

The safety of the PEAR-004 app and its effects on schizophrenia symptoms



Thank you!

Thank you to the participants who took part in the clinical trial for the **PEAR-004 app**. All of the participants helped the researchers learn more about how the PEAR-004 app works and how safe it is to use.

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public. An independent organization prepared this summary of the trial results.

We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: CPEA001A12201
Treatment studied: PEAR-004
Sponsor: Novartis



If you participated in the trial and have **questions** about the results, please speak with the trial doctors or staff at your trial site.

You can find **more information** about this trial by going to the websites listed on **page 11** of this summary.

This trial at a glance

What was the purpose of this trial?

[Read more on page 3](#)



The purpose of this trial was to learn if a smartphone application called the PEAR-004 app could lower the severity of people's schizophrenia symptoms. The PEAR-004 app is designed to provide therapy content.

This trial was designed to answer these questions:

- Did the PEAR-004 app lower the severity of the participants' schizophrenia symptoms?
- Did the PEAR-004 app affect if a participant stayed in this trial?
- What medical problems did the participants have during this trial? Keeping track of the medical problems helped to learn about the safety of the PEAR-004 app.

Who was in this trial?

[Read more on page 4](#)



- 112 men and women were in this trial
- Participants in this trial were 22 to 65 years old and had schizophrenia

What treatments did participants use?

[Read more on page 4](#)



Each participant was assigned to use one of these treatments:

- **PEAR-004 app**
- **Placebo app** – this looked like the PEAR-004 app but did not have any therapy content. Using the placebo app helped the clinical trial team better understand the actual effects of the PEAR-004 app.

Each participant used their assigned app on their smartphone for 12 weeks. They also continued their regular therapy and medicines for schizophrenia.

What were the main results of this trial?

[Read more on page 7](#)



- The participants who used either app had lower severity of schizophrenia symptoms by the end of this trial. The clinical trial team concluded that the PEAR-004 app did not have a meaningful effect.
- The percent of participants that stayed in the trial was similar in both treatment groups. The clinical team concluded the PEAR-004 app did not affect if a participant stayed in this trial.
- The clinical trial team concluded that the PEAR-004 app was safe for the participants in this trial.

[Read about other results of this trial on page 10](#)

What was the purpose of this clinical trial?

Researchers are looking for better ways to treat the symptoms of schizophrenia.

Schizophrenia is a serious mental illness that changes how a person thinks, feels, and behaves. It can make it hard for someone to decide what is real and what is not in their life. The symptoms of schizophrenia can include:

- Hallucinations – seeing or hearing things that don't exist
- Delusions – thoughts or beliefs that differ from reality
- Inability to carry out daily tasks or follow through with plans

There is no cure for schizophrenia, but therapy and medicines can help lower the severity of symptoms. One therapy used to treat schizophrenia is called **cognitive behavioral therapy**, also known as CBT. This type of therapy aims to change unwanted behaviors or thoughts and improve mental health by building coping strategies. However, not everyone has access to CBT.

Researchers want to learn if **prescription digital therapeutics**, also called PDTs, can help provide therapy to more people. The **PEAR-004 app** is a PDT that is designed to provide CBT to people with schizophrenia. Researchers do clinical trials to find out how safe PDTs are and how well they work.

What is a prescription digital therapeutic (PDT)?

A PDT is a non-drug therapy, such as a software or application (app). Doctors can prescribe PDTs to help treat or manage the symptoms of certain diseases.

This trial was designed to answer these questions:

- Did the PEAR-004 app lower the severity of the participants' schizophrenia symptoms?
- Did the PEAR-004 app affect if a participant stayed in this trial?
- What medical problems did the participants have during this trial?
Keeping track of the medical problems helped to learn about the safety of the PEAR-004 app.

Who was in this trial?

112 participants began this trial and 2 participants left the trial before treatment. 110 of the participants used a trial treatment – 72 men and 38 women. Everyone was 22 to 65 years old. Their average age was 45.

Every participant in this trial had schizophrenia. They also:

- Used a smartphone that could download the treatment apps
- Had no major changes in their main medicines to treat schizophrenia for the past month
- Were otherwise in good overall health

This trial took place in the United States.



Visit novctrd.com for more information about:

- Who could and could not be in this trial
- The participants in this trial, such as their age, gender, and race

Use trial number **CPEA001A12201** to find the scientific summary.

What treatments did the participants use?



A computer program was used to randomly assign each participant the treatment they used:

- **PEAR-004 app** – provided therapy content
- **Placebo app** – looked like the PEAR-004 app but did not have any therapy content. Using a placebo app helps to better understand the actual effects of the PEAR-004 app.

Using a computer program to assign the treatments helped make sure the results were compared as fairly as possible.



Each participant was asked to open their assigned app on their smartphone several times a day for 12 weeks.

The participants assigned the PEAR-004 app downloaded an app called “Thrive” on their smartphone. The app notified the participants when to open it each day. When opened, it delivered information to help them build skills for coping with certain challenges, such as unwanted thoughts or voices, depression, and problems with social relationships.

The placebo app notified participants when to open it each day. The app had a timer that showed how much time was left until the end of trial treatment. When the participants opened the app, they would only see the timer and no therapy content.

The trial staff who measured the participants' schizophrenia symptoms did not know which app each participant used during the trial. This was because knowing which app participants used could influence the results. Not knowing which app the participants used helped make sure the results were looked at fairly.

Each participant also continued their regular therapy and medicines for schizophrenia.

What happened during this trial?

The trial began in December 2018 and ended in September 2019. 20 participants didn't complete this trial:

- 2 participants left before they used a trial treatment
- 18 participants left after they used a trial treatment at least one time

During this trial, the trial staff measured the severity of the participants' schizophrenia symptoms using the **Positive and Negative Symptom Scale (PANSS)**. PANSS is a set of questions that a doctor asks a person with schizophrenia to measure 3 types of symptoms:

- Positive symptoms – includes hallucinations, false thoughts, and disorganized thinking
- Negative symptoms – includes not making plans, not feeling emotions, or not feeling motivated
- General symptoms – includes anxiety, depression, and guilt

A participant's PANSS score is based on their answers to these questions. A **lower PANSS score** means the severity of their schizophrenia symptoms is lower. A **higher PANSS score** means the severity of their schizophrenia symptoms is higher.

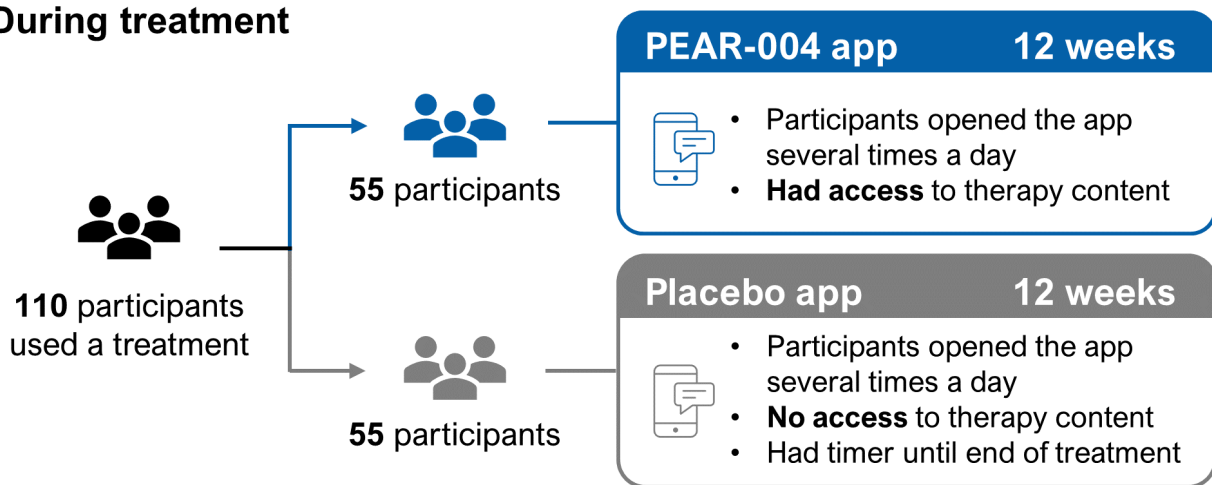
The chart on the next page shows how the trial was done.

Here's how this trial was done:

Before treatment

- The trial doctors checked each participant's physical and mental health to make sure they could be in this trial
- The trial staff measured the severity of each participant's schizophrenia symptoms using the PANSS and other measures
- 112 participants joined this trial and 2 left before treatment

During treatment



- Each participant continued their regular therapy and medicines for schizophrenia
- The trial doctors checked each participant's physical and mental health about every 4 weeks
- The trial staff measured the severity of each participant's schizophrenia symptoms using the PANSS and other measures

After treatment

- About 4 weeks after their last treatment, each participant visited the trial site for the trial doctors to check their physical and mental health

What were the main results of this trial?



This is a summary of the overall results of this trial. Individual results from each participant may be different and are not included in this summary.

Researchers need many trials to learn if a drug or other treatment is safe and works well. Other trials may provide new information or different results. Always talk to a doctor before making any changes to your health care.

Did the PEAR-004 app lower the severity of the participants' schizophrenia symptoms?



The participants who used either app had lower severity of schizophrenia symptoms by the end of this trial. The clinical trial team concluded that the PEAR-004 app did not have a meaningful effect.

The trial staff measured the severity of the participants' schizophrenia symptoms using the PANSS before, during, and after the participants used their assigned app.

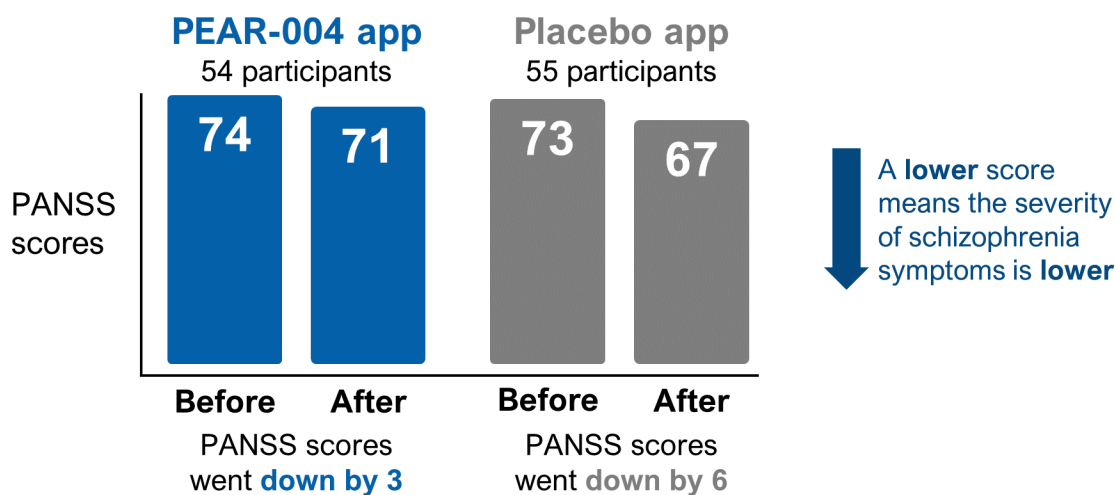
The clinical trial team compared the participants' PANSS scores from before they started treatment to their scores at the end of their treatment. The end of their treatment occurred after 12 weeks or at their last visit to the trial site.

If someone's PANSS score goes down, it means the severity of their schizophrenia symptoms is lower.

On average, the PANSS scores for participants who used either app went down slightly at the end of treatment. The trial team didn't find this change to be meaningful.

Change in the participants' PANSS scores

The participants' average scores before and after using their assigned app for 12 weeks – or until their last visit to trial site



Note: The team couldn't include one participant who used the PEAR-004 app in this chart because the participant didn't return to the trial site after their first visit.

Did the PEAR-004 app affect if a participant stayed in this trial?



The clinical trial team concluded that the PEAR-004 app did not affect if a participant stayed in this trial.

The clinical trial team kept track of the participants who stayed in the trial and those who left the trial early. They concluded that the number of participants who stayed in the trial in each group was not meaningfully different. Most of the participants who left the trial had stopped going to trial visits and the trial staff was not able to reach them. The chart below includes the 2 participants who left the trial before treatment – one in each group.

Percent of participants who stayed in this trial



What medical problems did the participants have during this trial?

Medical problems that happen during trials are called “adverse events”. An **adverse event** is any unwanted sign or symptom that participants have during a trial. An adverse event is considered “**serious**” when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death.



Adverse events may or may not be caused by treatments in the trial.

Many trials are needed to know if a drug or treatment causes an adverse event. Trial doctors keep track of all adverse events that happen in trials, even if they think the adverse events might not be related to the trial treatments.



The clinical trial team concluded that the PEAR-004 app was safe for the participants in this trial.

The trial doctors looked for adverse events when they checked the participants’ health at the trial site. The participants also reported adverse events.

Participants who had adverse events

Participants who had:	PEAR-004 app out of 55 participants	Placebo app out of 55 participants
Serious adverse events	0% 0 of 55	2% 1 of 55
Non-serious adverse events	22% 12 of 55	18% 10 of 55
Left this trial due to adverse events	0% 0 of 55	2% 1 of 55

What serious adverse events did the participants have?

No participants who used the PEAR-004 app had serious adverse events during this trial. One participant who used the placebo app had a serious adverse event:

- **Suicidal thoughts** (suicidal ideation)

The participant received treatment and then left the trial.

There were no other serious adverse events reported, including deaths.

What non-serious adverse events did the participants have?

About 20%, or 22 of the 110 participants, had adverse events that were not serious. The table below shows the adverse events that happened to **2 or more participants**. Other adverse events were reported by fewer participants.

Non-serious adverse events

Participants who had:	PEAR-004 app out of 55 participants	Placebo app out of 55 participants
The common cold Nasopharyngitis	4% 2 of 55	2% 1 of 55
Trouble falling and staying asleep Insomnia	2% 1 of 55	2% 1 of 55
Upper respiratory tract infection Such as the common cold or the flu	2% 1 of 55	2% 1 of 55



For more information about the adverse events the participants in this trial had, visit [novctrd.com](https://www.novctrd.com). Use trial number **CPEA001A12201** to find the scientific summary.

What other results were learned?



The PEAR-004 app did not affect other aspects of schizophrenia more than the placebo app.

The clinical trial team also looked at whether the PEAR-004 app affected other aspects of schizophrenia. They measured participants':

- Motivation or enjoyment from life
- General quality of life
- Overall level of depression
- Opinions and willingness to take their medicines to treat their schizophrenia symptoms
- PANSS responses when compared in different ways

The team found that the PEAR-004 app did not have a greater effect on any of these aspects of schizophrenia compared to the placebo app.

What was learned from this trial?

This was the first trial to learn about how well the PEAR-004 app works for people with schizophrenia. The clinical trial team found that the PEAR-004 app was safe for the participants in this trial. However, it did not have a meaningful effect on the severity of the participants' schizophrenia symptoms.



The results presented here are for one trial. One trial cannot give a complete picture of the benefits and risks of a prescription digital therapeutic. The results of many trials are needed to find out which treatments can be used for people with schizophrenia. This summary shows only the main results from this trial. Other trials may provide new information or different results.

Where can I learn more about this and future clinical trials?



This is a summary of the results for one trial.

You can find detailed results and more information about this clinical trial on the Novartis Clinical Trial Results website:

1. Visit novctrd.com
2. Click on “Clinical trial results and trial summary for patients” at the top right of the page
3. Read and scroll down, then click “I accept” to agree to use the information and the website
4. Select “Search by study number” on the bottom left of the page
5. Type “**CPEA001A12201**” in the search box and click search

If you would like to view the website in a language other than English, you can click the “Google Translate” button on the top right of the page.



If you were in this trial and have questions about the results, please speak with the doctor or staff where you took part in this clinical trial.

This trial was registered on the following websites:

- ClinicalTrials.gov – <https://clinicaltrials.gov/>
To find this trial, type **CPEA001A12201** in the **Other terms** search box

Full trial title:

A randomized, sham-controlled study of PEAR-004 as an adjunct to standard-of-care treatment for schizophrenia

If more trials are planned in schizophrenia or with this app, they will appear on the public websites listed above.

Thank you!

Novartis would like to thank all of the people who participated in this clinical trial. The participants made this clinical trial possible and helped researchers answer important health questions and learn about a possible medical treatment. Many volunteers and many clinical trials are needed to advance medical science.



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