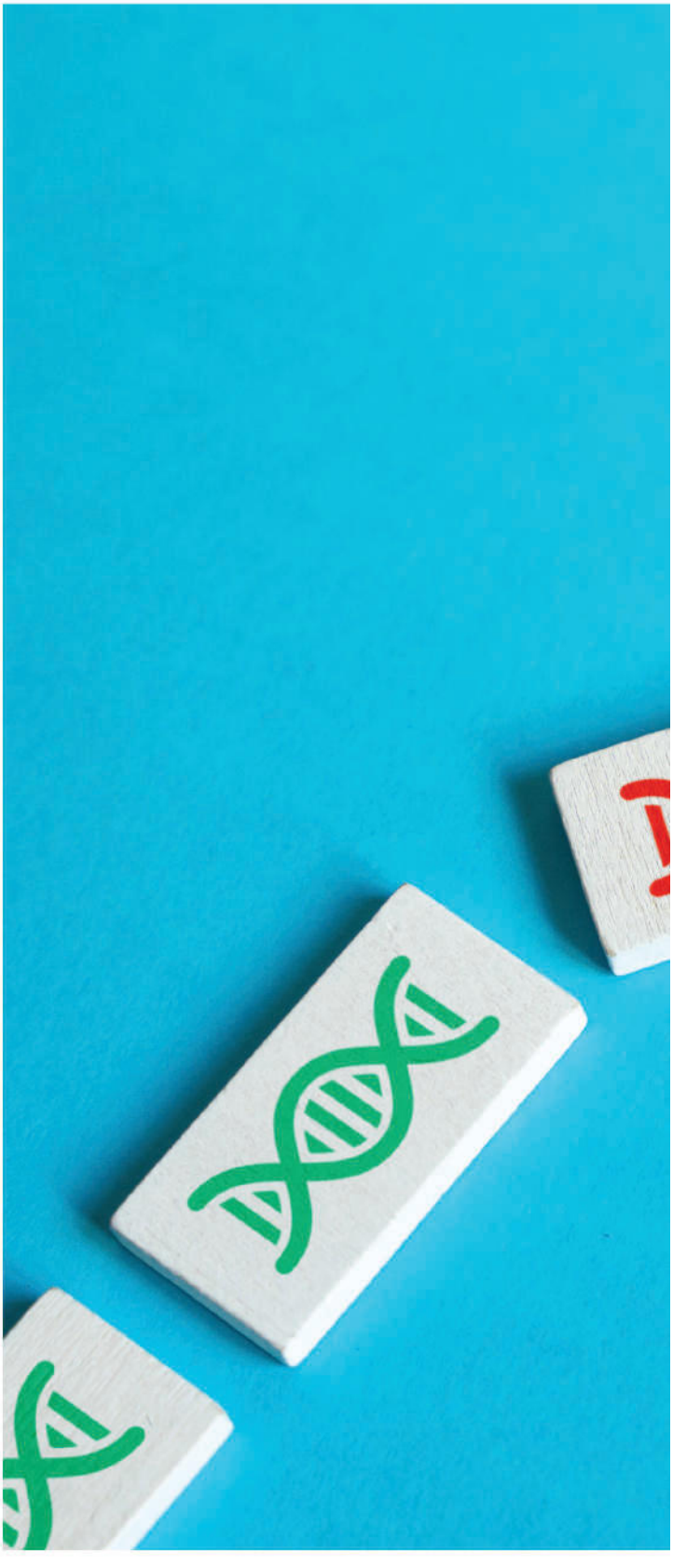
The study involved 29 patients with Huntington's disease who were given one of two doses of gene therapy that targeted the Huntington gene, which is mutated in the disease. The aberrant gene makes a form of the huntingtin protein that clumps into toxic aggregates, which prevent nerves from functioning normally. Eventually, nerve cells—particularly those in the part of the brain that regulates movement and cognitive skills like motivation, habit formation, and decision-making—degrade, leading to physical and cognitive symptoms.

Everyone in the trial was monitored for a number of biological and behavioral measures, including markers for degraded nerve proteins in spinal fluid and their ability to perform normal daily activities, manage their finances, and keep working. The gene therapy involved a 12- to 15-hour brain operation in which surgeons drill through the skull to access a deep part of the brain called the striatum, where nerve cells are most affected by the damaged huntingtin protein. The surgeons injected the gene therapy, which included DNA delivered by an inactivated virus vector, coding for instructions to turn off production of the huntingtin protein.

The 17 people who received the high dose showed a 75% slowing in the progression of their symptoms overall. The 12 people who got the lower dose—which was 10 times less concentrated—showed similar progression as placebo, although some of their symptoms improved.

Because the brain surgery was invasive and risky, the researchers had to find a reliable way to evaluate what effect the gene therapy was having without subjecting some patients to a sham surgery, says Dr. Walid Abi-Saab, Uniqure's chief medical officer. The participants who received the gene therapy were monitored for several years and compared to a group of about 2,000 untreated Huntington's patients—because there are currently no treatments for the disease—who were matched to the study patients getting the gene therapy by factors like age and stage of disease.

The 75% slowing in the progression of the disease among those receiving the gene therapy is "huge," says Tabrizi, who has been studying potential therapies for Huntington's



*Researchers think gene therapy may someday prevent Huntington's disease from developing*

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**'I personally want to start thinking about how we can get this therapy to people at Stage 0 or I to prevent this disease.'**

**—DR. SARAH TABRIZI, DIRECTOR OF THE UNIVERSITY COLLEGE LONDON HUNTINGTON'S DISEASE CENTER**

for two decades. "I have never seen anything that shows that [benefit]," she says. In Huntington's patients, levels of neurofilament, which is produced by damaged nerve cells, in the spinal fluid increase by 30% to 45% in the early years of the disease, Tabrizi says. People receiving the gene therapy in the study actually showed drops in their levels—below their baseline levels, in some cases. "That tells you that neurons are being saved," she says.

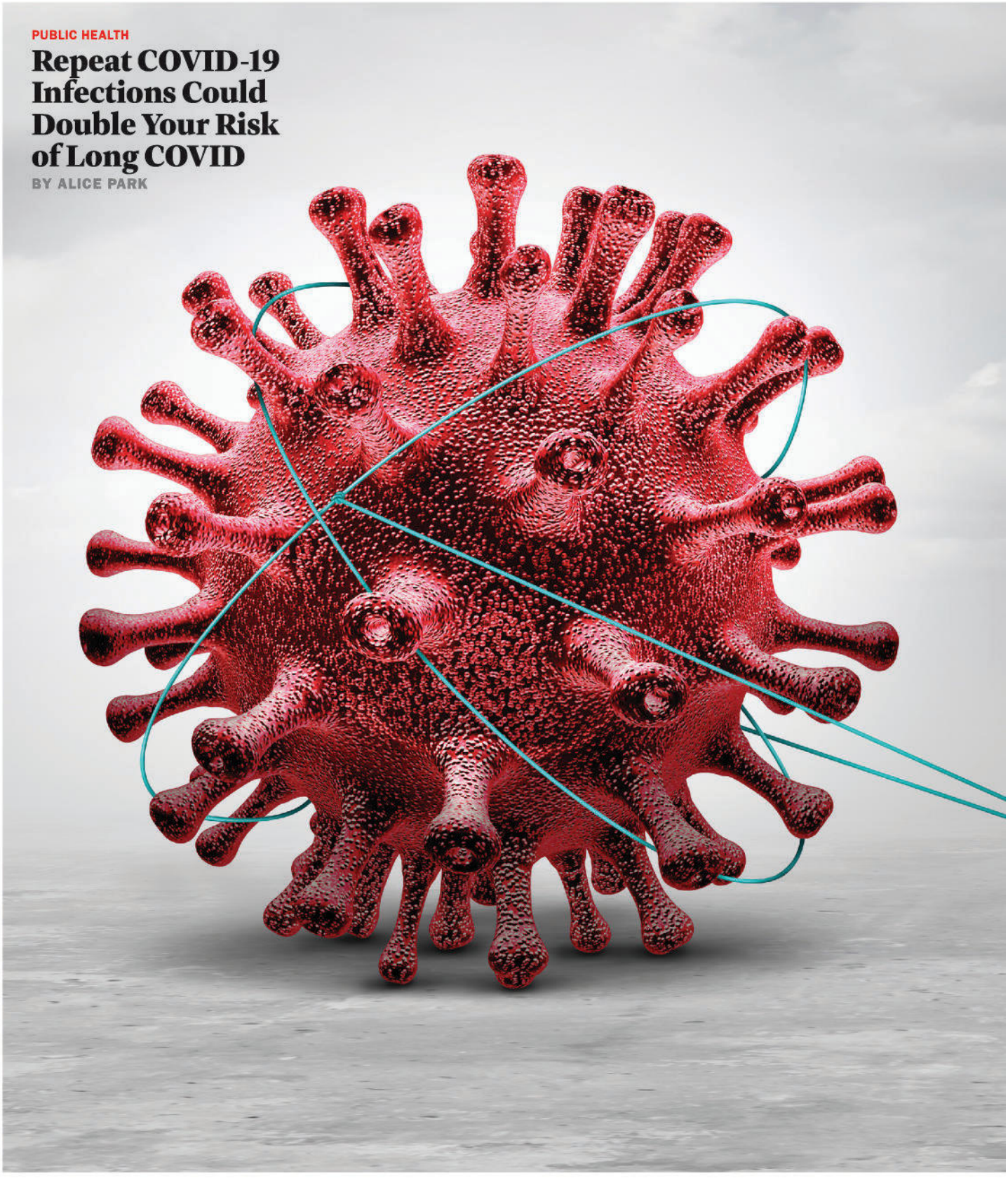
Tabrizi adds that the encouraging results are inspiring her to think about extending the benefits to people even earlier in their disease, with the hope that they might be able to prevent many of the disease's worst symptoms from ever appearing. The patients in the trial were at Stage II or III, but, "when people who carry the Huntington's gene are completely well, we might be able to prevent the disease from ever occurring and prevent the symptoms from ever occurring," she says. "I personally want to start thinking about how we can get this therapy to people at Stage 0 or I to prevent this disease."

Matt Kapusta, CEO of Uniqure, says the therapy is "transformational" and that giving patients more time with loved ones, with milder or fewer symptoms, is "priceless." Uniqure plans to submit a request for the U.S. Food and Drug Administration to grant accelerated approval of the gene therapy to treat Huntington's in the first part of 2026, and, if approved, is prepared to provide it to patients later in the year.

PUBLIC HEALTH

# Repeat COVID-19 Infections Could Double Your Risk of Long COVID

BY ALICE PARK



MOST OF US NOW VIEW COVID-19 AS more of a nuisance than a danger, thanks to vaccines and past exposure to the virus—all of which have built up our immunity.

But research suggests that multiple COVID-19 infections pose a risk for developing Long COVID. In the largest Long COVID study of young people to date, scientists led by a team at the University of Pennsylvania report that young people who got infected twice with COVID-19 were twice as likely as those who got COVID-19 once to develop Long COVID symptoms that affect major organs like the heart, kidney, and lungs, as well as taste and smell.

The ongoing research project, called RECOVER, is funded by the National Institutes of Health and explores the impact of COVID-19 infections on long-term health. Yong Chen, professor of biostatistics and director of the Center for Health AI and Synthesis of Evidence (CHASE) at the University of Pennsylvania, and his colleagues focused on people 21 and younger to better understand how COVID-19 reinfection affects health. "People think that reinfections don't matter as much and don't take them seriously," Chen says. "Our primary message is that reinfections still matter, and you should do what you can to avoid reinfection by taking a vaccine or wearing a mask."

The study involved data collected from more than 460,000 children, adolescents, and young adults from 40 pediatric hospitals who were diagnosed with a first COVID-19 infection around January 2022; some went on to develop a second infection after that. At the end of 2023, the researchers compared the group with only one infection to the group with a second infection, focusing on Long COVID-like symptoms such as abdominal pain, respiratory distress, changes in taste and smell, fatigue, chest pain, myocarditis, or irregular heartbeat.

Those who developed a second infection were more than twice as likely as the group with only one infection to get a diagnosis of Long COVID, and the reinfected people were nearly three times as likely to report changes in taste and smell as those who only had one COVID-19 infection. This risk remained regardless of whether people were vaccinated or not, or regardless of how severe their infections were.

However, "vaccination status" referred to whether people had been vaccinated before the study period—not how recently they had received the shot. (The study was also initiated before the first updated vaccines targeting Omicron were available.) The authors emphasize that the results do not suggest that vaccines do not help to reduce the risk of Long COVID. Rather, the data show that kids who were vaccinated were much less likely to get COVID-19 in the first place and were also less likely to get reinfected compared to unvaccinated children.

Getting vaccinated, Chen says, is an important first step in protecting against possible Long COVID.

However, the study shows that even if you're vaccinated, reinfection poses a significant enough risk to double your chances of developing Long COVID compared to just getting it once.

"The message is about how seriously you should treat your potential risk of getting a second COVID-19 infection," says Chen. These results, along with other research, suggest that there might be a cumulative harmful effect of repeat COVID-19 infections on the body, and scientists are trying to better understand those potential long-term effects. Chen is also continuing the work to study what effect getting vaccinated following a first infection might have on not just the risk of additional infections, but on the development of Long COVID as well.

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**'Our primary message is that reinfections still matter, and you should do what you can to avoid reinfection by taking a vaccine or wearing a mask.'**

**—YONG CHEN, PROFESSOR OF BIOSTATISTICS AND DIRECTOR OF THE CENTER FOR HEALTH AI AND SYNTHESIS OF EVIDENCE (CHASE) AT THE UNIVERSITY OF PENNSYLVANIA**

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# HOW HAVING ECZEMA AFFECTS MENTAL HEALTH

## The emotional toll should be addressed alongside the itch

**BY TANYA BRICKING LEACH**

KRISTIN BELLESON LEARNED EARLY THAT HER ECZEMA HAD AN impact on a lot more than just her skin. It showed up at night, when the itching would not stop and sleep slipped away. It carried into the next day as fatigue, distraction, and irritability. Gradually, it shaped dozens of small decisions that rarely registered as medical at all, including what to wear and whether anyone else noticed.

Belleson's experience is not unique. Adults with eczema report higher rates of sleep disruption, anxiety, and depression than the general population, according to surveys conducted by the National Eczema Association (NEA). Many say those effects shape daily life more than the rash itself. "Eczema is not just about skin," Belleson says. "It affects sleep. It affects mood. It affects how you show up at work, in relationships, and in public."

Belleson, of Carmel, Indiana, has lived with eczema for nearly 25 years. She's now president and CEO of the NEA, which describes itself as the voice and resource hub for more than 31 million Americans who are living with some form of eczema. In her role, she hears from adults whose symptoms may look controlled on the surface but still dominate their daily lives, often in ways clinicians never see. "What people experience emotionally is very real," she says. "But it doesn't always make it into the exam room."

## When care focuses on the skin only

Eczema care has long centered on what clinicians can see. Treatment has focused on reducing inflammation, controlling flares, and calming irritation. What often goes unaddressed is how much of the condition plays out beyond the exam room.

Myles Marquez, now 24, has had eczema since he was a baby. It most often appears on his face, especially his forehead and around his mouth. The condition followed him into adulthood, shaping how he moves through daily life. "I think about it almost all the time," says Marquez, a social media manager in the San Francisco Bay area. "I'd say that I am thinking about my eczema or my itch or my redness 80% of the time throughout my day."

He watches the weather. He thinks about what he wears. He checks dark clothing for flakes. He braces for redness that can flare without warning. "If I'm meeting new people, am I red on the face?" he says. "If I'm wearing dark clothing, am I going to have skin flakes on me right now?"

> 'I THINK ABOUT IT ALMOST ALL THE TIME. I'D SAY THAT I AM THINKING ABOUT MY ECZEMA OR MY ITCH OR MY REDNESS 80% OF THE TIME THROUGHOUT MY DAY.'
>
> —MYLES MARQUEZ, ECZEMA PATIENT

For years, Marquez avoided regular dermatology visits. When he did go, he says the focus felt limited and procedural. "They would ask how long I've had it," he says. "'Does it hurt?' 'Is it bleeding?' Those were always the questions." But the mental load was rarely discussed even though eczema constantly occupied his mind. It shaped his social interactions and daily routines, especially in public and at work, long after his appointments ended.

That omission is not unusual, clinicians say. Appointments move quickly. Patients learn which details seem relevant and which ones do not. They stop offering information that doesn't seem to change the plan. For Marquez, that meant carrying the mental load of the condition on his own. He adjusted his routines. He tracked triggers. He stayed alert. But none of that was discussed at his typical office visits.

Dr. Jason Miller, a board-certified dermatologist and regional medical director for New Jersey and Long Island at Schweiger Dermatology Group, says recognizing the emotional strain often arrives indirectly. "People don't come in and say, 'I'm anxious' or 'I'm depressed,'" he says. "They'll say they're not sleeping. Or they'll show you photos from a bad flare and say they're afraid it's coming back." Sleep, he says, often opens the door to everything else. "If someone is waking up multiple times a night because they're itchy, that's going to affect everything else," he says.

Dr. Long Ly, a board-certified dermatologist with MetroDerm, a large skin care practice in Atlanta, sees patient expectations shift over time. After they see some relief of more severe eczema symptoms, people will say they're OK being a little itchy, he says. "They're just happy not to be as bad as before. But we should be trying to get them not itching." The gap between a patient being satisfied with some relief instead of full relief matters because persistent itch, even if it is minor, still carries a mental burden.

## The cost of never turning it off

Dr. Barbara Sparacino, a Miami, Florida-based psychiatrist who treats people with chronic medical conditions, says the emotional effects often surface after years of managing physical symptoms. People arrive worn down. They feel irritable at work. Sleep breaks into fragments. Stress spills into daily life. "The most important thing is to validate that chronic eczema is very exhausting," she says. "It takes an emotional toll, and it's not just a cosmetic issue." That kind of exhaustion is not always recognized as trauma. The exhaustion does not always follow a single event, she says. It can build up over time.

Dr. Jim Jackson studies what happens when that kind of strain accumulates. Jackson is the author of *Reclaiming Your Life from Medical Trauma* (due out in April 2026 from Little, Brown Spark), and a clinical psychologist and a research professor of medicine and psychiatry at Vanderbilt University Medical Center in Nashville. "You've got something that you wish you didn't have," Jackson says. "And, with support, you can find a way to live with it." In his work, Jackson sees this pattern across many chronic conditions that may not be labeled as traumatic. People adapt. They adjust expectations. They stop naming the effort it takes to get through the day. What looks like coping from the outside can mask ongoing strain.

But when patients feel that their trauma is validated, it can make all the difference. After years of managing eczema on his own, Marquez began to see a new dermatologist. This time, things felt different, he says, because the new doctor asked him about what was going on in the rest of his life. "Leading with empathy first makes people want to come back," he says. "It makes them want to continue care." The visit did not change that fact that Marquez had eczema. But it changed how he dealt with it emotionally.

## The mind-body connection

Marquez's experience does not surprise clinicians who see how easily eczema gets minimized. Dr. Dina Strachan, a board-certified dermatologist in New York City and an assistant clinical professor at New York University, says people often adapt to living with eczema. "I find that some people play it down," she says. But when patients do play it down, it can limit what gets addressed in an office visit. When symptoms

*Clinicians should consider how stress, sleep, and daily habits affect a patient's skin*

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get framed as manageable or expected, clinicians may never hear how much the condition is affecting a patient's daily life.

Dermatologists are trained to treat skin disease. They are not mental health providers. Still, Strachan says eczema deserves to be taken seriously, even when symptoms seem mild. Being "a little better," she notes, is not the same as being well.

Some clinicians try to close that gap by considering what drives flares in the first place. Dr. Paul Jarrod Frank, chief medical officer of PFRANKMD, a New York City dermatology practice, and a clinical associate professor of dermatology at the Icahn School of Medicine at Mount Sinai, pays close attention to how stress, sleep, and daily habits show up on the skin. Before training in dermatology, he set out to become a psychiatrist. He says that background still shapes how he thinks about skin disease. "For a lot of dermatologic conditions, but especially eczema, there's a lot more than just genetics or outside causes," Frank says. "How we live our lives is going to affect chronic disease."

That perspective also shapes the tools Frank uses. He offers ExoMind, his practice's name for transcranial magnetic stimulation, or TMS. The noninvasive treatment, approved for major depression, uses magnetic pulses to stimulate areas of the brain that regulate mood. He uses it to address stress and low mood, which he says can intensify eczema flares. He is careful to say it does not treat the skin itself, but the emotional strain that can make symptoms harder to control. "I don't believe stress is the cause," he says. "But I believe stress and lifestyle have a dramatic impact on any disease on our body."

## Ask the right questions

Successfully treating both the mental and physical load of eczema can depend on how much time a clinician has to spend with the patient. Dr. Faranak Kamangar, a board-certified dermatologist in Silicon Valley and president of the San Francisco Dermatological Society, sees how easily key details can slip past when office visits move too quickly. "A lot of time, it's missed," Kamangar says of the emotional burden that often comes along with chronic eczema. "Sometimes with eczema, we kind of call [the emotional burden] 'the invisible itch.'"

When clinicians ask open-ended questions, patients are more likely to mention their quality of sleep, concentration, and daily functioning, she says. Those details often indicate whether a treatment is truly working or simply keeping symptoms tolerable. "If you don't ask about what their day is like, or whether they're able to focus, or whether they're itchy all the time, sometimes it's not that apparent," she says.

Kamangar is the founder of DermGPT, an artificial intelligence platform designed to help support dermatologists, and host of *The Future of Dermatology* podcast. Her interest, she says, is not in adding more to already packed visits. It is in making sure important information does not get lost. For patients like Marquez, that difference is tangible. When visits allow space for those conversations, the care feels more complete. When they do not, the mental effects of eczema stay invisible. Marquez has even discussed the importance of empathy in eczema treatment on Kamangar's podcast.

For Belleson and other eczema patients, feeling heard is part of the healing process. "What people are asking for isn't therapy in the dermatology office," she says. "They want to be seen. They want to be taken seriously. They want a plan." The plan does not have to be complicated. It may start with a question about sleep. It may involve acknowledging the emotional weight of chronic itch. Often, it begins by naming what has gone unspoken for years, she says.

In her role at the NEA, Belleson has heard this story play out across countless conversations. People disengage when they feel dismissed. They return when they feel heard. "When people feel seen," she says, "they stay engaged in care." That, she says, is where better support begins.

# Why It's So Hard to Make School Lunches Healthier

The costs and effort required to upgrade are prohibitive for most school districts

**BY ALANA SEMUELS**

STUDENTS AT THE TAHOE Truckee Unified School District in California dine on locally sourced fruits and vegetables, homemade pozole (a Mexican stew), and fresh tuna poke bowls. Food in the school district is free of high fructose corn syrup, artificial dyes, and additives. Most of it is cooked from scratch by a full-time kitchen staff, and, like about 29% of other districts in the country, everyone eats for free.

The district's meals, in other words, are about as good as it gets in the U.S.—and a prime example of how to improve public-school lunch programs. They're also exactly the type of healthy, nourishing food that U.S. Health and Human Services Secretary Robert F. Kennedy Jr. and his Make America Healthy Again movement say they want to be served across the country. In May 2025, Kennedy promised "dramatic" changes to school lunch programs, which he called "poison" because he said they contained high levels of ultra-processed foods.

But this success won't be easy to replicate. Tahoe Truckee has spent hundreds of thousands of dollars annually since switching to so-called "scratch cooking" more than a decade ago—making food in district kitchens rather than just buying premade food and heating it up. Last year it spent about $400,000 on its school meals program with help from the district's general fund, an unrealistic amount for most other districts.

"Our food service program is generally not in the black," says Todd Rivera, the district's assistant superintendent and chief business officer. "Before scratch cooking, the cost was pretty nominal, but as we added up staff and built up the program, we started to see the cost increase."

**The transition to scratch cooking is difficult, expensive, and likely impossible for some districts without making radical changes.**

School meals have been changing since at least 2010—mostly for the better—when the Healthy, Hunger-Free Kids Act passed in the Obama Administration aiming to improve the nutritional quality of school meals and increase access to healthy food for kids. When the nutrition standards from the law went into effect in 2012, they limited calories, reduced sodium and saturated fats, and increased the amount of fruits, vegetables, and whole grains required in school meals.

Many of those standards were weakened during the first Trump Administration—even as Agriculture Secretary Sonny Purdue vowed to "make school lunches great again." While many schools have added more vegetables and whole grains since 2012, nutritionists and advocates have their sights set on a much higher bar. They want more districts to transition to scratch cooking, as the Tahoe Truckee district did, and make school breakfasts and lunches in their own kitchens with their own staff.

## THE CHALLENGES OF MAKING FOOD FROM SCRATCH

The transition to scratch cooking is difficult, expensive, and likely impossible for some districts without making radical changes. Some schools, especially those with older buildings, don't even have kitchens, so cooking meals from scratch is not doable. Cooking from scratch also requires trained staff who know how to work in a large-scale kitchen.

Making the upgrades to build a suitable kitchen—or even having enough electricity or power to add appliances—is an extremely costly proposition.

"I've been to districts where I've asked, 'Why don't you get a walk-in freezer?' and they say, 'I don't even have the electrical infrastructure to support a walk-in freezer,'" says Donna Martin, a registered dietitian nutritionist who has worked in school nutrition for over 30 years, most recently at Burke County Public Schools in rural Georgia.

Tahoe Truckee started improving its lunch program in 2006, when the U.S. Department of Agriculture (USDA) required districts that participated in the National School Lunch Program to create a wellness policy that included incorporating community input. At the time, heat-and-serve was the industry standard, says Kat Soltanmorad, the district's current director of food and nutrition services.

A group of concerned parents started pushing the district to serve fewer processed foods, and by the time Soltanmorad joined in 2012, she had a mandate to try to transition to scratch cooking. She started scratch cooking test recipes three days a week with input from parents. One parent, for instance, suggested a recipe for a chocolate beet muffin that the school still serves today.

One of the most difficult steps, Soltanmorad says, was to build up staff and find people with culinary experience. Because the school district wasn't hiring full-time workers at the time, it had a hard time competing with restaurants, which typically offer higher pay. "We're competing with all the other jobs that aren't three hours a day," she says. The district slowly transitioned to full-time jobs that come with benefits and wages that are competitive with the private sector.

More schools are transitioning to scratch cooking now, but the staffing costs and facility requirements are difficult for some to overcome. Costs of equipment like food warmers and refrigerators have gone up dramatically since the pandemic; Soltanmorad says she was recently quoted $11,000 for a piece of equipment that cost just $2,500 in 2019.

Rather than deal with all these hassles, it's much easier for schools to just get pre-made food like chicken nuggets and warm them up. "Making that change to scratch cooking is extremely challenging for districts, because you're going up against an industry that's not set up for that," Soltanmorad says.

## HOW SCHOOLS GET THE FOOD THEY COOK

Another reason schools struggle to make healthy lunches is how they acquire some of the food they cook. Districts get a certain amount of money allocated to them from the Department of Agriculture. They then can buy either whole foods like ground beef and canned vegetables from the USDA with those dollars and cook those in their kitchens, or divert those whole foods from the USDA to industry, which processes them into meals. Even Tahoe Truckee still diverts some of its chicken to a processor to make mandarin orange chicken.

The USDA procurement rules sometimes make it difficult for schools to access fresh, locally sourced foods, says Katie Wilson, executive director of the Urban School Food Alliance, which represents 19 of the largest school districts in the country. "It's the procurement rules that are constraining us," she says.

Her organization is working to change the procurement process so schools can get access to more local food. It recently ran a pilot program that pressured providers to offer antibiotic-free chicken on the USDA procurement list.

Processors must meet the requirements from the Healthy, Hunger-Free Kids Act to qualify to serve food, she says, but that doesn't mean the food is necessarily healthy. "We're more concentrated on meeting the requirements than we are on the quality of food, and that's where things have to change," says Wilson. For example, every child has to take a fruit or a vegetable with a meal, which creates waste.

Cleaning up the foods that come from USDA allocation is one way to help districts that can't afford to do scratch cooking, Wilson says. Some districts are moving instead to "speed scratch," which means they're cooking some things in the district and combining it with healthier USDA


*The industry is not set up to make the transition to scratch cooking viable*

processed food. Many find it much easier to use the procurement process because the specific nutritional value of the foods from industry is calculated in advance to meet USDA requirements. Otherwise, there's a lot of labor required to make sure that meals are meeting the requirements.

## MAJOR FEDERAL OBSTACLES TO CHANGE

The Healthy, Hunger-Free Kids Act helped a lot of districts improve, says Wilson, who was the USDA Deputy Under Secretary of Food, Nutrition, and Consumer Services in the Obama Administration. That's because it forced districts, parents, and educators to be laser-focused on the nutritional value of what they were serving.

"School meals have been really good for a long time," says Wilson. "A lot of school districts are even way ahead of the MAHA movement, and eliminated ingredients out of our products a long time ago."

Still, federal changes since 2012 have weakened some of the standards of the Healthy, Hunger-Free Kids Act. The first Trump Administration delayed implementation of science-based nutrition standards that would have reduced sodium and sugar in school meals, says Meghan Maroney, campaign manager for Federal Child Nutrition Programs at the Center for Science in the Public Interest. The Biden Administration then restored some of those standards, but they were not as stringent as they had been in the initial law. "There was a lot of conversation about the nanny state and too many regulations and giving power back to the local communities," Maroney says. Districts are going to be required to restrict added sugars in breakfast and lunch by the 2027-2028 school year.

The food industry will have to reformulate some of its products to meet those standards, but for districts to satisfy them without relying on industry, they'll have to focus more on scratch cooking—an increasingly costly proposition.

That's in part because of inflation; the cost of food, equipment, and labor keeps rising. But it's also because federal reimbursement rates for school lunches have not kept pace with inflation. Right now, schools get reimbursed a little more than $4 per student by the federal government. Restaurants would struggle if diners paid that little for food.

"Because of reimbursement levels, most schools can't compete with culinary restaurants or retail stores that start at $20 an hour," says Bettina Applewhite, a registered dietitian who consults school districts to help them make the transition to scratch cooking.

The MAHA movement and Robert F. Kennedy, Jr. have not made much progress in changing school lunches so far—in part because school meals are run by the USDA, rather than HHS. But if the government really wants to change school lunches, it should probably start with the reimbursement rate, says Maroney.

"Removing ultra-processed foods is going to cost a lot of money," she says. "In order to do that, there have to be significant investments in the reimbursement rates, training, culinary technical assistance, and funding."

Soltanmorad, of Tahoe Truckee, says that the investment is worth it. The district could, she says, just serve a lot of pizza and make its kids happy, but that wouldn't be good for their health or their nutritional education. Now, they're learning how to nourish their bodies and eat well—skills they'll take with them once they've graduated to be healthy adults.

PHOTO ILLUSTRATION BY TIME (SOURCE IMAGE: BLAKEDAVIDTAYLOR/GETTY IMAGES); GETTY IMAGES

# Doctor's Notes

*'EVEN A MODEST AMOUNT OF EXERCISE CAN HAVE MEANINGFUL HEALTH BENEFITS.'* —PAGE 28

WOMEN'S HEALTH

## What Menopause Does to the Brain

BY LAURYN HIGGINS

GETTY IMAGES

MENOPAUSE MARKS THE END OF A WOMAN'S reproductive years. But the transition affects far more than reproductive health: it also reshapes the brain. As estrogen and progesterone decline, cognitive issues can arise, altering memory, attention, mood, and sleep.

Here's what to know about how menopause affects the brain.

### Hormone shifts can cause brain fog

Brain fog—difficulty concentrating, forgetfulness, or a sense of mental cloudiness—is one of the most common and disruptive cognitive symptoms of menopause. Research suggests that up to 60% of menopausal women experience brain fog, and hormonal changes are the primary driver.

"During perimenopause, levels of estrogen and progesterone fluctuate before going into a sharp decline," says Dr. Beth McQuiston, a neuroscientist and medical director of diagnostics at Abbott. These hormonal shifts directly affect the brain, because both estrogen and progesterone are critical to brain health and support the hippocampus and prefrontal cortex: two regions involved in learning and memory.

During menopause, certain neurotransmitters also become less active, including those key to attention, word recall, working memory, mood, and good sleep. That last component is critical for cognitive function, says Dr. Heather L. Hinshelwood, chief of medicine at Fraum Health. "If we don't sleep, we don't heal well and don't make memories well as a result," she says. "Given all this, it's no wonder that brain fog occurs," says McQuiston.

**Research suggests that up to 60% of menopausal women experience brain fog, and hormonal changes are the primary driver.**

### Is it just normal aging or menopause?

Forgetfulness during midlife can feel like a normal part of aging, but menopause-related cognitive changes are distinct.

"It all comes down to timing, pattern, and underlying biology," says McQuiston. "Working with a doctor well trained in this area is critical." A proper workup when assessing memory complaints will include evaluating hormone levels, metabolic health, thyroid function, and sleep disorders, she says.

"Doctors can tell the difference between age-related changes in memory compared to those caused by menopause by looking more at the timing and context of the changes, what kind of memory is affected, and if other symptoms are involved," adds Dr. Sharon A. Brangman, a geriatrician and trustee of the McKnight Brain Research Foundation.

Age-related memory loss can begin around the same time many women start menopause, so doctors will ask questions to try to figure out if their patients' memory complaints started around the time of hormonal changes, hot flashes, and sleep problems—key signs of menopause.

There are other clinical hints. Typically, menopause-related changes affect working and verbal memory—tasks such as remembering phone numbers or details from conversations—while normal aging causes milder changes that rarely disrupt daily life, notes Brangman.

### Mood, anxiety, and the emotional brain

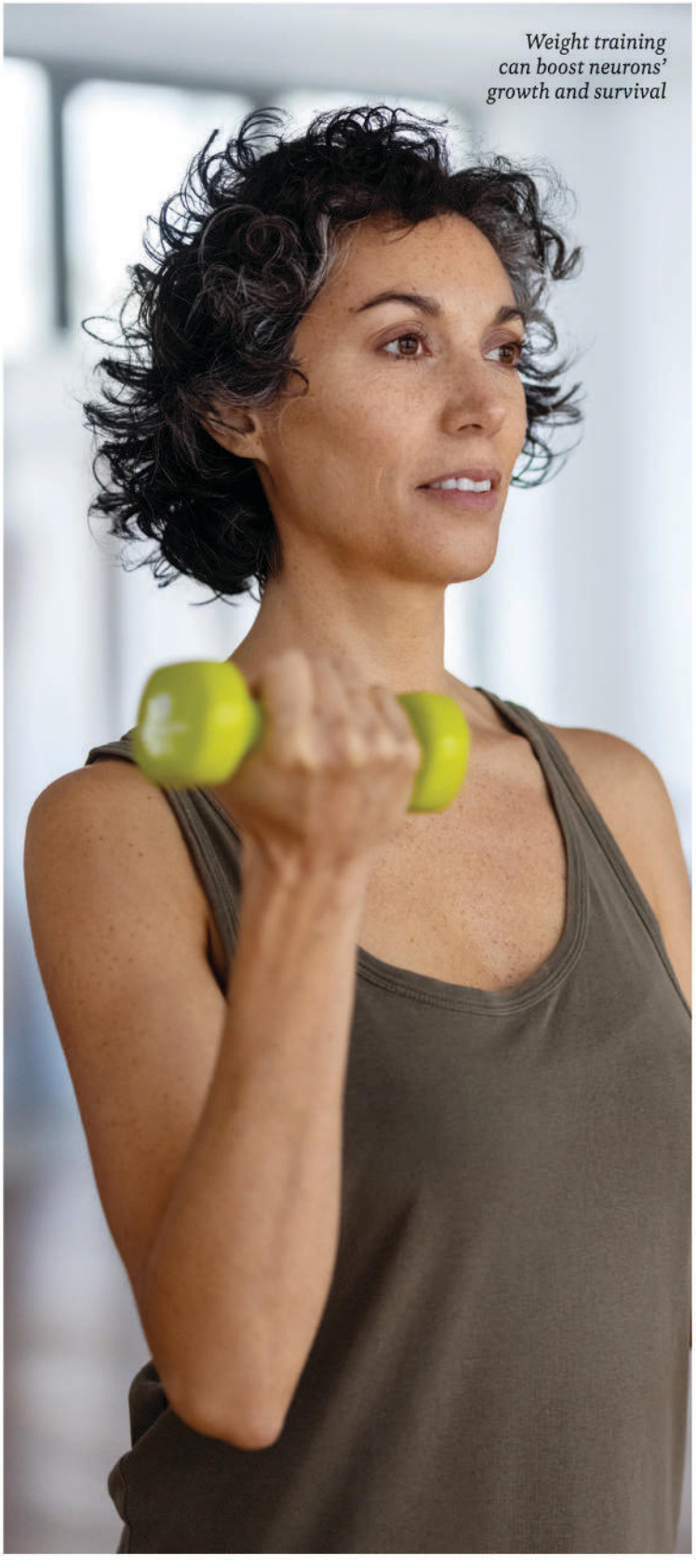
The hormonal shifts of menopause affect not just cognition, but also mood. "We have evidence from longitudinal prospective studies from the U.S. and global populations that demonstrate an increased risk of depression during the perimenopausal transition," says Dr. Marika Osterbur Badhey, an ob-gyn and assistant professor at NYU Langone Health. About one third of women going through menopause may experience depression. This is partly because estrogen plays a central role in regulating brain chemicals that support emotional stability, motivation, and focus. "When estrogen levels drop, it can cause women to experience irritability and mood swings, concentration issues, anxiety, and depression," says Brangman.

Estrogen helps control the activity of emotion-regulating areas in the brain, such as the amygdala and hippocampus, and that influence helps buffer against negative information and stress.

Brangman emphasizes the long-term stakes: "We know that women have higher rates of Alzheimer's disease than men. Research is focused on how the loss of estrogen's protective effect on the brain during menopause may place women at higher risk for dementia as they age."

### A path forward

The brain is accustomed to being influenced by estrogen, McQuiston says. But the brain is remarkably adaptive: brain-imaging studies have



*Weight training can boost neurons' growth and survival*

shown that during menopause, the brain undergoes measurable remodeling and metabolism, and "in time, compensatory pathways pick up." For instance, during menopause, the brain may rely more on ketones—a byproduct of the breakdown of fats—as backup fuel, she says.

The cognitive cost of menopause is tangible, but it's not fixed: timely intervention, lifestyle optimization, and hormone therapy in some cases can help preserve memory, attention, and executive function.

"That said, even one day of brain fog is one day too many," says McQuiston. "There is a lot that can be done with the right assessment and treatment plan."

Research is continuing to reveal the mechanisms behind cognitive disruption during this transition, but women shouldn't wait to take action. "I like to encourage people who are going through this or seeing loved ones wrestling with the physiological changes related to menopause: don't delay, see a specialist as soon as you can."

**What to do about the brain symptoms**

If you've noticed brain fog, forgetfulness, or mental fatigue during menopause, you're not alone—and experts say this stage can also be an opportunity to invest in long-term brain health. "Menopause can be a time of vulnerability, but it is also a time of opportunity to maximize brain health for the future," says McQuiston.

Start with the basics: prioritize quality sleep, regular exercise, good nutrition, and social connection. "Lifestyle changes that are good for your overall health…will also benefit your brain," says Brangman. Strength training, in particular, can boost brain derived neurotrophic factor (BDNF), a key compound for brain function.

For some, menopausal hormone therapy (MHT) can help relieve symptoms that affect cognition, such as hot flashes and poor sleep. While studies haven't confirmed long-term cognitive benefits, treatment can improve sleep and mood, which in turn helps mental clarity.

And managing modifiable lifestyle factors like blood pressure, diabetes, and cholesterol remains one of the best ways to protect brain health in the long run, Badhey says.

Supporting your brain during menopause is about combining healthy habits with individualized care. "The menopausal transition can be an extremely challenging time," says McQuiston. "It can impact women and those around them, which is why it's important to work with health care professionals to change how we address women experiencing menopause and help empower them to understand this stage of life better."

THE BRAIN

# What to Know About the Brain Disease CTE

BY ALICE PARK

WHEN SHANE DEVON TAMURA walked into a midtown Manhattan office building with an assault rifle in July 2025, he also carried a note in his back pocket that provides the only hint at why he opened fire on people in the building. Tamura killed four and badly wounded another before shooting himself in the chest.

In the note, Tamura claimed to have CTE—chronic traumatic encephalopathy, a brain injury condition due to repetitive trauma to the brain—and that he wanted researchers to study his brain. Tamura played high school football in California, a sport that's been linked to a higher risk of CTE. A source close to the investigation allegedly told CNN that Tamura had written a three-page note and complained about the way the National Football League managed players with CTE. "You can't go against the NFL [National Football League], they'll squash you," CNN reported that he wrote. (The NFL's headquarters are located in the building, but Tamura reportedly went to a different floor.) He asked that his brain be studied by researchers to better understand CTE.

The New York City Office of Chief Medical Examiner told CNN it would analyze Tamura's brain as part of a complete autopsy. Depending on the wishes of his family, Tamura's brain could go to other CTE researchers following that analysis for more detailed study.

Here's what brain experts know about CTE.

*Any activity that exposes people to repeated trauma can put them at risk of developing CTE*

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### What is CTE?

"CTE is linked to repetitive brain trauma and has a distinct pathology that can only be diagnosed at autopsy," says Dr. Ross Zafonte, a principal investigator of the Football Players Health Study at Harvard University and executive vice dean at the University of Missouri School of Medicine.

The changes that occur in traumatic brain injury are generally too small and too subtle to pick up on brain scans, unlike strokes, says Dr. Maura Boldrini, professor of psychiatry at Columbia University Medical Center. "We are talking more about microstrokes in which repeated shaking can cause the capillaries [tiny blood vessels in the brain] to break. This leads to some leaking into the brain and starts the process of inflammation, which can lead to the death of brain cells and brain neurons."

CTE can only be diagnosed after death by experts studying slides of brain tissue from a deceased individual, says Zafonte. But there is a related clinical syndrome called traumatic encephalopathy syndrome (TES) that researchers are beginning to use in research studies to identify living patients who might be affected by CTE. It's not clear yet what CTE looks like in living patients, so TES remains a research tool while scientists continue to refine how to diagnose CTE outside of postmortem studies.

### How common is CTE?

Because CTE is caused by repetitive brain injury, any condition that exposes people to repeated trauma can put them at risk. That includes contact sports like football, hockey, and boxing, as well as certain kinds of military

training and combat. Because it can only be diagnosed postmortem—and in cases where no crime has been committed, a person or family must donate the brain for study in order for the test to be performed—it's not entirely clear how common the condition is among those at high risk. But Chris Nowinski, cofounder and CEO of Concussion Legacy Foundation and member of the UNITE Brain Bank at the Boston University Research CTE Center, says that current CTE brain banks generally find that about half of donated brains show evidence of the condition.

**What are the symptoms of CTE?**

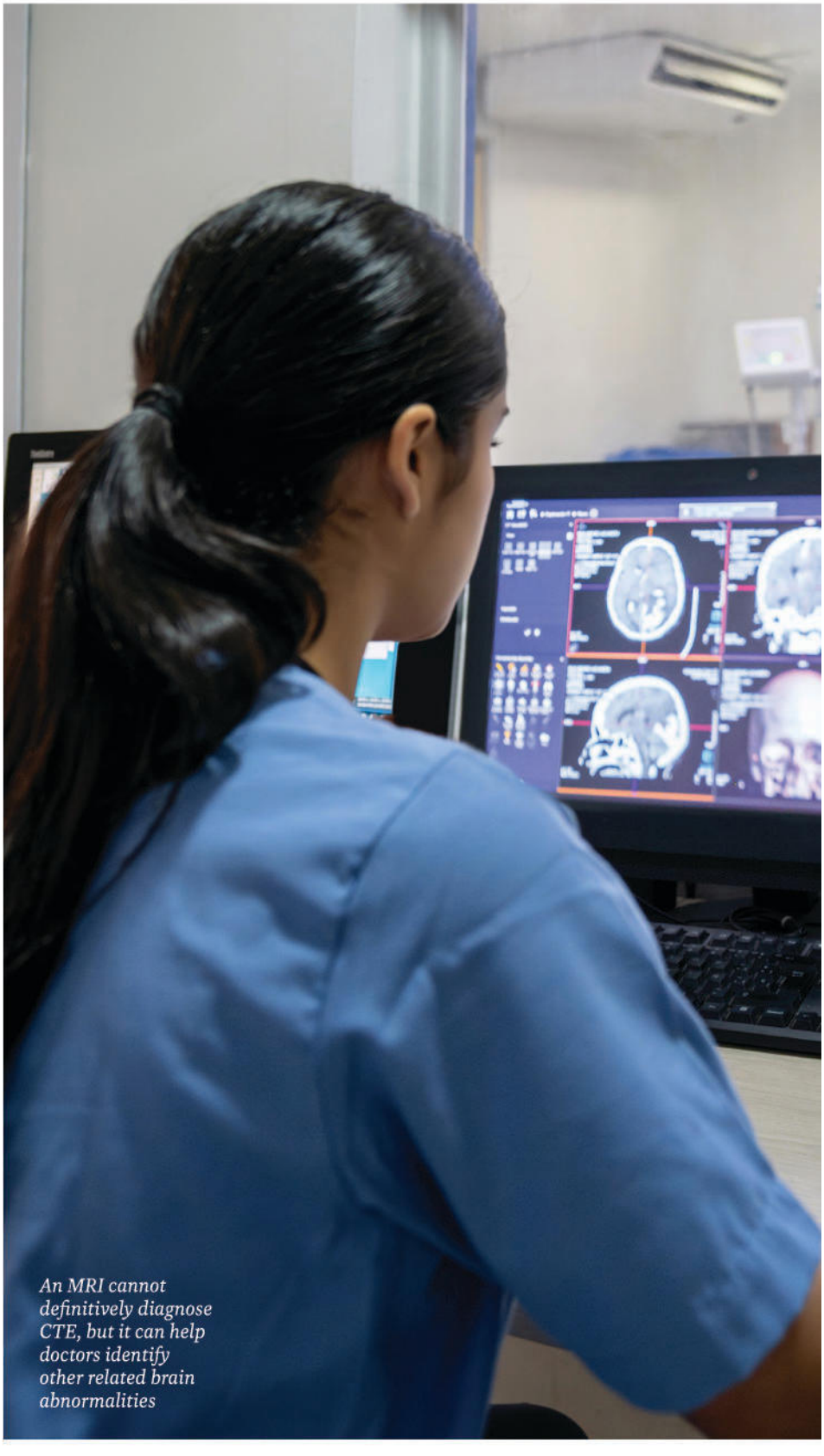
Depending on which parts of the brain are affected by the repetitive trauma, different types of symptoms may appear. These can include cognitive impairment, changes in memory, altered mood, and changes in executive brain functions like logical thinking and reasoning. Irrational, aggressive, and impulsive behavior are also common.

In CTE, these changes tend to get progressively worse. "You generally don't see symptoms two days after exposure; it's usually a delayed onset, but things get worse and not better," says Zafonte. "No other condition fully accounts for this."

**Can CTE be treated?**

Because CTE and TES result from damage to brain tissue, no known treatment can reverse the condition. But, says Zafonte, "there are things that can bend the curve in the way the symptoms appear."

The idea is to build the brain's resilience, or ability to withstand trauma, by keeping it as healthy as possible before any injury occurs. That includes a range of things such as physical activity including aerobic exercise and strength training, staying cognitively engaged, avoiding social isolation, and getting enough sleep. For athletes, Zafonte says addressing any chronic pain is also important, since living with chronic pain can affect mood. "All of these things interact with [brain] pathology, we believe, to form a nasty Gordian



*An MRI cannot definitively diagnose CTE, but it can help doctors identify other related brain abnormalities*

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knot," he says. "But how much reserve people have at the onset of symptoms is important."

Boldrini says that there is some evidence that medications like anti-epilepsy treatments and antidepressants may help address symptoms linked to CTE. In some people, levels of serotonin may be out of balance, and certain antidepressants can help to bring levels closer to normal. Anti-epilepsy drugs can help to calm electrical activity that goes awry. These drugs can also "protect [neurons] from dying as well," she says.

**What research is being conducted on CTE?**

The biggest priority is finding markers in the blood or in brain scans that can help to identify people with CTE while they are living, say experts. Scientists are sequencing the genomes in brain regions that postmortem studies show are affected by CTE to understand which cells and genes are aberrant. So far, says Boldrini, that research is showing that genes controlling processes like inflammation and the metabolic function of cells are likely driving some of the changes. Future treatments might target some of these changes to counteract them so cells remain functional and aren't susceptible to damage, especially in people who might be at higher risk of repetitive brain trauma. "If we eventually had something we could use for athletes to help them sustain their brain health while engaging in these [high risk] sports, that would be great," says Boldrini.

Scientists are also studying ways to potentially reverse that damage, including how to help neurons regrow or recover from trauma. "Right now, we can't say that we have things that can reverse brain damage," says Boldrini.

One of the fastest ways to deepen understanding of CTE is to begin collecting data on suspected patients' blood and other factors while they are alive, so that if they are diagnosed with CTE postmortem, researchers can compare what measurable factors made them different from people without the condition.

**'I'm excited for the future of biomarkers and biomedical targets that can mitigate some of the consequences of traumatic brain injury.'**

**— DR. ROSS ZAFONTE, PRINCIPAL INVESTIGATOR OF THE FOOTBALL PLAYERS HEALTH STUDY**

The UNITE Brain Bank now has the world's largest collection of such brains—1,600—and Boston University's CTE Center is leading two studies that could yield important advances in CTE diagnosis in coming years, says Nowsinski. One involves former NFL and college players who agree to provide blood and other samples and then donate their brains upon their death. They will be compared with people without head trauma and those with Alzheimer's disease to determine what distinguishes them.

Another study is following more than 900 former athletes who are providing blood samples and taking cognitive tests; they have also agreed to donate their brains upon their death. Over time, with enough people who end up being diagnosed with CTE postmortem, researchers should have a good sense of which factors in blood are good indicators of who might have CTE and who likely does not, says Nowinski.

"I'm excited for the future of biomarkers and biomedical targets that can mitigate some of the consequences of traumatic brain injury," Zafonte says. "But we can also tell folks [at risk of] repetitive head trauma that there are many things they can do to potentially make themselves a little bit more resilient. We do what we can now, and when we know better, we will do better."

EXERCISE

# How Many Steps Do You Need in a Day? A New Study Has a Surprisingly Low Answer

BY VERONIQUE GREENWOOD

**The new study suggests 'it's not all or nothing… even just starting with one day can be incredibly meaningful for your health.'**

**—AMANDA PALUCH, KINESIOLOGY PROFESSOR AT THE UNIVERSITY OF MASSACHUSETTS IN AMHERST**

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YOU'VE PROBABLY HEARD THIS ONE a few times before: Research suggests that exercise is linked to a longer life.

What's more surprising is that a tiny amount of activity could have a noticeable effect, according to a study published in October in the *British Journal of Sports Medicine* that included more than 13,000 women with an average age of 72. For these women, walking just 4,000 steps one day a week was enough to start seeing a decline in likelihood of dying or developing heart disease over the course of the study. The findings suggest that walking a mile or two once a week is still beneficial, even if your other days are less active.

### Small steps, big change

Fitness apps and wearable trackers often set a goal for users to reach 10,000 steps per day. Yet many experts agree that number is arbitrary. Amanda Paluch, a professor of kinesiology at the University of Massachusetts in Amherst who studies step counts as a measure of physical exercise, says the popular benchmark seems to have been inspired by a Japanese pedometer device made decades ago. "It has not been backed up by scientific evidence," she says.

Still, steps are a handy way to think about physical activity, so researchers have been working to understand exactly how many per day are linked to improved health.

In the study released in October 2025, participants wore step counters for a week, and the researchers recorded the number of days each woman achieved step counts greater than 4,000, 5,000, 6,000, and 7,000. Then, for more than a decade, they tracked whether the women developed cardiovascular disease or died.

The goal was to determine whether even relatively small numbers of steps, logged on just a handful of days, would affect the women's health, says study author Dr. Rikuta Hamaya, an instructor in medicine at Brigham and Women's Hospital.

Women who walked 4,000 steps once or twice a week experienced a 27% lower risk of developing cardiovascular disease and a 26% lower risk of dying during the study period, compared to those who didn't—a substantial difference.

### Shifting from an all-or-nothing mindset

The new study suggests "it's not all or nothing…even just starting with one day can be incredibly meaningful for your health," said Paluch, who was not involved in the work. The findings are similar to her own previous research suggesting that even 6,000 steps a day are linked to lower risk of heart disease in adults aged about 60. The new research is also reminiscent of other teams' work on "Weekend Warriors," or people who pack their exercise into just a day or two a week but see better health outcomes than those who don't exercise.

Dr. Shaan Khurshid, a cardiac electrophysiologist at Massachusetts General Hospital, agrees that even a modest amount of exercise can have meaningful health benefits. "[That finding] enables us to empower patients by saying…even if you're not exercising every day or walking every day, you're still getting a benefit from that," he says.

Other factors might influence the link between movement and health. The researchers can't conclude, based on observing study participants, that movement definitively caused their better health outcomes. Preexisting frailty could have been at play, as well—although the researchers did their best to control for this, there's always the chance that some of the people who walked very little did so because they were already not in the best of health.

Plus, Hamaya points out, this study followed only older, mostly white women. More diverse studies with younger people are needed to determine the effects of step counts for other groups.

Still, as studies suggesting even small amounts of exercise are beneficial continue to pile up, the latest findings are an encouraging sign that, if you're considering upping your activity level, even a little bit can make a difference.

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The American Cancer Society is partnering with Black women to better understand why and how cancer and other health conditions disproportionately impact Black women in the US. Our groundbreaking VOICES of Black Women initiative is more than just a study; it's a collective commitment to understanding and improving the health of Black women across the nation – for generations to come.

With more than 70 years of trusted cancer research studies and breakthroughs under our belt, the American Cancer Society is uniquely positioned to make monumental change by identifying the root causes of health disparities among Black women and addressing those issues.

**WE NEED YOUR VOICE.**

**We are calling on Black women from all walks of life to join this movement. The time is now to help us change the future of cancer as we know it.**

**Visit voices.cancer.org to learn more.**

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