Clinical Trial Results Summary

A clinical trial to test if electronic reminders help participants take their medicine on time

Protocol number: CIDD001D2402

Thank You!

Novartis, the sponsor of this clinical trial, would like to thank you for taking part in this trial.

As a clinical trial participant, you belong to a large community of people around the world. Your invaluable contribution to medicine and healthcare is greatly appreciated.

Important note: Please note that this summary only shows the results of a single clinical trial. Other clinical trials may have different findings. Researchers and health authorities, such as the FDA and EMA, look at the results of many clinical trials to understand which drugs work and if they are safe. It takes many people in multiple clinical trials around the world to advance medical science and healthcare. If you have any questions about these trial results, please talk to the doctor or staff at your trial site.

How long was this trial?

This trial was designed so that an individual participant could take part for 6 months. The trial started in July 2018 but was stopped early, in January 2019. The entire duration, from enrolling the first participant to when the trial was stopped, was about 6 months.

This trial was not completed as planned because of recording problems with the electronic part of the inhalers. Since the inhalers could not record times and dates of when the participants used them, no results could be collected. When the trial was stopped, a report was created with the information that was available. This summary is based on that report.

Why was the research needed?

Researchers were looking for a way to help patients take their medicine on time. Participants in this trial had a condition called chronic obstructive pulmonary disease (COPD), a lung condition that causes inflammation in the airways, making it hard to breathe. People who have this condition are sometimes given medicine that needs to be taken using an inhaler. Inhalers are devices that deliver medicine into a person's lungs as a spray. Previous research and medical practice show that medicine that is taken by mouth often have a high number of missed doses of treatment.

The main goal of this trial was to test if electronic reminders helped participants use their inhaler on time more often than participants who were sent no reminders.

Researchers gave all the participants in the trial the same type of inhalers, equipped with electronic sensors in the base. However, only 1 group of participants was given an application running on an electronic tablet device so that they could receive electronic messages and reminders wirelessly from the inhaler. In this trial, the researchers did not measure the effect of the medicine on the participants' condition.

Trial purpose

The main questions the researchers wanted to answer in this trial were:

- Did receiving electronic reminders increase the percentage of days that participants took their medicine on time?
- Did receiving electronic reminders increase the total percentage of days that participants took their medicine?

Who was in this trial?

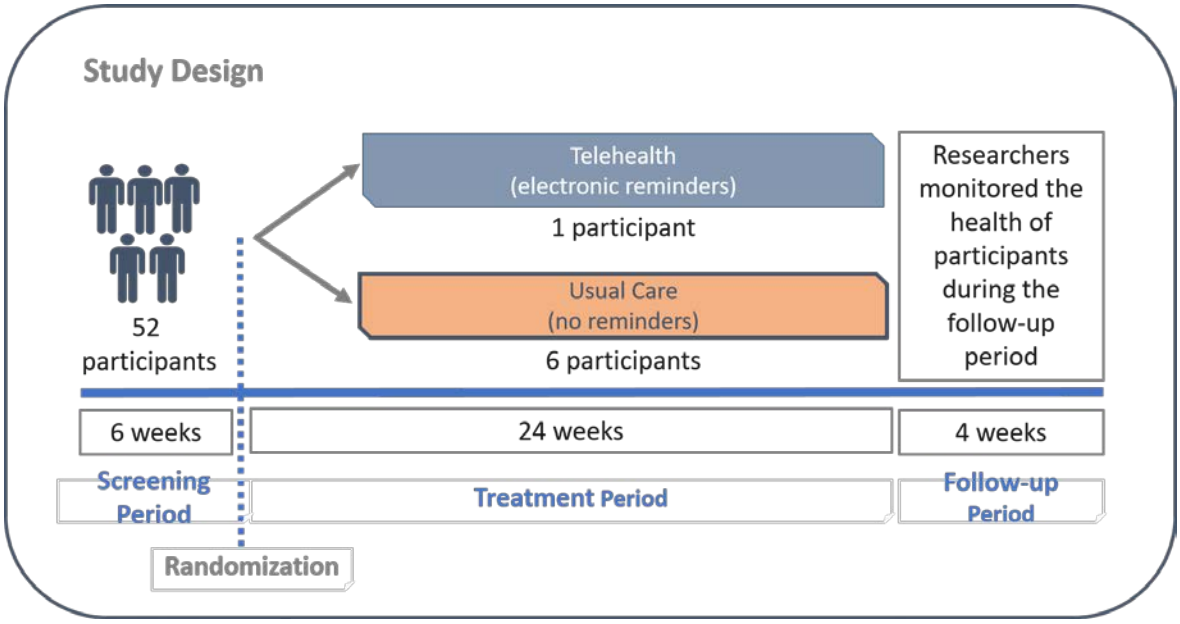
Men and women could take part in this trial if they:

- were 18 years or older and had COPD
- either currently smoked or used to smoke about 20 cigarettes a day for 10 years
- were already using a maintenance inhaler for at least 3 months but were not consistent with taking their medication on time
- were not using any other investigational medicines or devices for COPD
- did not have any other serious lung or heart conditions

At the time of trial termination, there were 7 participants in the trial. 4 participants were from Germany and 3 participants were from the Netherlands. The participants' age ranged from 61 years to 84 years. 3 out of 7 participants were female.

What happened during this trial?

This was an open-label trial, which means that both the researchers and the participants knew what treatment was given to participants. At the start of this trial, approximately 146 participants were planned to be included in this trial. 52 participants actually entered the screening period, but only 7 participants passed screening. These 7 participants were randomly put into 2 groups: the Telehealth group with the electronic reminders and the Usual Care group, with no electronic reminders, as shown in the study design figure.



What were the key results of this trial?

Due to recording problems with the electronic sensors in the base of the inhalers and the electronic tablet device, researchers could not record times and dates of when the participants used their inhalers. The trial was terminated after 7 participants entered the treatment period.

What medical problems did the participants have during the trial?

Medical problems that happen in clinical trials are called “adverse events”. An adverse event is an unwanted sign or symptom that participants have during a trial. An adverse event is considered “serious” when it is life-threatening, causes lasting problems, or the participant needs hospital care. These problems may or may not be caused by the trial drug.

This section is a summary of the adverse events that happened during this trial. The websites listed at the end of this summary may have more information about these adverse events.

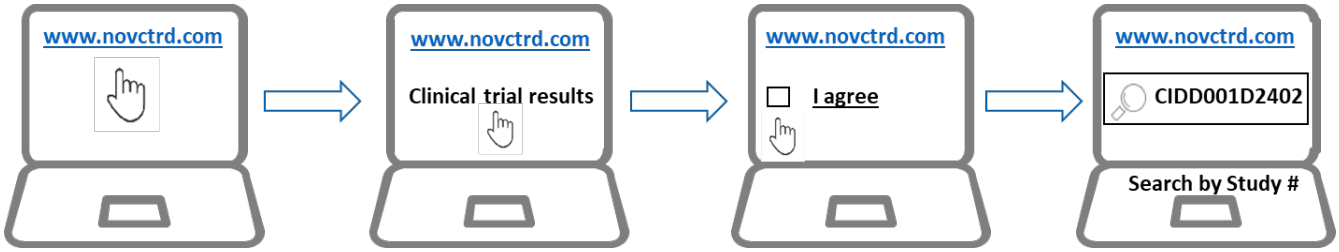
What were the adverse events?

The single participant in the Telehealth group who received electronic reminders did not report any adverse events. Out of the 6 participants in the Usual Care group who did not receive electronic reminders, 1 participant reported a cough and another participant reported a cough and a nose and throat infection.

No participants reported serious adverse events or died during the trial. No participants stopped the trial due to adverse events.

Where can I learn more about this trial?

More information about the results and adverse events in this trial can be found in the scientific summary of the results available on the Novartis Clinical Trial Results website (www.novctrd.com).



You can find more information about this trial on the following websites:

- www.clinicaltrials.gov. Use the NCT identifier NCT03379233 in the search field.
- www.clinicaltrialsregister.eu. Use the EudraCT identifier 2017-001593-42 in the search field.

Full clinical trial title: A 24-week randomized, controlled, multicenter, open-label study to evaluate the effect of reminder notifications and motivational/adaptive messaging on treatment adherence of COPD subjects receiving Ultibro® Breezhaler® treatment using the Concept2 inhaler for dose administration and tracking

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