

## This Clinical Trial Could Help Improve Caregiving for Schizophrenia Patients | Johnson & Johnson

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What if we could make caregivers' lives less stressful? For National



Family Caregivers Month, we're looking at how Janssen Clinical Development Director Branislav Mancevski, M.D., is helping pave the way.

By **Barbara Brody** November 12, 2017

If you were diagnosed with a chronic illness like heart disease, diabetes or arthritis, chances are your doctor would write you a prescription and you'd willingly take it. While medication might be just one part of your treatment regimen, it's often a crucial one. But what happens when patients neglect to take their medication as directed?

According to the National Council on Patient Information and Education, more than 50% of people who are prescribed medication for any ailment are non-adherent. Some might skip doses, use the drug incorrectly (like with or without food, or at the wrong time of day) or not take it at all. The result: poorer health outcomes, and an estimated 125,000 preventable deaths each year.

And when it comes to a serious mental illness like schizophrenia, the stakes can be even higher—yet medication adherence rates are often dismally low.

Data from the CATIE study (Clinical Antipsychotic Trials of Intervention Effectiveness), for instance, found that the *majority* of people with schizophrenia had stopped taking their medication within the first year after being diagnosed.

The reasons why are varied: Some people forget, dislike the side effects or have trouble paying for their medicine. The stigma of mental illness often plays a major role, too, as does the unwillingness of many people to make peace with their diagnosis.

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Branislav Mancevski, M.D., Director of Clinical Development for Janssen Scientific Affairs

Schizophrenia is a mental illness that experts believe originates in the brain. People who have it may seem out of touch with reality, experience hallucinations and have trouble making decisions in their everyday lives. It can be disabling, but with treatment—which usually includes antipsychotic medication and psychosocial support—patients can lead fulfilling lives.

The key, however, is to stick with their prescribed treatment in order for it to work and control their symptoms.



“It’s very difficult for patients, especially right after diagnosis, to accept that something is wrong with them, so they might decide that they don’t need medication, or that it’s not good for them,” says Branislav Mancevski, M.D., Director of Clinical Development for Janssen Scientific Affairs. “But it’s a well-known fact that getting off of medication increases the risk of relapse, so psychotic symptoms [like hallucinations and delusions] might reappear.”



More than 50% The amount of schizophrenia patients who don't adhere to their prescribed medication plan

While this is clearly problematic for patients themselves, it also puts excess pressure on family members and caregivers who struggle to keep their loved ones safe and healthy.

The FIRST trial (Family Intervention in Recent Onset Schizophrenia Treatment), led by Mancevski, is aiming to determine whether providing caregivers with specialized psychoeducation and skills training can help ease some of this burden, while simultaneously helping patients follow their treatment plan.

We sat down with Mancevski to learn more about why this clinical trial is so important, and how it has the potential to improve the health of people with schizophrenia and those who care for them.

Q:

Why are caregivers such an essential part of treatment for schizophrenia patients?

A:

About 8.4 million Americans are providing care for loved ones with serious mental illnesses, including schizophrenia.

These caregivers are really the closest people to the patients and provide essential care that physicians can't: They accompany patients to doctor appointments, assist with everyday tasks, ensure that prescriptions get filled and more. That's extremely valuable, but it's also a tremendous burden.

These family members (and sometimes close friends) spend an estimated 32 hours a week providing care. That's almost like a full-time job, but it's unpaid—and it's on top of everything else they're doing in their own lives, like going to work, maintaining their households and spending time with other family members.

This burden has long been recognized in the field of psychiatry, but the support that caregivers get is very inconsistent.

Depending on where you live and what resources you have access to, you might only get a 15-minute chat with your loved one's doctor, or you might be enrolled in a sophisticated, in-depth training program.

Q:

Why is Johnson & Johnson uniquely positioned to lead research in this area?

A:

As a company, we are committed to improving the lives of people and families suffering from mental illness. Part of that involves providing effective medication.

That's why, for example, we developed healthcare professional-administered long-acting medication for schizophrenia that patients can take just once a month or even less frequently (depending on what their doctor has prescribed) instead of having to remember to take a pill every day.

~~~~~ “ ~~~~~ If the trial is successful, it should lend added credence to the field of psychiatry. Similar programs could potentially benefit people across the country, as they'd be able to access the support and training they need from the comfort of their homes.

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We also acknowledge that caregivers are an important element in the treatment process. Our goal is to figure out how to relieve some of the stress that caregivers experience by offering them in-depth psychosocial support, so they will be better equipped to help their loved ones.

Q:

What, specifically, is the FIRST clinical trial studying?

A:

We're aiming to find out whether caregivers might fare better after participating in a specialized support and training program. By extension, we're also hoping to figure out whether this training and support of caregivers translates to better patient outcomes.

The FIRST trial follows patient/caregiver pairs. The patients will continue taking the antipsychotic medications (oral or long-acting injectable (LAI)) their doctors have prescribed for them throughout the trial as a part of their usual clinical practice. The caregivers are randomized into two groups: One group, the control, doesn't get any special intervention. The caregivers are simply encouraged to access whatever resources are available to them locally, which could be minimal or nothing. The intervention group is enrolled in an individualized training program.

To create and run the psychosocial program, we're partnering with a company called MyHealios. Caregivers assigned to the intervention group are connected with a clinician who provides the training through an online platform. You schedule sessions and interact with a clinician in real time. Everyone gets up to 16 sessions within the first six months, but it's up to caregivers and their clinicians to decide when and how often to "meet."

The program is somewhat standardized, as it was designed using evidence-based science. But the clinicians tailor the sessions to each caregiver in an effort to best meet their needs. For example, if a caregiver is already pretty knowledgeable about schizophrenia itself, then they spend less time on the disease basics and delve right into topics like coping, communication and conflict resolution. It's not one-size-fits-all.

Q:

What stage is the trial in?

A:

We just finished recruitment, and the study is going to last for another year. The first six months are the intervention phase, which is when caregivers assigned to the online training program are working with clinicians.

Then there's a six-month follow-up period. So the total study period for each caregiver-patient pair is one year, and we will evaluate both the caregivers and patients at set intervals during that time frame.

Q:

How are you hoping the trial will help people?

A:

We are hopeful that this study will show the importance of engaged, confident caregivers.

The study is "open label," meaning the investigators know who's in the intervention group and who's not, so we can't discuss any early findings at this time. We don't want to influence the results or create any bias while the trial is ongoing.

But we're expecting that the intervention will benefit the caregivers and translate into better care for patients.

If we're right, and the trial is successful, then it should lend added credence to the field of psychiatry. Similar programs could potentially benefit people across the country, no matter where they live, as they'd be able to access the support and training they need from the comfort of their homes.

And that is going to have a majorly positive impact on patients and their loved ones—which is exactly what we're working toward.

Caring for Someone With Schizophrenia?

The FIRST clinical trial is currently recruiting participants for their yearlong study. Find out how you might participate.

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