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Stephanie Collier, MD, MPH
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Learning Objectives

After reading these articles,
you should be able to:

1. List the pros and cons of nonpharmacologic and pharmacologic treatments for insomnia in older adults.
2. Minimize drug risks through effective medication management for older adults.
3. Identify potential pharma industry strategies for promoting drugs to clinicians.
4. Summarize some of the findings in the literature regarding psychiatric treatment for older adults.

Managing Insomnia in Older Adults

Julia Cromwell, MD, Medical Director, Senior Adult Psychiatry Unit, Salem Hospital, Salem, MA.

Dr. Cromwell has no financial relationships with companies related to this material.

Mr. Johnson is a 74-year-old man with depression, hypertension, and obesity. He presents to your clinic complaining of trouble falling asleep. He has tried trazodone in the past to poor effect. What do you do next?

Over 50% of older adults (OAs) report sleep difficulties (Patel D et al, *J Clin Sleep Med* 2018;14(6):1017-1024). Specific criteria for insomnia vary, but all include subjective discontent with sleep quality or quantity, with one or both of the following: difficulty initiating sleep (sleep-onset insomnia) or frequent awakenings and/or early-morning awakenings (sleep-maintenance insomnia).

Durational definitions of insomnia include:

Highlights From This Issue

Feature article

From newer DORAs to old favorites, there are safer medications for sleep.

Feature Q&A

Older adults are using cannabis products, and they may help in refractory agitation in dementia.

Q&A on page 8

Pharmaceutical companies use sophisticated marketing techniques, and we can help you decode them.

- Episodic insomnia: lasting at least one month but less than three months
- Persistent insomnia: occurring at least three nights per week for longer than three months
- Recurrent insomnia: two or more episodes in one year

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Cannabis Use for Managing Agitation in Dementia Aaron Greenstein, MD

Geriatric psychiatrist in private practice, Denver, CO.

Dr. Greenstein is a medical advisor for BrainCheck, Sensi.AI, and Optimize VBC. He is a consultant for GE Healthcare and LEK Consulting. Relevant financial relationships listed for the author have been mitigated.

CGPR: What sparked your interest in cannabis use among older adults (OAs)?

Dr. Greenstein: After Massachusetts legalized recreational cannabis, I noticed more older veteran patients using it. Unsure how to advise them, my colleague and I researched its effects on OAs, including side effects, risks, and reasons for use. This topic became personal when my grandmother suffered severe agitation related to her memories of Auschwitz trauma during her end-stage dementia. Geriatric psychiatrists were hard to come by, so I stepped in, working with her PCP. Traditional medications, from selective serotonin reuptake inhibitors (SSRIs) to atypical antipsychotics, were ineffective. Desperate for an alternative that wouldn't oversedate her, I considered cannabis. I was inspired by the promising results I witnessed during my fellowship (Woodward MR et al, *Am J Geriatr*



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Managing Insomnia in Older Adults

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Although the incidence of insomnia increases with age, it is not a normal part of aging. Normal sleep changes in OAs include:

- Decreased total sleep needs
- Decreased slow-wave and REM sleep
- Advanced sleep phase (eg, falling asleep earlier and waking up earlier)

(Source: Hirshkowitz M et al, *Sleep Health* 2015;1(1):40–43)

Evaluation

Insomnia is a clinical diagnosis, so taking a good history is the first step. Knowing basic risk factors for insomnia (eg, alcohol use, overnight disruptions, poor sleep hygiene, certain medications) and

understanding that insomnia can be a primary disorder or comorbid condition can help guide questions (see “Risk Factors for Insomnia in Older Adults” table).

Diagnostic tools

Additional diagnostic tools include brief screens such as the:

- Geriatric Depression Scale (GDS) for depression
- Generalized Anxiety Disorder 7 (GAD7) for anxiety
- Insomnia Severity Index (ISI) and the more detailed Pittsburgh Sleep Quality Index (PSQI) for sleep problems

Mr. Johnson scores in the moderate range on both the GDS and GAD7. You ask him to start a sleep journal. During a follow-up, you note that he spends up to 12 hours in bed, with around five awakenings nightly. He identifies a lack of daytime structure and excessive napping as contributing to his poor sleep. You suggest tweaks to his nightly routine, such as going to bed later and replacing TV with reading before bed. You also suggest he download the CBT-I Coach mobile application.

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EDITORIAL INFORMATION

Publisher: Daniel Carlat, MD

Editor-in-Chief: Stephanie Collier, MD, MPH

Deputy Editor: Talia Puzantian, PharmD, BCPP, professor at the Keck Graduate Institute School of Pharmacy in Claremont, CA

Director of Digital Content: Laurie Martin

Senior Editor: Ilana Fogelson

Associate Editor: Harmony Zambrano

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Sleep diary

Most evaluations for insomnia also include a patient-recorded sleep diary (minimum two weeks) to clarify patterns of going to bed and waking up, number of awakenings, and total time spent in bed. Sometimes a sleep diary can show that a patient's sleep parameters are appropriate for their age. These patients do not need treatment beyond education and reassurance that it is normal to occasionally sleep poorly.

Additional testing

Only order a polysomnography if you think the patient might have comorbid sleep apnea or parasomnias. While consumer devices for wrist actigraphy, such as smart watches, can compare overall sleep before and after treatment, their accuracy on specific metrics is usually poor. They can also heighten anxiety in patients by putting a focus on their numbers. No specific imaging is needed for the diagnosis either (Patel et al, 2018).

Risk Factors for Insomnia in Older Adults

Behavioral Factors	<ul style="list-style-type: none"> • Alcohol usage • Caffeine • Excessive time spent in bed • Irregular schedule 	<ul style="list-style-type: none"> • Limited physical activity • Napping • Nicotine
Environmental Factors	<ul style="list-style-type: none"> • Bright lights • Disruptive bed partner • Electronics (TV) 	<ul style="list-style-type: none"> • Loud noises • Room temperature
Medications	<ul style="list-style-type: none"> • Antiandrogens • Beta agonists • Beta blockers • Bupropion • Decongestants • Dopamine agonists 	<ul style="list-style-type: none"> • NSAIDs • Opioids • SSRIs/SNRIs • Steroids • Stimulants
Medical Conditions	<ul style="list-style-type: none"> • Asthma • CHF • Chronic pain • COPD • Diabetes • Fibromyalgia 	<ul style="list-style-type: none"> • GERD • Hyperthyroidism • Menopause • Nocturia • Nocturnal angina • Pruritis
Neurological Conditions	<ul style="list-style-type: none"> • Headaches • Neurodegenerative disorders • Neuropathies 	<ul style="list-style-type: none"> • Restless legs syndrome • Strokes • TBIs • Tumors
Psychiatric Conditions	<ul style="list-style-type: none"> • Anxiety • Depression • Eating disorders • Mania 	<ul style="list-style-type: none"> • Psychosis • PTSD • Substance use disorders
Sleep Disorders	<ul style="list-style-type: none"> • Circadian rhythm sleep-wake disorders • Parasomnias 	<ul style="list-style-type: none"> • Periodic limb movements • Sleep apnea
Other	<ul style="list-style-type: none"> • Being divorced, separated, or widowed • Caregiving • Female gender • History of childhood trauma 	<ul style="list-style-type: none"> • Reduced mobility • Reduced social interactions • Retirement

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Managing Insomnia in Older Adults

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Nonpharmacologic treatment

Sleep hygiene

With any sleep complaints, first address comorbid medical or psychiatric conditions. Then provide counseling on sleep hygiene principles:

- Maintain regular bed and wake times
- Exercise regularly
- Minimize external disruptions
- Eliminate caffeine after lunch
- Decrease nighttime nicotine and alcohol intake
- Reduce napping and time spent in bed outside of sleep and sex

Therapy

After these steps, the first-line treatment for chronic insomnia is cognitive behavioral therapy for insomnia (CBT-I). Compared to medications, CBT-I has longer-lasting effects on sleep and limited side effects (Mitchell MD et al, *BMC Family Pract* 2012;13:40). However, it can be difficult to find both CBT-I clinicians and patients willing to complete

the CBT-I recommendations. Another option is the Brief Behavioral Treatment for Chronic Insomnia (BBTI), which requires fewer sessions and is available in some PCP offices (Buysse DJ et al, *Arch Intern Med* 2011;171(10):887–895). Motivated patients with smartphones can try the free CBT-I Coach app or the moderately priced, FDA-cleared Somryst app.

Despite a couple weeks of restricting his time in bed, Mr. Johnson still struggles with significant fatigue and anxiety. He tells you his mood is even more depressed. You discuss medication options.

Pharmacologic interventions

Despite nonpharmacologic efforts, some patients may need medications for insomnia. The goal is for short-term usage only. FDA-approved medications for insomnia include:

- Ramelteon (a melatonin receptor agonist)
- Doxepin (a histamine receptor antagonist)
- Daridorexant, lemborexant, and suvorexant (dual orexin receptor antagonists (DORAs))
- Benzodiazepine receptor agonists (includes nonbenzodiazepines such as eszopiclone, zolpidem, and zaleplon)

Choosing a medication for insomnia

For OAs, avoid benzodiazepine receptor agonists given their potential side effects (eg, increased falls, confusion, daytime sedation, dependence). Note also that benzodiazepines disrupt sleep architecture by further decreasing both slow-wave and REM sleep. See *CGPR* April/May/June 2022 for more.

Beyond this general recommendation, the choice of medication is highly individualized (Sateia MJ et al, *J Clin Sleep Med* 2017;13(2):307). Factors include:

- Type of insomnia
- Medication price
- Prior medication trials
- Comorbidities

See “Preferred Medications in Older Adults” table for more.

Comorbidities

Patients presenting for a mental health condition often also report insomnia. In these patients, it is common to use off-label medications to treat multiple symptoms at once:

- Mirtazapine: can help patients with depression and insomnia, but may lead to weight gain (sometimes a desirable side effect).
- Trazodone and amitriptyline: also used for insomnia; not effective for the treatment of depression at doses used for sleep.
- Gabapentin: taken at night; benefits patients with chronic pain, restless legs syndrome, or alcohol use disorder and insomnia.
- Sedating antipsychotics (eg, quetiapine): for patients with a primary psychotic disorder or bipolar disorder to help with sleep. Risks do not outweigh the benefits for use as a sleep aid for nonpsychotic patients!

Over-the-counter options

There are also many over-the-counter (OTC) sleep aids and dietary supplements patients might ask about:

- Diphenhydramine and doxylamine: not recommended for OAs due to anticholinergic properties. Some research suggests anticholinergics can increase dementia risk (Coupand C et al, *JAMA Intern Med* 2019;179(8):1084–1093).
- Melatonin: well tolerated when taken a few hours before bedtime; can help slightly shorten sleep onset.
- Other OTC options: not enough research to confidently give patients other recommendations.

Preferred Medications in Older Adults		
	Medication	Notes
FDA Approved	Daridorexant	<ul style="list-style-type: none"> • Helps with sleep-maintenance insomnia • Dose: 25–50 mg QHS • Cost: \$\$\$\$
	Doxepin	<ul style="list-style-type: none"> • Helps with sleep-maintenance insomnia • Dose: 3–6 mg QHS • Cost: generic (tablets, liquid, or 10 mg capsule dissolvable in juice): \$–\$\$; Silenor: \$\$\$\$
	Lemborexant	<ul style="list-style-type: none"> • Helps with sleep-maintenance insomnia • Dose: 5–10 mg QHS • Cost: \$\$\$\$
	Ramelteon	<ul style="list-style-type: none"> • Helps with sleep-onset insomnia • Dose: 8 mg QHS • Cost: \$
	Suvorexant	<ul style="list-style-type: none"> • Helps with sleep-maintenance insomnia • Dose: 5–10 mg QHS • Cost: \$\$\$\$
Off-Label Options for Comorbidities	Gabapentin	<ul style="list-style-type: none"> • For chronic pain or alcohol use disorder • Dose: 100–400 mg QHS • Cost: \$
	Mirtazapine	<ul style="list-style-type: none"> • For depression • Dose: 7.5–15 mg QHS • Cost: \$
	Quetiapine	<ul style="list-style-type: none"> • For psychosis or bipolar disorder • Dose: 12.5–300 mg QHS • Cost: \$
OTC	Melatonin	<ul style="list-style-type: none"> • Dose: 0.5–6 mg QHS • Cost: \$

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Expert Interview – Cannabis Use for Managing Agitation in Dementia

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Psychiatry 2014;22(4):415–419). Patients who were unresponsive to conventional treatments for agitation in dementia benefitted from dronabinol, a synthetic cannabinoid. Consequently, my family tried a dissolving sublingual cannabis product from a dispensary (due to my grandmother's trouble swallowing). It worked wonders, easing her agitation, helping her sleep, and allowing her to spend her final weeks without distress.

CGPR: Could you give us an overview of your discoveries and their implications?

Dr. Greenstein: Many OAs who use cannabis report they are using it for medicinal purposes rather than recreationally. Common ailments that cannabis is used for include chronic pain, insomnia, and some psychiatric conditions. Studies indicate that OAs report generalized improvements in their well-being from cannabis products (Yang KH et al, *J Am Geriatr Soc* 2021;69(1):91–97). This explains its appeal among the elderly for “therapeutic” use. It's worth noting, however, that the term “medicinal” is somewhat fluid since medical cannabis does not have FDA approval for any indications.

CGPR: What's the difference between CBD and THC?

Dr. Greenstein: CBD and THC are both extracts of cannabis plants and are the two best-known cannabinoids. There are hundreds of others, and we don't know much about them. Marijuana is the colloquial term for cannabis plants that produce the psychoactive compound THC, while hemp is the term for cannabis plants that primarily produce the non-psychoactive CBD. Hemp is not regulated under the same strict DEA policies as marijuana, and this is why CBD, a hemp product, is readily available across the country. Common side effects of CBD include decreased appetite, dry mouth, diarrhea, and somnolence, whereas side effects of THC include increased appetite, tachycardia, dry mouth, and dry eyes. THC can also cause anxiety and psychosis (*Editor's note: See “Using Cannabis Products in Older Adults” table on page 5*).

CGPR: Are there strains that work better in OAs? How do you choose?

Dr. Greenstein: Unfortunately, studies have shown that strain names and even indica/sativa/hybrid designations are not clinically useful because they are not standardized (Smith CJ et al, *PLoS One* 2022;17(5):e0267498). The plants themselves are generally understood to be hybridized to the point that they aren't all that different. While most effects of cannabis are attributed to THC and CBD, the extraction process often results in the co-extraction of other cannabinoids. For instance, cannabitol (CBN), another cannabinoid, is frequently added to cannabis products marketed for sleep and is being studied as a treatment for insomnia. Anecdotally, multiple patients previously dependent on zolpidem for sleep have transitioned to using cannabis products containing CBN, THC, and CBD. They report significant improvements in sleep initiation and maintenance, as well as fewer cognitive effects. I reserve dronabinol prescriptions for patients who are resistant to standard treatments, cannot tolerate them, refuse pharmaceuticals in favor of “natural” products, or have family members who are concerned about the black box warning on antipsychotics. In my experience, products from dispensaries that contain a range of cannabinoids are noticeably more effective in managing dementia-related agitation than dronabinol, which contains only THC.

CGPR: When treating agitation in dementia, when would you consider a dronabinol trial for your patients?

Dr. Greenstein: My initial approach is standard of care, which includes behavioral interventions and pharmaceuticals. If they aren't effective or tolerated, I consider cannabis products. The literature behind dronabinol use in this population is not robust, so it's not first line. I think of it in patients who don't improve after the classic algorithm of starting an acetylcholinesterase inhibitor, augmenting with an SSRI or serotonin and norepinephrine reuptake inhibitor, augmenting or switching to an atypical antipsychotic, and perhaps divalproex sodium (Depakote). I also consider dronabinol in patients with dementia with Lewy bodies or Parkinson's disease dementia with severe agitation or hallucinations. The number of therapeutic options for these patients is limited because of adverse reactions to dopamine receptor inhibitors. I might first consider quetiapine, which is marginally effective for most people, followed by pimavanserin, and then clozapine. Small-scale studies of dronabinol haven't shown great effect in patients with synucleinopathies such as Parkinson's disease or dementia with Lewy bodies, although I've seen it work well in some cases. At present, it tends to be a treatment of last resort (Schimrigk S et al, *Eur Neurol* 2017;78(5–6):320–329).

CGPR: When discussing dronabinol with a patient and their family, how do you approach informed consent?

Dr. Greenstein: I approach it the same way I do for all medications, especially those that are prescribed for off-label indications. I educate the patient and family about the risks, possible benefits, and alternative treatments. I try to balance thorough informed consent and shared decision making with evidence-based recommendations. Although 10 states have dementia-related agitation as a qualifying condition for medical marijuana, my state is not one of them. Although I do not prescribe dispensary-sourced cannabis products, I still offer consultation on their potential risks and benefits.

CGPR: How receptive have your patients been to accepting dronabinol in treatment?

Dr. Greenstein: In Colorado, being ahead of the curve with legalization of cannabis products has shaped a general acceptance of its medical use. Patients or family members will often initiate the conversation about cannabis products for managing dementia-related agitation or other psychiatric illnesses. During informed consent, we must be upfront about

“Consider dronabinol in patients who don't improve after starting an acetylcholinesterase inhibitor, augmenting with an SSRI or SNRI, augmenting or switching to an atypical antipsychotic, and perhaps divalproex sodium (Depakote). Or consider it in patients with dementia with Lewy bodies or Parkinson's disease dementia with severe agitation or hallucinations.”

Aaron Greenstein, MD

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Expert Interview – Cannabis Use for Managing Agitation in Dementia

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black box warning on antipsychotics and the evidence around psychotropic use in OAs. This conversation sometimes leads patients or families toward wanting to try dronabinol first, as it does not garner as much fear. Like antipsychotics, cannabinoids aren't universally effective and we don't yet have definitive data on which specific subsets of patients they benefit. The same uncertainty applies to many pharmaceuticals—we won't know their efficacy until we administer them. My overall strategy for dronabinol is the same as for any other medication I prescribe: Monitor patients closely, maintain open communication, and don't be beholden to a medication if it is ineffective or not tolerated.

CGPR: Which risks do you highlight?

Dr. Greenstein: In terms of the safety profile of dronabinol and other cannabis products, there are studies that show they increase the risk of falls, motor vehicle accidents, delirium, and cognitive impairment (Solomon HV et al, *Harv Rev Psychiatry* 2021;29(3):225–233). Those are the main categories that we talk about when obtaining informed consent. In some patients we worry about drug-drug interactions (*Editor's note: See "Possible Drug-Cannabinoid Interactions" table*). The main ones are blood thinners: warfarin, apixaban, etc. Cannabinoids can increase the serum levels of these drugs. You don't want to cause somebody to be at higher risk for bleeding as a result of using these compounds. Based on the literature on CBD, it seems that the dose needed to increase the serum level is hundreds of milligrams at a time, as CBD has lower bioavailability (Millar SA et al, *Pharmaceuticals (Basel)* 2020;13(9):219). Still, I'm cautious. We don't have guidelines on this, and I therefore stay very conservative.

CGPR: How do you discuss dosing cannabis products with patients?

Dr. Greenstein: In patients choosing to use cannabis from a dispensary, we review approximate amounts of THC—for example, smoking contains variable THC, whereas doses in edibles are standardized but more potent. Dronabinol, which is pure THC, is available in capsules with the smallest dosage being 2.5 mg. I start low, go slow, and titrate until there is benefit or poor tolerance. For instance, one patient with Korsakoff dementia responded well to 2.5 mg BID of dronabinol, which made her much less agitated and more directable, enhanced her participation in care, and helped her sleep well at night. I did not titrate the dose any further. I often warn OAs that cannabis products can hang around for longer in their systems than in younger adults. These products are fat soluble—and with increasing age, people have more body fat relative to water. Additionally, I mention that gummies or tinctures can take up to two hours to reach their full effect—so I suggest waiting between doses to minimize accumulation and risk for overdose.

CGPR: Can you share any other notable outcomes you've observed with cannabis use?

Dr. Greenstein: I'm working on a challenging case of a woman in her 60s with early-onset Alzheimer's (imaging and clinical presentation not consistent with frontotemporal dementia). She displayed extremely violent tendencies, leading to multiple evictions and elopements from memory care facilities. Initially, she was managed at home with 24-hour care. Securing inpatient psychiatric care was difficult due to reluctance by facilities in Colorado to involuntarily admit patients diagnosed with dementia with behavioral disturbances. Her agitation was not responsive to behavioral interventions. I trialed various atypical antipsychotics, divalproex sodium, and benzodiazepines, but none were able to reduce

Using Cannabis Products in Older Adults		
	Notes	Side Effects
CBD	Starting dose: 300 mg/day Titrate in 300 mg/day increments	<ul style="list-style-type: none"> Decreased appetite Diarrhea Dry mouth Elevated liver enzymes Somnolence
Dronabinol	Starting dose: 2.5 mg Titrate in 2.5 mg increments	<ul style="list-style-type: none"> Cognitive impairment Delirium Gait instability Increased fall risk Increased risk of motor vehicle accidents
THC	Edibles: starting dose 2.5 mg Titrate in 2.5 mg increments Standard unit: 5 mg Smokable cannabis: THC content varies (0.1%–30% by weight) Cannabis concentrates (rosin, wax): 54%–80% THC	<ul style="list-style-type: none"> Anxiety Delirium Dry eyes Dry mouth Falls Gait instability Increased appetite Psychosis Tachycardia

Possible Drug-Cannabinoid Interactions	
Drug	Interactions
Alcohol	May increase effects of both alcohol and cannabis
Anticoagulants	Can increase levels of apixaban or warfarin, potentially increasing bleeding risk
CNS depressants	May increase sedative effects
Protease inhibitors	May decrease effectiveness of antivirals

her scores on the Neuropsychiatric Inventory–Questionnaire (NPI-Q) or eliminate her need for 1:1 24/7 care. With her court-appointed guardian's consent, we offered her a cannabis product containing THC and CBD. She titrated up the dose of THC to 20 mg, at which point she became calm. The cannabis product produced this effect for four to six hours. Currently she's on 60 mg of THC daily, dosed 20 mg TID. She has shown immense improvement, living in an assisted living facility, and no longer requiring 24/7 1:1 supervision.

CGPR: That's a fascinating case. Are there specific scenarios or medical conditions that make you hesitate to prescribe cannabis?

Dr. Greenstein: Exercise caution with patients who have severe gait instability, history of negative reactions to marijuana or other substances, and severe psychosis due to the potential correlation between cannabis and psychotic disorders. Patients on blood thinners or who are still driving also prompt me to reconsider.

CGPR: Have you recommended CBD instead of THC for specific conditions, considering its milder psychoactive properties?

Dr. Greenstein: I haven't yet. While CBD has lower oral bioavailability, studies are exploring its use for dementia and agitation. As with any psychotropic medication, individuals may respond differently to CBD, mixed cannabinoids, or THC.

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Addressing Polypharmacy in Older Adults

Jose Antonio Ribas Roca, MD. Associate Professor, Psychiatry and Behavioral Sciences, Baylor College of Medicine, Houston, TX.

Carolyn TK Tran, PhD. Instructor, Psychiatry and Behavioral Sciences Baylor College of Medicine, Houston, TX.

Dr. Ribas Roca and Dr. Tran have no financial relationships with companies related to this material.

Ms. Andrews is 87 years old with stage 4 bladder cancer and recent visual hallucinations. She has just completed a course of ciprofloxacin for a presumed urinary tract infection (UTI). She has taken amitriptyline 50 mg for many years to manage neuropathic pain and relies on over-the-counter (OTC) ibuprofen PM for insomnia. Her PCP initiates quetiapine 50 mg QHS to address her hallucinations and refers her to you for further evaluation.

We know polypharmacy poses risks for older adults (OAs), including side effects, drug interactions, and decreased medication adherence. In this case-based article, we offer tips for preventing these problems and ensuring your prescribing decisions make sense.

Confirm the diagnosis

In our case vignette, the patient was prescribed quetiapine for presumed visual hallucinations—which is reasonable at first glance. But good prescribing means taking time to confirm your diagnosis, especially when contemplating risky medications like an antipsychotic.

Your psychiatric evaluation reveals that Ms. Andrews has no history of psychosis and has only experienced visual hallucinations after taking “strong pain medications” following a hip fracture. Her daughter tells you she has no history of dementia and her memory seemed fine before her recent UTI. You notice she occasionally struggles to find the right words, displays variable attention, and demonstrates small gaps in her recent memory. Given the recent onset of this cognitive impairment, you diagnose her with delirium.

Cognitive complaints always call for a review of the history:

- Has the impairment been documented in the past?
- Has there been a gradual decline consistent with major neurocognitive disorder, or has the decline been abrupt?
- Is there a connection between recent medical issues and psychiatric symptoms?
- Have you spent enough time interviewing informants such as family members or past caregivers?

Reconsider medication and dose

According to her daughter, Ms. Andrews has taken quetiapine 50 mg nightly for the last five days. On interview, the patient is sedated and tremulous. Her daughter says she has been less steady on her feet.

When finding the right medication for OAs, take the patient’s medical history and comorbidities into account and try to prevent potential drug interactions. See “Psychotropic Medications With Adverse Effects” table on page 7.

Determining the right dose is especially important in OAs, who may be more sensitive to medications due to age-related physiological changes:

- Aging affects medication distribution due to changes in muscle mass and body fat
- Decreases in hepatic and renal function slow the elimination of medications

In this patient’s case, a too-high dose of quetiapine resulted in unsteadiness, tremulousness, and sedation. She may have tolerated quetiapine better at a lower dose, such as 12.5 mg.

Evaluate treatment response

We often become impatient when a patient’s symptoms are not improving. But it’s important to wait for a drug to take effect to know whether the patient responds to it. Before increasing dosage or adding new medications, confirm that the patient takes the medication as prescribed. If adherence is not an issue, educate patients on the time it takes for their medication to work.

Employ shared decision making

Shared decision making prioritizes the patient’s treatment goals and preferences. Before changing medications, consider asking the patient:

- What matters to them? Are they more interested in avoiding side effects, or are they willing to tolerate side effects to achieve full symptom resolution?
- Are they prepared to manage one more medication?
- Can they participate in necessary monitoring (eg, attending appointments and obtaining labs)?

Use these discussions to educate patients about the risks of polypharmacy and as a starting point to reduce their medications.

Identify key medications

Among a patient’s medication list, a few probably stand out as essential. Prioritize these medications and try to reduce anything that could harm the patient. The two sets of criteria from the American Geriatrics Society and the British Geriatrics Society—Beers and STOPP criteria, respectively—can help identify these potentially inappropriate medications (2023 American Geriatrics Society Beers Criteria Update Expert Panel, *J Am Geriatr Soc* 2023;71(7):2052–2081; O’Mahony D et al, *Age Ageing* 2015;44(2):213–218).

OTC medications

Often overlooked, OTC medications can significantly impact a patient’s medication profile. Review commonly used OTC medications like antihistamines (in cold and flu products, antiemetics, and sleep preparations), proton pump inhibitors, and nonsteroidal anti-inflammatory drugs with every patient. Pay attention to “PM” sleeping aids, which often contain anticholinergic activity.

Acknowledge patient vulnerabilities

Identify each patient’s vulnerabilities to guide discussions about potential side effects. Ask about past adverse medication experiences, considering:

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THE CARLAT REPORT: GERIATRIC PSYCHIATRY

Addressing Polypharmacy in Older Adults

Continued from page 6

- Frailty
- Cognitive impairment
- Appetite changes

Simplify medication regime

Try to use medications that address multiple symptoms at once. Look for regimens that require fewer daily doses to minimize the pill burden (eg, using extended-release drug formulations).

Ms. Andrews' hallucinations resolve after she finishes the ciprofloxacin course. You explain that her nighttime medications (especially ibuprofen PM, which contains diphenhydramine) may have increased her risk for delirium. After learning that her OTC medication can affect her cognition, she decides to discontinue it.

Monitor for adverse events and prescribing cascades

This patient's use of ibuprofen PM could have gone under the radar for a long time. As clinicians, we should proactively ask about symptoms that patients might not report, such as changes in memory, urinary incontinence, and orthostasis.

Think of new symptoms as medication related until proven otherwise and remain vigilant for prescribing cascades—when one drug leads to another due to side effects, creating a domino effect of prescriptions (Rochon P and Gurwitz J, *Lancet* 2017;389(10081):1778–1780). Example cascades include:

- Prescribing medications for urinary incontinence after starting a cholinesterase inhibitor
- Starting antihypertensives after prescribing stimulants or venlafaxine
- Adding medications for nausea or constipation after starting a selective serotonin reuptake inhibitor

Questions to Minimize Polypharmacy

- Is the new medication being prescribed to treat side effects from the first medication?
- Is the first medication necessary?
- Can the first medication be substituted with a safer alternative? Is there a non-pharmacologic alternative?
- Can the first medication be prescribed at a lower dose?

Psychotropic Medications With Adverse Effects

Medication Class	Risks
Anticholinergics	<ul style="list-style-type: none"> • Anticholinergic toxicity • Increased risk of cognitive decline in patients with delirium or dementia
Antipsychotics	<ul style="list-style-type: none"> • Confusion, extrapyramidal symptoms (EPS), falls when used long term (over one month) • May worsen EPS when used long term (over one month) in Parkinson's disease or Lewy body dementia • Increased risk of stroke and death in patients with dementia
Barbiturates	High risk of dependence, overdose
Benzodiazepines; benzodiazepine receptor agonist hypnotics (Z-drugs)	<ul style="list-style-type: none"> • Prolonged sedation, confusion, delirium, impaired balance, falls, motor vehicle accidents • Risk of substance use disorder when used for over one month
First-generation antihistamines	Sedation and anticholinergic effects
Opioids	<ul style="list-style-type: none"> • Exacerbation of cognitive impairment • Drowsiness, postural hypotension, vertigo • High risk of dependence, overdose
Selective serotonin reuptake inhibitors (SSRIs)	<ul style="list-style-type: none"> • Significant hyponatremia (<130 mmol/L; confusion, altered mental status, fatigue) • QT prolongation (citalopram, escitalopram)
Tricyclic antidepressants	<ul style="list-style-type: none"> • Worsening cognitive impairment • Potential to induce or worsen delirium

Source: O'Mahony D et al, *Age Ageing* 2015;44(2):213–218

Ms. Andrews discontinues quetiapine after you determine that her hallucinations were likely secondary to her UTI. She is agreeable to a trial of lowering her amitriptyline dose to 25 mg QHS after you explain the physiologic effects of aging on drug metabolism.

Specific medication classes

Although many psychiatric medications increase fall risk and affect cognition in OAs, a few stand out:

- Benzodiazepines and benzodiazepine receptor agonists (eg, zolpidem and zopiclone)
- Certain antidepressants and mood stabilizers
- Antipsychotics
- Strong anticholinergic medications

For more information, visit www.thecarlatreport.com/highriskmedsolderadults and www.thecarlatreport.com/anticholinergicactivity.

Sedatives, anxiolytics, lithium, and antipsychotics significantly increase emergency department (ED) visits compared to other psychiatric medications. Zolpidem has been implicated in adverse drug event-related ED visits more frequently than any other psychiatric medication, especially among OAs (Hampton LM et al,

JAMA Psychiatry 2014;71(9):1006–1014).

When using sleep aids, peel back these medications first and encourage consideration of other treatments, including good sleep hygiene and relaxation techniques. If behavioral interventions aren't enough, consider switching to a medication with fewer risks (eg, melatonin or ramelteon).

End-of-life care considerations

Goals of care discussions often prompt reconsideration of a patient's medications:

- Discontinue medications when the benefits materialize after weeks or months, possibly exceeding a patient's life expectancy.
- Shift focus to maximize quality of life. Reach for high-risk medications, such as opioids, sedatives, and anticholinergics, to make the patient comfortable (for more on end-of-life care, see *CGPR* Oct/Nov/Dec 2023).

CARLAT VERDICT

Address polypharmacy, especially after hospitalizations, transitions of care, and when multiple clinicians are involved. Engage patients and their families in shared decision making to ensure optimal prescribing.

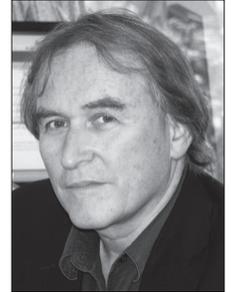
Q & A
With
the Expert

Decoding Drug Promotion Tactics in Geriatric Psychiatry

David Healy, MD, FRCPsych

Chief Scientific Officer, Data Based Medicine Ltd, Bangor, Wales, UK.

Dr. Healy has no financial relationships with companies related to this material.



CGPR: Why is it important for psychiatrists to be aware of company marketing strategies?

Dr. Healy: Pharmaceutical companies use randomized controlled trials (RCTs) and evidence-based medicine as key strategies to influence doctors. They also engage in apparent conflicts of interest through interactions with sales reps, free lunches, and control over continuing medical education. However, these conflicts are nothing compared to industry influence on published studies. Medical journals frequently carry articles that endorse drugs and minimize their risks, even reporting negative studies as positive. These ghostwritten articles are the true advertisements, going unquestioned. Psychiatry, historically at the forefront with its specialist journals, hospitals, and early RCTs, has not been immune to pharma's influence.

CGPR: What's the scale of pharma marketing to physicians versus the public?

Dr. Healy: Once our drugs became prescription only, doctors became the primary consumers for pharmaceuticals, prescribing medications without personal cost or health risks. This unique consumer status means that the industry targets physicians intensely: In the US, there is roughly one physician per 329 people, a small consumer base with a huge financial return. Data from the US show that the average number of prescriptions per person has increased over the past few years (www.cbo.gov/publication/57772). That's potentially thousands of pills per person each year. Some medications cost as much as a cell phone, making doctors the critical gateway to this lucrative market. Researchers have tried to find good data on the proportion of industry spending on marketing to doctors compared to industry-funded scientific research spending (Schwartz LM and Woloshin S, *JAMA* 2019;321(1):80-96). It's hard to nail down, but the consensus is that much more goes into marketing. But we really should ask "What does industry spend on research other than market research?"

CGPR: Can you speak about the influence of pharmaceutical companies on clinical trials?

Dr. Healy: The post-thalidomide 1962 amendments to the Food and Drugs Act, which were intended to regulate the pharmaceutical industry, instead resulted in greater industry control of medicine. These regulations, which remain in place today, state that before marketing a drug, companies have to prove that their drugs are not only safe but efficacious. Companies now only need two positive placebo-controlled trials to get a license (one positive trial if the medication is granted accelerated approval). Roughly half of the antidepressant trials submitted for approval between 1990 and 2008 were negative (Turner EH et al, *N Engl J Med* 2008;358(3):252-260). Alarmingly, although some trials remain unpublished, many negative trials were published as positive.

CGPR: Do you have an example?

Dr. Healy: Pediatric depression trials were universally negative but published as positive. In 2012, GlaxoSmithKline submitted three depression trials to the FDA and told the FDA that these trials were negative. However, Study 329, the main trial, had already been published as glowingly positive. In the adult trials leading to market approval, 11 studies were published in a way that conveyed a positive outcome, even though the FDA viewed these studies as having negative or questionable results. These examples are all listed in an appendix to Erick Turner's 2008 article (Turner et al, 2008).

CGPR: How can understanding the limitations of published data help us improve our care?

Dr. Healy: As doctors, we tend to believe medical experts and publication journals like the *New England Journal of Medicine*. We may benefit from increasing our skepticism and closely watching our patients—they may not show the benefits that the articles claim, or they may experience hazards that an article denies—but we should believe the patient. (*Editor's note: We recommend taking a patient seriously when they think a medication causes side effects, even if it's not due to a published drug reaction. Work collaboratively to come up with a plan that may involve decreasing the dose or discontinuing the medication.*)

CGPR: Are there specific issues with older patients?

Dr. Healy: There are. Pharmaceutical companies and regulators set low benchmarks for drug approval, like slight improvements (two or three points) on activities of daily living scales for antimentia drugs, without providing real clinical benefits or improving survival rates. Often, these drugs show increased mortality and serious adverse events with active treatment. Psychotropic drug trials in older people are rare, with companies using adult trials for marketing. An unpublished company trial I led compared paroxetine against a tricyclic in older adults (OAs), designed to investigate cognitive function; paroxetine's unfavorable results kept it out of journals. Industry practices among the elderly have also misbranded anticholinergic drugs as causing antidepressant side effects actually triggered by serotonergic or catecholaminergic effects (Healy D, *The Adv Psychopharmacol* 2023;13:20451253231176375). This has led to misrepresentation of many drugs as anticholinergic, resulting in the unnecessary discontinuation of effective, cheaper drugs.

Continued on page 9

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Expert Interview – Decoding Drug Promotion Tactics in Geriatric Psychiatry

Continued from page 8

CGPR: Do you have any examples?

Dr. Healy: Absolutely. One example is oxybutynin, which is now often replaced by mirabegron due to concerns about oxybutynin's anticholinergic activity. Over half the drugs listed to reduce anticholinergic burden don't affect cholinergic systems (Lavrador M et al, *Pharmaceutics* 2023;15(1):230). When selective serotonin reuptake inhibitors or anticonvulsants cause problems, for example, it is commonly incorrectly attributed to their anticholinergic actions.

CGPR: Are there other ways marketing has influenced the rise of polypharmacy in OAs?

Dr. Healy: Yes indeed. In the 1980s, company marketing led doctors to treat risk factors like minimally raised blood pressure or glucose levels, dramatically impacting polypharmacy among OAs. We no longer accept natural age-related increases in blood pressure and glucose—and we now have more hospital admissions because of drugs used to manage risks than we have from osteoporosis, hypertension, or diabetes. Ironically, older people are often wary of polypharmacy, preferring to reduce their medication burden with their doctor's approval (Rubin R, *JAMA* 2023. Epub ahead of print). However, aligning medical advice with this preference is challenging.

Clinicians, aiming to adhere to guidelines for various risk factors, find themselves in a legally defensible position, yet this stance conflicts with more person-centered guidelines, which advise limiting patients to no more than three medications when possible. (*Editor's note: For more information, see article on "Addressing Polypharmacy in Older Adults" in this issue.*)

CGPR: You have often mentioned rating scales as a marketing tool—do these affect diagnosis and treatment among OAs?

Dr. Healy: ADHD drugs offer an extreme example. The ADHD drugs for children brought ADHD rating scales in their wake. While there is a clear disorder we call ADHD, scales asking about abilities to focus led to an overdiagnosis of adult ADHD (Harrison AG and Edwards MJ, *J Atten Disord* 2023;27(12):1343–1359). Now, if people in their 60s report concentration problems, their doctor might give them an ADHD scale with a high score leading to an ADHD diagnosis and medication, when until recently ADHD often resolved in the teenage years. A high score on a screening tool now trumps clinical judgment.

CGPR: What use do companies make of other indirect strategies to inform clinicians about their products?

Dr. Healy: In addition to rating scales, companies have long been adept at selling diseases in order to sell the product. It's only later that their drug turns up as the "solution" to that problem. These strategies are common and shape our perspectives and treatment choices. Examples include elevated blood pressure, cholesterol, and glucose levels—they are all risk factors of minimal importance if the rest of a patient's risk profile is relatively safe, but companies aggressively market them as serious problems.

CGPR: How can clinicians best communicate with OAs about their medication choices?

Dr. Healy: As with everyone these days, OAs access guidelines but may be unaware that these are based primarily on commercial exercises companies carry out. Even real RCTs only reveal average drug effects; they do not tell us how to treat the person in front of us. All science, particularly in clinical practice, relies on building a consensus that includes the patient's perspective, especially when their experiences diverge from established evidence. The critical question isn't just about communicating effectively with patients. Rather, it's asking "Can we create a situation where we hear what our patients have to say?"

CGPR: Where can we find unbiased medication information?

Dr. Healy: The only point today at which we have full access to the data in giving a pharmaceutical is when we have a patient in front of us. The patient has no reason to mislead us, particularly if the patient is having problems. If at the end of the day the consensus is that the drug has caused the problem, then this is the scientific method in operation in clinical practice.

CGPR: Thank you for your time, Dr. Healy.

"Companies are adept at selling diseases to sell the product, which can shape our perspectives and treatment choices.

Examples include elevated blood pressure, cholesterol, and glucose levels—they are all risk factors of minimal importance if the rest of a patient's risk profile is relatively safe."

David Healy, MD, FRCPsych

News of Note

Advances in Alzheimer's Diagnosis: AIRAmed and Labcorp

The FDA recently greenlit AIRAscore, a promising brain volumetry software from German medical tech company AIRAmed. Designed to assist clinicians in diagnosing Alzheimer's disease (AD), as well as to help differentiate other dementias and neurological conditions, AIRAscore uses deep learning and artificial intelligence to analyze MRI scans in just five minutes. It offers precise measurements of different brain areas and structures, comparing them to a vast reference population, and even correcting for factors like age and sex. The result? Data that are as easy to digest as your typical lab report. After being used in Europe for four years, AIRAscore is expected to appear in the US early this year.

Parallel to AIRAmed's strides in brain imaging, LabCorp is enhancing blood biomarker diagnostics for AD through its ATN

Profile. This diagnostic tool identifies amyloid plaques, tau tangles, and neurodegeneration, helping clinicians detect and interpret these biomarkers. A positive result on ATN Profile would require further confirmation via CSF biomarkers or PET scan, but patients with a negative finding could be spared these invasive procedures.

Although we are hopeful that these tools will positively change the management of AD, we would like more research to suggest that they improve patient outcomes. Keep in mind the indirect harms of positive screening results, including additional workup, stigma, and patient and caregiver anxiety.

—**Stephanie Collier, MD.** Dr. Collier has no financial relationships with companies related to this material.

DEMENTIA

MIND Diet: A Potential Path to Cognitive Resilience

Neha Jain, MD, FAPA. Dr. Jain has no financial relationships with companies related to this material.

REVIEW OF: Dhana K et al, *J Alzheimers Dis* 2021;83(2):683–692

STUDY TYPE: Prospective cohort study

The MIND diet, a fusion of the Mediterranean and Dietary Approaches to Stop Hypertension (DASH) diets, has previously been associated with a reduced risk of dementia in cognitively intact older adults (OAs) (Morris MC et al, *Alzheimers Dement* 2015;11(9):1007–1014). But are there potential benefits on cognitive function in OAs with existing brain pathologies like mild cognitive impairment and Alzheimer's disease (AD)?

This prospective cohort study involved 569 OAs enrolled in the Rush Memory and Aging project. Participants underwent neuropsychological testing, and researchers assessed their dietary habits by asking about their usual consumption frequency of 144 food items over the past year. The MIND diet score was calculated as the sum of 15 component scores, including:

- Ten brain-healthy food groups: green leafy vegetables, other vegetables, nuts, berries, beans/legumes, fish, olive oil, whole grains, poultry, wine
- Five unhealthy food groups: red meat, fried/fast foods, sweets, butter, cheese

Subjects enrolled in the study were followed until their deaths. Autopsies were conducted to examine brain pathology.

Researchers found that two-thirds of the participants had dementia pathology postmortem, though only one-third received a clinical AD

diagnosis around the time of death. They observed an association between higher MIND diet scores and higher cognitive scores, as well as a slower decline in cognitive scores. The MIND diet was not associated with brain pathology, suggesting that its mechanism supporting cognitive resilience works in an unrelated manner.

CARLAT TAKE

This well-designed, population-based study generated results consistent with the hypothesis that the MIND diet is associated with improved cognitive function, independent of other risk factors for dementia. However, correlation does not imply causality. It is possible that people with dementia or cognitive limitations may choose less healthy foods due to their cognitive impairments. Also keep in mind that minoritized older adults often live in food deserts without access to healthy foods and/or lack financial resources to purchase foods advised through the MIND diet. Nonetheless, the MIND diet is based on diets that have known cardiovascular benefits, which in turn may improve brain health. We recommend management of modifiable cardiovascular risk factors such as hypertension and smoking in addition to following a brain-healthy diet (green leafy vegetables, berries, olive oil, beans, whole grains, and fish) and limiting processed foods and saturated fats. For more on the MIND diet, see www.tinyurl.com/2z42nmkw.

Large Longitudinal Study Links Mild Depression and Dementia

Kathryn Kieran, MSN, PMHNP-BC. Ms. Kieran has no financial relationships with companies related to this material.

REVIEW OF: Zhu Y et al, *Age Ageing* 2022;51(1):afab191

STUDY TYPE: Prospective cohort study

Depression in older adults (OAs) is correlated with dementia, but we don't know exactly how. Does depression

lead to the development of dementia? Or is it a prodromal condition in people who are fated to develop dementia? If depression causes dementia, we would be even more motivated to treat it aggressively in OAs.

Previous studies suggested that persistent or worsening depression is associated with cognitive decline. However, these studies were short term (<3 years), limiting our understanding about how the course of depression over many years may affect cognition.

To try and understand the connection, researchers combined data from two large cohort studies (one from the US and one from England) of community-dwelling adults 50 years and older. A total of 17,556 participants were followed over 18 years and evaluated for both depression and cognitive performance annually.

The results were in line with prior studies. There seemed to be a dose-response relationship between depression and cognitive decline. The "mild depressive symptoms" group had half the cognitive decline of the "worsening" and "persistent depressive symptoms" groups. The most interesting finding here is that even those with subclinical depression symptoms were at increased dementia risk.

The sample was heavily White and female, which limits generalizability. The very brief and slightly different executive function assessments between studies, and lack of evaluation or adjustment for genotypes such as apolipoprotein E that modify the association between depression and dementia, mean this study may be affected by information and confounding biases.

CARLAT TAKE

You'd be forgiven for expecting big things of this study, with such a large cohort. It provides more evidence of a relationship between depression and cognitive decline, but doesn't resolve whether depression is a prodrome versus an independent risk factor for dementia—it may well be both.

CME Post-Test

To earn CME or CE credit, log on to www.TheCarlatReport.com to take the post-test. You will be given two attempts to pass the test. You must answer 75% of the questions correctly to earn credit. Tests must be completed within a year from each issue's publication date. The Carlat CME Institute is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. Carlat CME Institute maintains responsibility for this program and its content. Carlat CME Institute designates this enduring material educational activity for a maximum of two (2) *AMA PRA Category 1 Credits*TM. Physicians or psychologists should claim credit commensurate only with the extent of their participation in the activity. This page is intended as a study guide. Please complete the test online at www.TheCarlatReport.com. Learning Objectives are listed on page 1.

1. What is the first-line treatment of insomnia in older adults (OAs) (LO #1)?
 a. Z-drugs
 b. Cognitive behavioral therapy for insomnia
 c. Caffeine cessation
 d. Melatonin supplementation
2. Which medication is responsible for the most adverse drug event-related emergency department visits in OAs (LO #2)?
 a. Diazepam
 b. Lorazepam
 c. Zolpidem
 d. Aripiprazole
3. What regulatory requirement must pharmaceutical companies meet to qualify for FDA approval (LO #3)?
 a. Companies must provide evidence of safety, but not efficacy
 b. Six of 11 placebo-controlled trials must yield positive results
 c. Two positive trials are sufficient for licensing, while one is adequate for accelerated approval
 d. All trial results must be published, favorable or not
4. True or false: A 2021 study on the MIND diet and cognition found no association between the MIND diet and brain pathology (LO #4).
 a. True
 b. False
5. Which of the following can be a low-cost option for the treatment of insomnia in OAs (LO #1)?
 a. Doxepin
 b. Quetiapine
 c. Suvorexant
 d. Daridorexant
6. According to Dr. Greenstein, clinicians should exercise greater caution when prescribing cannabis in which of the following scenarios (LO #2)?
 a. Patients taking warfarin
 b. Patients with Parkinson's disease dementia
 c. Patients with insomnia
 d. Patients with a history of substance abuse
7. According to Dr. Healy, what is a common clinician mistake due to influence from pharmaceutical companies when treating OAs (LO #3)?
 a. Undertreating age-related increases in blood pressure, cholesterol, and glucose
 b. Overdiagnosis of adult ADHD due to overreliance on pharma-promoted rating scales
 c. Making OAs wary of polypharmacy, leading to discontinuation of their medications
 d. Promoting drug-seeking behavior through the use of rating scales
8. Which of the following was a key finding of a 2021 study on the MIND diet and cognition (LO #4)?
 a. Dementia diagnosis was not associated with worsening depressive symptoms
 b. Subclinical depression was not linked to moderate cognitive decline
 c. Those with persistent depressive symptoms experienced twice the cognitive decline of those with mild depressive symptoms
 d. White females were the group at the highest risk of dementia

Managing Insomnia in Older Adults

Continued from page 3

After joining a gym, starting ramelteon 8 mg oral nightly for one month, and implementing basic CBT-I principles, Mr. Johnson sees a 20-minute improvement in sleep onset in his sleep diary.

CARLAT
VERDICT

Addressing comorbidities and reducing risk factors is a good first step in improving sleep. CBT-I is the first-line treatment for insomnia in OAs. Try to avoid benzodiazepine receptor agonists. If a patient needs a short-term medication, then DORAs, ramelteon, and doxepin are FDA approved for insomnia. For patients who may have difficulty affording newer medications, use generic doxepin or ramelteon. Melatonin is also a safe and affordable alternative.

THE CARLAT REPORT GERIATRIC PSYCHIATRY

P.O. Box 626
Newburyport, MA 01950

This Issue:
**Minimizing Drug Risks
in Older Adults**
January/February/March 2024

Next Issue:
**Ethical Issues in
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Expert Interview – Cannabis Use for Managing Agitation — in Dementia

Continued from page 5

CGPR: Given your experience with cannabis products, how do you track patient outcomes?

Dr. Greenstein: I rely on standard agitation scales, such as the NPI-Q or the Pittsburgh Agitation Scale. I also use the Caregiver Strain Index when appropriate to gauge patient well-being based on caregiver distress.

CGPR: How do legal aspects of prescribing cannabis vary? What precautions should be taken when patients can't provide informed consent?

Dr. Greenstein: Legal aspects are complex and vary by state. In Colorado, for instance, individuals (and their guardians) can consent to cannabis use. If prescribing to those who can't fully consent, consult an attorney regarding liability. There are associated risks, and we should be prepared for adverse reactions. I clarify to all my patients that any cannabis product they use is obtained independently, as I do not prescribe cannabis or certify a medical cannabis license for dementia-related agitation. I do, however, provide guidance to patients and families who are considering cannabis after standard treatments have failed or were poorly tolerated. Cannabis is far from a panacea, but it appears to have clinical benefits that we are just starting to define.

CGPR: Thank you for your time, Dr. Greenstein.

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