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Chris Aiken, MD
Editor-in-Chief

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IN THIS ISSUE

Focus of the Month:
Mental Health Apps

Learning Objectives
After reading these articles, you should be able to:

1. Identify the strengths and weaknesses of current options for sexual dysfunction in women.
2. Evaluate the benefits of mental health apps for engaging patients in treatment.
3. Summarize some of the current research on psychiatric treatment.

Treating Sexual Dysfunction in Women

Adam Strassberg, MD. Dr. Strassberg treats sexual dysfunction through his private practice in Silicon Valley, CA.

Dr. Strassberg has disclosed that he has no relevant financial or other interests in any commercial companies pertaining to this educational activity.

Highlights From This Issue

Vyleesi and Addyi are FDA approved for low libido in women, but their benefits are modest and their risks give us pause.

A host of anti-inflammatory medicines are effective in treatment-resistant depression, particularly celecoxib.

Prescription apps have arrived, but Dr. Torous reminds us that the key ingredient in a mental health app is the therapeutic relationship.

With the marketing of two new treatments for female sexual dysfunction, one thing is certain: You can expect to see more patients asking for these medications. What's less certain is whether they will work. Flibanserin (Addyi) and bremelanotide (Vyleesi), the two FDA-approved treatments, both have small effect sizes (0.3–0.4) on various measures of libido.

In this article, I will review the assessment of sexual dysfunction in women and give you a brief survey of both FDA-approved and off-label treatments for this disorder.

Evaluation of sexual dysfunction

There are several types of sexual dysfunction, including low sexual desire, difficulty achieving orgasm, and sexual pain. The most common type of sexual problem in women is low libido, affecting about 40% of all women. Of this 40%, about 1 in 4 report significant distress regarding the low libido, and this distress is one of the criteria necessary for female hypoactive sexual desire disorder (FHSDD) (Shifren JL et al, *Obstet Gynecol* 2008;112(5):970–978).

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Q&A With the Expert

Using Mental Health Apps
John Torous, MD, MBI

Director of the digital psychiatry division, Department of Psychiatry at Beth Israel Deaconess Medical Center, Boston, MA

Dr. Torous has disclosed that he has no relevant financial or other interests in any commercial companies pertaining to this educational activity.

TCPR: Computer-assisted therapies have been around for decades. What makes mental health apps different?

Dr. Torous: Computers have been used to support psychotherapy in many forms—email, video conferencing, texting, and online or desktop programs. Mental health apps take this to another level because they work through a device that most people keep with them 24/7: their smartphone. One of the problems with computer therapy programs was that patients didn't stick with them. Apps have the potential to be more engaging.

TCPR: How do patients get these?

Dr. Torous: Anyone can download these programs from the app store on their smartphone. There are apps that remind patients to take their medication, or that connect them to peer support networks or directly to their provider through telepsychiatry. There are apps that guide patients through behavioral

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Treating Sexual Dysfunction in Women

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Before making the diagnosis of FHSDD, you must rule out medical causes. I typically coordinate with the PCP or OB-GYN and screen for hypertension, diabetes, thyroid disorders, urinary incontinence, elevated prolactin, amenorrhea, and other gynecological conditions. Vitamin D is worth checking; correcting this common deficiency improved libido in an open-label study of 47 women (order as Vitamin D, 25-hydroxy; ICD-10 code E55.9) (Krysiak R et al, *Endokrynol Pol* 2018;69(2):168–174).

Common psychiatric causes of FHSDD include substance use disorders, anxiety, OCD, and depression. Depression comes with a 50%–70% increased risk of sexual dysfunction, and conversely, sexual dysfunction multiplies the risk of depression by 1.3–2.1. Antidepressants, antipsychotics, and mood stabilizers can cause sexual side effects (see *TCPR* May 2019 for antidotes to these side effects).

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Non-medication treatment

Sex therapy, both individual and couples, can be very effective, as can mindfulness and cognitive behavioral therapy. The aim of mindfulness is to reduce distraction and increase awareness of pleasure during sex, while CBT works by altering underlying beliefs and behaviors that contribute to the problem (Clayton AH et al, *Mayo Clin Proc* 2018;93(4):467–487).

FDA-approved medications

After I've dealt with modifiable risk factors, I consider what, if any, medication options I can offer women with low or absent libido (see table below).

There are two FDA-approved options: flibanserin and bremelanotide. Neither one is my first choice, for reasons I'll explain below.

Flibanserin (Addyi)

Flibanserin is a mixed serotonin agonist/antagonist that had originally been tested—unsuccessfully—as an antidepressant. There was, however, a small signal of improved sexual function in those studies, which led to specific trials for the treatment of FHSDD. In controlled trials, about 50% of over 3500 women responded to flibanserin. The gains, however, were modest: Participants reported an additional 0.5–1 more satisfying sexual encounters per month as a result of treatment, and a small to moderate effect size (0.2–0.5) on various measures of sexual functioning (Pyke RE & Clayton AH, *Sex Med Rev* 2018,6(3):358–366). Although it is approved only for *pre*menopausal women, it is effective in *post*menopausal women and presents no specific dangers in that group (Simon JA et al, *Menopause* 2014;21(6):633–640).

Flibanserin's starting and target dose is 100 mg at night, and its effects build up over a month. Side effects include dizziness (9%), somnolence/fatigue (4%–8%), and nausea (7%). In theory, its antidepressant-like effects on serotonin, dopamine, and norepinephrine could trigger mania, and though this has not been officially reported, I have seen it happen in practice.

Flibanserin has a black box warning about hypotension and syncope with alcohol, a potentially dangerous reaction that was seen in 1 in 5 people who took the medication along with two 12-ounce cans of beer. The FDA relaxed

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Treatments for Sexual Dysfunction in Women

Agent	Dose	Notes
Bremelanotide (Vyleesi)	1.75 mg SC injection PRN, 45 minutes before sex.	FDA approved, but benefits are small. SE:[1] nausea (40%), hypertension, and potentially permanent skin discoloration (1%).
Bupropion XL (Wellbutrin)	300–450 mg QAM.	Modest benefits.
Buspirone (Buspar)	15–60 mg divided BID to TID.	Lacks controlled trials.
Flibanserin (Addyi)	100 mg nightly.	FDA approved, but benefits are small. SE: syncope when taken with alcohol.
Maca root	3,000 mg daily.	Good products: Nutrigold Maca Gold capsules, Maca Magic powder, Gaia Herbs Gelatinized Maca powder ($3–$10/month).
Saffron	15 mg BID.	Good products: Swanson Superior Herbs, Elixir, BCN Saffron Ultra ($10–$20/month).
Testosterone transdermal patch	300 mcg/day transdermal patch applied 2x/week. Requires a compounding pharmacy to create this low dose. Monitor serum testosterone to avoid supraphysiologic levels.	Not FDA approved, but licensed in Europe for postmenopausal women. Potential long-term risks (breast cancer, heart disease) warrant coordination with PCP, OB-GYN, or endocrinologist. SE: acne, breast pain, headache, weight gain, hirsutism.
Zestra (botanical cream)	Apply vaginally before sex.	SE: mild burning sensation. Available at www.zestra.com.

[1]SE = side effects

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that warning in September 2019, eliminating the REMS system that required patients and providers to register for the drug, and advising women to avoid alcohol within 2 hours of their flibanserin dose instead of avoiding it entirely. That may be a safe strategy for some, but the 2-hour window may not be enough if the drinking is excessive or if the patient has a history of hypotension or takes a CYP3A4 inhibitor (which would raise flibanserin levels).

Cost can be a hindrance, but the company has new programs to ease that. Patients can receive their first 8 weeks of medication free, regardless of insurance coverage (https://hcp.addyi.com). Currently, the average cost per 30 tablets of 100 mg of Addyi is in the $400 range without health insurance coverage or discounts (see www.goodrx.com/addyi).

Bremelanotide (Vyleesi)

See the News of Note on page 5 for details on this recent release, which the FDA approved in June 2019. Briefly, bremelanotide is a self-injected hormone analogue that is used as needed before sexual encounters.

Off-label medications

Though off-label, bupropion (Wellbutrin) is my first choice among FHSDD medications. It is safer, cheaper, and better tolerated than the current FDA options. It helps for many psychiatric comorbidities, and there are a few RCTs to support its use in low libido. In a randomized, double-blind, placebo-controlled trial in non-depressed women, it had modest benefits for orgasm, arousal, and sexual satisfaction at 300–400 mg/day (Segraves RT et al, *J Clin Psychopharmacol* 2000,20(2):122–128). This result supports earlier bupropion studies in mixed-gender populations—one other randomized double-blind placebo-controlled trial (Crenshaw TL et al, *J Sex Marital Ther* 1987;13(4):239–252) and a single-blind prospective study (Modell JG et al, *J Sex Marital Ther* 2000;26(3):231–240).

After a bupropion trial, I often consider buspirone, particularly if an anxiety disorder is present. Although buspirone's clinical studies are limited to SSRI-induced sexual dysfunction, its mechanism suggests that it could treat FHSDD as well through 5-HT_{1A} partial agonism.

Naturopathic treatments

I also find naturopathic treatments useful, particularly when they align with the patient's preference.

Zestra is a proprietary botanical cream worth trying in FHSDD. In two randomized controlled trials, it improved desire and arousal in 276 women (Ferguson DM et al, *J Sex Marital Ther* 2010;36(1):66–86). It is applied vaginally before sex, and the main side effect is a mild burning sensation on application that was reported by 14% of women. It is available over the counter at www.zestra.com.

Two other naturopathic agents to consider are saffron and maca root. Both have multiple controlled trials in antidepressant-induced sexual function, and may work for FHSDD as well. Saffron improved multiple phases of sexual activity: desire, lubrication, and orgasm. It is well tolerated and has promising studies in depression, weight loss, and ADHD. Maca root has testosterone- and estrogen-like effects, and is also well tolerated.

Testosterone

Though rejected by the FDA in 2004, transdermal testosterone has been approved in Europe since 2007 for FHSDD in postmenopausal women. This patch notably improves sexual desire and the frequency of satisfying sexual events, doubling those events from 2–3/month up to 5/month, in multiple trials of postmenopausal women with FHSDD. Benefits build gradually over several weeks to months, and a 6-month trial is necessary to evaluate its effects. There are no studies of transdermal testosterone in women of reproductive age.

Testosterone is reasonably safe and well tolerated in the short term, with no serious adverse effects found in a meta-analysis of 36 randomized controlled trials (Islam RM et al, *Lancet Diabetes Endocrinol* Jul 25 2019 [Epub ahead of print]). Side effects include acne, breast pain, headache, weight gain, and hirsutism. The problem is that long-term use could cause breast cancer or cardiac disease, and we don't have reliable safety data beyond 2 years. For distressed patients, consider a referral to endocrinology for transdermal testosterone as a second- or third-line agent. Endocrinologists can better evaluate and monitor its risks.

TCPR VERDICT: Screen for FHSDD with direct questions. Before jumping to treatment, look for modifiable causes. Referrals are often needed (to couples or sex therapy, primary care, OB-GYN, or endocrinology). After therapy, bupropion is a good first choice. Flibanserin and bremelanotide may have larger studies, but they have small benefits and concerning side effects.

How Much Sex Is "Normal"?

There's no such thing as a normal amount of sex, but we do have a good sense of the statistical averages. The best data are from the General Social Survey (GSS), run by the University of Chicago's National Opinion Research Center. Average frequency of sexual intercourse is 1–2 times a week for married couples 18–60 years old, once every 2 weeks for couples in their 60s, and once every 3 weeks for partners in their 70s and up (See Frequency of Sexual Intercourse in Marriage table).

Around 2% of married couples reported no sexual intercourse in the past year. Sex therapists define a "sexless marriage" as one in which the couple has sex 10 times or less per year, in which case 20% of couples in the 1994 GSS survey qualify as "sexless."

The desire for sex varies widely, and though mismatched desire is a common problem for couples, that is not necessarily the same thing as hypoactive sexual desire disorder, where the low libido is personally distressing. Changes to libido are natural over time, rising and falling in response to personal events or partner-related issues. In both genders, libido decreases with age.

Frequency of Sexual Intercourse in Marriage

Age range	Intercourse (mean number of events per month)
18–29	9
30–39	7
40–49	6
50–59	4
60–69	3
70+	1

Source: General Social Survey (GSS)

Expert Interview

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psychotherapies, using audio/video narration or interactive programs. There are even video game apps with therapeutic benefits. Patients are starting to use these health apps, and they may not be telling you. That can be a problem because most of the apps that are available are poorly designed and lack research support. Some give bad advice—like telling people with bipolar disorder to drink alcohol to sleep. On the other hand, those that have good studies behind them are often not available to the public (see table below). Some of the better-studied apps are coming out as prescription-only products that are approved by the FDA as "digital therapeutics."

TCPR: How does a prescription app work, exactly?

Dr. Torous: Right now there's just one that's FDA approved in psychiatry, reSET Connect by Pear Therapeutics, which is for addictions. The app is available for anyone to download, but to actually use it, patients need a prescription code, which they get when their physician enrolls them (www.resetconnect.com). The app has 61 CBT-based educational modules which patients are supposed to complete 3–4 times a week. The doctor then monitors the progress and enters the patient's urine screen results on a separate dashboard. Patients get rewards, including gift cards, for sobriety. So it's an app, but it's really an interactive, therapeutic program that uses well-known behavioral techniques.

"Patients are starting to use health apps and they may not be telling you, which can be a problem because most of the apps that are available are poorly designed and lack research support. So you want to consider privacy, evidence, and ease of use. Some of the better-studied apps are coming out as prescription-only products that are approved by the FDA as digital therapeutics."

John Torous, MD, MBI

Evidence-Based Apps

CBT		*IntelliCare* is a series of NIH-funded CBT-based apps for anxiety, depression, and insomnia. The full suite is at http://intellicare.cbits.northwestern.edu/ and individual modules are in most app stores.
Deep breathing		*Breathe2Relax* teaches deep breathing exercises.
Insomnia		*CBT-i Coach* is a free app that helps patients track their progress in CBT-Insomnia.
Mindfulness		*Stop, Breathe & Think* is an accessible mindfulness app. Other mindful options include *Insight Timer, Smiling Mind, iMindfulness,* and *Mindfulness Daily.*
Mood charting		*DBSA Wellness Tracker* teaches patients how to rate their mood in a daily chart. Most other mood trackers focus on emotions rather than symptoms that are more specific to mania and depression.
Suicidality		*Virtual Hope Box* reminds clients of reasons to live and employs CBT-based crisis survival skills for suicidality.
Med reminders		*Medisafe* was the top-ranked app in a systematic review of 272 options. For privacy, it can be used without registering. The free version works fine, but $4 a month gets reminders in Barack Obama's voice and a host of other features.

TCPR: What kind of evidence does it have?

Dr. Torous: FDA requirements aren't as rigorous for apps as they are for medications because the FDA views these devices as low risk. In reSET's case, approval was based on a 3-month randomized controlled trial that compared reSET to usual care in 399 patients with alcohol, cocaine, marijuana, or stimulant use disorders. Abstinence rates were about double with the reSET app (40% vs 18%). There's also reSET-O, approved for opioid use disorders. That one had a 3-month, unblinded, randomized controlled trial that was partially positive. Unlike with other substances, the program didn't improve abstinence from opioids, but it did help patients stay in treatment longer (82% vs 62%). Interestingly, both trials used a desktop computer version of reSET, even though it was approved as an app.

TCPR: What else is in the pipeline?

Dr. Torous: Some of the CBT-insomnia apps are seeking FDA approval. There's also a video game for ADHD in the works called "Project Evo." The game requires children to multitask, such as steering a boat down a river while tapping on fish that pop up. There's also an element of impulse control—players have to avoid tapping on certain-colored fish or birds. The game adapts to the player's skill in real time—it gets harder or easier—which keeps it from getting too frustrating or boring (Yerys BE et al, *J Autism Dev Disord* 2019:49(4):1727–1737).

TCPR: Is the game fun?

Dr. Torous: I would guess so. Adherence rates were very high. Children were supposed to play it for 30 minutes each day, but there was some concern that it could get addictive, so it shuts off for the day after 45 minutes of play.

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News of Note

FDA Approves a Hormonal Injection for Low Libido in Women

On June 24, 2019, the FDA approved Vyleesi (bremelanotide injection) for the treatment of hypoactive sexual desire disorder (HSDD) in premenopausal women. Bremelanotide is an analogue of the α-melanocyte-stimulating hormone, which activates melanocortin in the nervous system. This hormone was originally explored as a sunless tanning agent in the 1980s. Through an accidental discovery, it was found to cause spontaneous erections after one of the scientists self-administered it. Studies in sexual dysfunction began in the 2000s in both men and women, and though the drug was effective in both genders, it was only pursued for an indication in women (most of the male data is unpublished, so we aren't sure of its effectiveness there and we are not recommending it in men).

How is it dosed?

Bremelanotide has to be injected because it has low oral bioavailability. It comes as a single-dose, disposable, 0.3 mL auto-injector that contains 1.75 mg of the drug. Patients self-administer 1 dose subcutaneously in the abdomen or thigh, as needed, at least 45 minutes before anticipated sexual activity. Its half-life is 2.7 hours, but effects can last up to 24 hours. Due to concerns about blood pressure elevations and skin pigmentation, patients should not exceed 1 dose in a 24-hour period or more than 8 doses in a month.

How effective is it?

Statistically, this drug makes a difference, but it's not clear that the difference is meaningful or worth the risk. The overall effect size was small and comparable to that seen with flibanserin (Addyi): 0.3 for bremelanotide vs 0.4 for flibanserin (Pyke RE and Clayton AH, *Sex Med Rev* 2018;6(3):358–366). Two large, 24-week RCTs earned its FDA approval, but fewer than 60% of patients on the drug completed those trials (n = 1247). There was no difference in the number of sexual events between the treatment and placebo groups, but the average patient improved 0.6 points in sexual desire on the 6-point Female Sexual Function Index (FSFI) questionnaire.

What are the side effects, contraindications, and drug interactions?

The most common side effects are nausea (40%), flushing (20%), injection site reactions (13%), and headaches (11%). Blood pressure rises and heart rate decreases after each dose, so avoid in patients with cardiovascular risks. Focal hyperpigmentation is a rare side effect (1%), with a risk that increases with darker skin and more frequent use. This discoloration is not limited to the injection site and did not resolve after discontinuation in half of the women who experienced it. Unlike flibanserin, there is no interaction with alcohol. Bremelanotide slows gastric emptying, which may reduce absorption of some oral medications, most notably oral naltrexone, antibiotics, and analgesics. Animal studies show fetal harm, so avoid in pregnancy.

What is the cost?

Bremelanotide is sold in 4-dose packs and is only available through online specialty pharmacies that providers can access at www.vyleesipro.com by e-prescription or fax. For patients whose insurance covers bremelanotide, a copay card will lower their cost to $0 for the first 4-pack and $99 for every 4-pack refill. Its manufacturer is planning a benefit program for patients whose insurance does not cover it.

TCPR'S TAKE: Bremelanotide has some large hurdles to overcome, including cost, self-injection, modest benefits, high rates of nausea, and a rare but potentially permanent side effect of skin discoloration.

Marketing of FHSDD medications has reached new extremes. *Take Vyleesi, where the maker hired a telemedicine practice to prescribe it directly through the Vyleesi website. In our October 14 podcast, we go undercover to investigate.* Search for "Carlat" on your podcast store.

Expert Interview

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TCPR: There are thousands more health apps that are not FDA approved. How do we navigate that sea?

Dr. Torous: There are three steps to consider: privacy, evidence, and ease of use. Here are some basic things to look for.

1. **Privacy.** Check if the app has a privacy policy. Even FDA approval does not guarantee privacy protection. The FDA lists apps in the health and wellness space, which means they are not subject to HIPAA law.
2. **Evidence.** This could involve a PubMed search or an informal eyeball test—much as you would do before recommending a self-help book. Is the app following at least basic therapeutic principles or best practices?
3. **Ease of use.** Apps have a very strong decay curve. Patients don't stick with them very long. Some are too complex, with difficult navigation and annoying reminders that might make patients give up on them.

In addition, you must make sure the app ties into something that matters to the patient. The patient must be motivated to use the app.

TCPR: What do we need to know to evaluate clinical trials of apps?

Dr. Torous: One thing that's different from medication trials is the digital placebo. This is the idea that interacting with a digital device may have a therapeutic effect of its own, regardless of the app's content. This has implications for study design: What type of placebo are we going to use? Some type of active control is necessary, and a lot of studies of apps used only a wait-list control. We did a review of depression apps and found that their effect size went down from medium to small when they went from a wait list control to an active control like journaling or using an informational app (Firth J et al, *World Psychiatry* 2017;16:287–298).

TCPR: It's surprising that screen time itself can be therapeutic. Can you give an example?

Dr. Torous: One intriguing example is a randomized controlled trial of the Headspace app, which is a popular mindfulness program. They created a placebo version of the app that had the same visual experience, the same feel,

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Research Updates IN PSYCHIATRY

DEPRESSION

Anti-Inflammatories as Antidepressants?

REVIEW OF: Köhler-Forsberg O et al, *Acta Psych Scand* 2019;139(5):404–419

STUDY TYPE: Meta-analysis of randomized controlled trials

Several lines of evidence suggest that chronic inflammation contributes to depression. For example, markers of inflammation tend to be elevated in depressed patients, and inflammatory syndromes elicit depressive symptoms. Many of the causes of inflammation also overlap with the causes of depression: stress, insomnia, poor diet, and chronic health problems. Medications with different anti-inflammatory properties have been noted to improve mood in some patients, but few have been adopted in clinical practice. This meta-analysis gives us a fuller account of the current research.

The Danish authors performed a systematic review and meta-analysis of randomized controlled trials that studied anti-inflammatory interventions in depression. Both monotherapy and augmentation trials were included in the analysis. Reduction in depressive symptoms was the primary outcome.

The authors identified 36 trials published between 1995 and 2017 with almost 10,000 participating patients. Nearly a third of these were large studies with over 100 subjects. The trials included the following anti-inflammatory agents: NSAIDs (13 studies), cytokine inhibitors (9), statins (7), minocycline (3), pioglitazone (2), and glucocorticoids (2). On average, the anti-inflammatory agents were superior to placebo as augmentation of antidepressants in major depression and as monotherapy in patients with medical disorders. With the exception of pioglitazone, all classes of anti-inflammatory agents were effective. The overall effect size was moderate (0.49). This is in the same range seen with atypical antipsychotics and lithium augmentation (0.5–0.6), but comparing effect sizes is an approximate art unless the treatments are compared in a head-to-head trial. Only 19 studies reported on side effects, which were generally minimal but showed a trend toward increased rates of infection. All studies showed a high risk of bias, as assessed by irregularities in study design and presence of commercial support.

Two classes of anti-inflammatories—cytokine inhibitors and glucocorticoids—carry significant long-term risks such as infections and diabetes, which would limit their use for most patients with depression. Others, like the statins, NSAIDs, and the COX-2 inhibitor celecoxib, are more straightforward for psychiatrists to implement. Although celecoxib is well tolerated in the short-term, long-term use can raise the risk of heart attacks, stroke, gastrointestinal bleeding, and possibly nephrotoxicity.

TCPR'S TAKE

Most anti-inflammatory agents are effective in depression, but only a few are ready for clinical use. Among them, celecoxib has the best evidence, with seven trials supporting a large effect size of 0.82 (dosed 200 mg BID). Why, then, is it not used more often? Celecoxib carries long-term medical risks, but so do most of the other options for antidepressant augmentation, as does untreated depression. It will take a cultural shift to see widespread adoption of these treatments. Short of that, it's reasonable to try an anti-inflammatory in severe cases of depression that haven't responded to traditional therapies. To minimize long-term risks, attempt to taper off after 6 months of recovery.

—Edmund Higgins, MD. Dr. Higgins has disclosed that he has no relevant financial or other interests in any commercial companies pertaining to this educational activity.

Expert Interview

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and the same narrator, but contained no discussion of mindfulness—in other words, they took out the active ingredient. They gave the real and the fake app to 91 healthy college students for 6 weeks and tested various cognitive outcomes that are associated with mindfulness practice. In the end, the digital placebo worked just as well (Noone C & Hogan MJ, *BMC Psychol* 2018;6(1):13).

TCPR: What are some apps that have good ease of use?

Dr. Torous: IntelliCare is a family of CBT-based apps that has a nice interface. The idea behind these apps is that no one wants to watch PowerPoint-style CBT slides on their phones, which is what was done in the early versions of computer-based therapy. Instead, IntelliCare breaks the CBT skills into micro-doses that can be learned in one- to 20-minute exercises (see Evidence-Based Apps table on page 4 for additional examples).

TCPR: How do you introduce apps to patients?

Dr. Torous: The first thing to consider is how the app can augment the therapeutic alliance. Apps don't work on their own, and you're going to get a lot more efficacy when you use them inside the context of a therapeutic alliance. You want the patient to understand that you are still there providing support. The technology is not running the show—it's a tool, and we must set expectations and boundaries around how we're going to use that tool. If the app is tracking rating scales or medication adherence, will you be looking at the data remotely or just during sessions, and how will you respond to the data?

TCPR: It sounds like the way we use the app in therapy is more important than the app itself.

Dr. Torous: Exactly.

TCPR: For those of us who are new to digital therapeutics, what's a good way to try it out?

Dr. Torous: Step counters are a good place to start. These apps are built into most phones, and

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CME Post-Test

To earn CME or CE credit, you must read the articles and log on to www.TheCarlatReport.com to take the post-test. You must answer 75% of the questions correctly to earn credit. You will be given two attempts to pass the test. Tests must be completed within a year from each issue's publication date. As a subscriber to *TCPR,* you already have a username and password to log onto www.TheCarlatReport.com. To obtain your username and password, please email info@thecarlatreport.com or call 978-499-0583.

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For those seeking ABPN Self-Assessment (MOC) credit, a pre- and post-test must be taken online at http://thecarlatcmeinstitute.com/self-assessment/

Below are the questions for this month's CME/CE post-test. This page is intended as a study guide. Please complete the test online at www.TheCarlatReport.com. Note: Learning Objectives (LO) are listed on page 1.

1. Which of the following mental health apps is currently FDA approved? (LO #2)
   [ ] a. Medisafe [ ] b. Daylio [ ] c. reSET/reSET-O [ ] d. CBT-i Coach
2. Which statement about female hypoactive sexual desire disorder (FHSDD) is true? (LO #1)
   [ ] a. It affects 40% of women
   [ ] b. A physiologic cause must be identified to make the diagnosis
   [ ] c. Most women with low libido do not meet criteria for FHSDD
   [ ] d. DSM-5 requires that the decrease in libido interferes with relationships
3. According to a 2019 study of anti-inflammatory interventions in depression, celecoxib showed the best evidence as an augmentation to antidepressants. (LO #3)
   [ ] a. True [ ] b. False
4. Which medications are FDA approved for treating women with low or absent libido? (LO #1)
   [ ] a. Bremelanotide and ospemifene [ ] c. Ospemifene and bupropion
   [ ] b. Bupropion and flibanserin [ ] d. Flibanserin and bremelanotide
5. According to Dr. Torous, one challenge in evaluating the effectiveness of mental health apps is that most studies use a wait-list control instead of an active control. (LO #2)
   [ ] a. True [ ] b. False

Expert Interview

Continued from page 6

physical activity, which is what they measure, is relevant to most psychiatric disorders. You could start by looking at the patient's steps and saying, "Let's set a target of being just a little bit more physically active and see if it improves your mood." Or you could phrase it as an experiment: "For the next week I want you to aim for this amount of steps a day. Then we'll talk about days that you were more and less active, compare that to your mood, and make a plan."

TCPR: What's a good target for daily steps with psychiatric patients?

Dr. Torous: Ten thousand a day is always thrown around as this kind of magical number. I work a lot with patients with psychosis and the idea of 10,000 steps can be discouraging. So it's worth taking whatever the patient's current baseline is and saying, "Hey, let's try to increase it by 500 steps a day."

TCPR: Some patients are using apps to monitor their sleep. Can we rely on the data from these apps?

Dr. Torous: Watches and wristbands can collect various types of sleep data based on your movements at night. There are also sensors that sit by the bed and estimate the stage of sleep from breathing patterns, like ResMed's S+ app. All these tools have flaws, but what they are best at telling us about is the duration of sleep, which can be a useful measure as it impacts almost every disorder we treat. They haven't yet replaced an EEG. It's very hard to measure REM vs non-REM sleep despite what companies claim. Another measure that's useful is medication adherence. There are apps that can track that and provide pop-up dose reminders.

TCPR: When would you use an app that tracks medication adherence?

Dr. Torous: The key thing is to consider how you're going to use the data in practice. Do you have a plan to encourage adherence when you get the information? You don't want to track for the sake of tracking. Finally, you need an end point. You and the patient must decide what the goal is, when you've reached it, and when you are going to stop using the app.

TCPR: Thank you for your time, Dr. Torous.

To learn more, listen to our 10/21/19 podcast, *"Prescription Mental Health Apps."* Search for "Carlat" on your podcast store.

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Mental Health Apps
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Next Issue:
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In Brief: A 16-Hour Ritalin

Adhansia XR is a new extended-release methylphenidate. Its distinguishing feature is its 16-hour duration, which breaks the previous record of 12 hours set by Concerta, Cotempla, Aptensio, and Quillivant. In that respect it is similar to Mydayis, the 16-hour version of Adderall. Adhansia XR releases 20% of its methylphenidate through instant-release beads. The other 80% is distributed through controlled-release layers. The max dose (85 mg) is slightly higher than other methylphenidate products because the drug is distributed over a longer period of time.

In essence, Adhansia XR is equivalent to Ritalin LA dosed BID, or Concerta with an instant-release methylphenidate added on at the 12-hour mark. Those generic versions offer the same pharmacokinetics at one-third the cost, and allow patients to take less on days when 12 hours of coverage is enough.