THE ADAPTABLE STUDY
Summary of Results

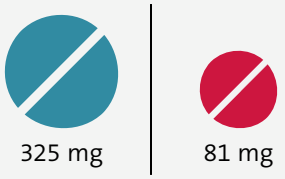
Adaptable
The Aspirin Study

Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness

On behalf of the ADAPTABLE team of patient partners, researchers, and clinicians we would like to thank you for participating in ADAPTABLE. As a research participant, you played a critical role in generating these study results. We truly appreciate your time and commitment to help advance the care of people with heart disease.

WHAT IS THE PURPOSE OF ADAPTABLE?

The purpose of ADAPTABLE is to find the best dose of aspirin, 81 mg or 325 mg, for people with known or existing heart disease to prevent death or another heart attack or stroke.



325 mg | 81 mg

WHEN DID ADAPTABLE TAKE PLACE?

The full research study was conducted from May 2015 to May 2021. The first participant enrolled in April 2016, and the last participant enrolled in June 2019.

WHO WAS INVOLVED?

15,076
people with heart disease

clinicians and researchers at

40

large health systems and one health plan across the nation that are part of PCORnet®, The National Patient-Centered Clinical Research Network.

WHY IS THIS RESEARCH IMPORTANT TO PATIENTS, CLINICIANS, AND OTHER RESEARCHERS?

Aspirin can help keep blood flowing. It is recommended for people with heart disease to prevent another heart attack or stroke. However, the best dose for people with heart disease is not known. This is most likely due to the lack of data from clinical trials.

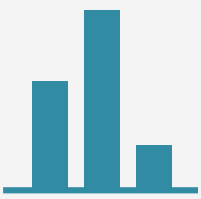
WHAT DID WE LEARN?

With your valuable contribution, we successfully completed a virtual trial with 15,076 participants.

There were no differences in rates of death, hospitalization for a heart attack or stroke, and bleeding between participants who took 81 mg and those who took 325 mg.

Over the course of the trial, participants who were assigned to 325 mg of aspirin were more likely to switch doses or stop taking aspirin than people assigned to 81 mg. This dose switching and discontinuation may have impacted the results.

Reasons for switching or stopping aspirin during the study may have been due to issues tolerating aspirin, health problems, and patient or clinician preference. In addition, new guidelines and articles in the media about aspirin for people who don't have heart disease may have caused confusion that led a participant to change their aspirin use.



HOW WILL THE RESULTS HELP PEOPLE WITH HEART DISEASE AND THOSE WHO CARE FOR THEM?

People with heart disease should discuss the following aspirin dosing guidelines with their clinicians:

If you are on 81 mg now:
Staying (rather than switching to 325 mg) is probably right since no differences were found between the two doses.

If you are resuming aspirin:
Starting a lower dose (81 mg) is probably right due to better tolerability and there is no conclusive evidence that a higher dose is better.

If you are on 325 mg now and doing okay:
Staying on it may be fine.

Since ADAPTABLE was people who were already taking aspirin at the time of enrollment, results from this study do not apply to people who are starting to take aspirin.

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WHAT WAS UNIQUE ABOUT ADAPTABLE? HOW WERE PATIENTS GIVEN A VOICE IN RESEARCH?

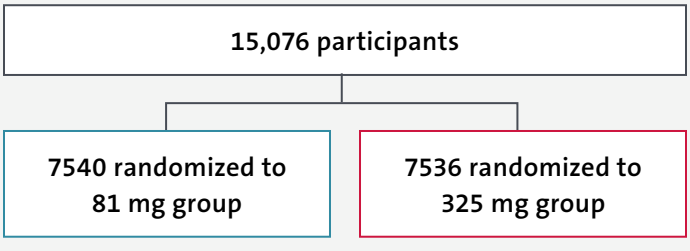
In ADAPTABLE, the role of the patient shifted from participant to partner. Adaptors are patient representatives who were involved in ADAPTABLE from the beginning to improve the research process for participants. Coordinated by the Health eHeart Alliance, the Adaptors provided the patient perspective by asking questions, sharing experiences, and participating in working groups and scientific meetings.

Adaptors and researchers created a unique culture of collaboration that helped shape the study experience for participants and created a dynamic environment where:

- Participants received study updates through the newsletter, in emails, or news items on the website.
- Participants asked questions and provided ideas for newsletter content.
- Participants shared their voice on the importance of ADAPTABLE, why they joined, and why heart disease research is important. Participants also told the team where we could share their insights — in the study newsletter, on the website, or through social media.

HOW DID WE GET TO THE RESULTS AND FINDINGS?

Enrolled participants were randomly assigned to 81 mg or 325 mg. Randomly assigned means there was an equal chance of being assigned to either dose.



The distribution of age, gender, race, and history of heart disease were similar between the two groups.

WHAT WERE PARTICIPANTS ASKED TO DO DURING THE STUDY?

ADAPTABLE included several innovative designs to make participating easier for participants. The study was completely online. After learning about the study, participants signed a consent form and enrolled in ADAPTABLE through an online portal.

Participants:

- Were assigned to take either 81 mg or 325 mg.
- Purchased aspirin over-the-counter.
- Completed surveys in an online portal every three or six months.
- Provided information about their aspirin use, use of other drugs, and recent hospitalizations.

Researchers also used information from a participant's electronic health record, Medicare claims data, or private health plan data to get a more complete picture of their health.

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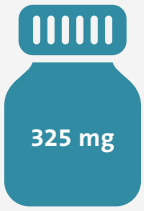
WERE THERE ANY LIMITATIONS TO THE STUDY?

ADAPTABLE was an open-label study, which means people knew what dose they were taking during the study. If participants did not know their dose, switching and discontinuation may have been different.



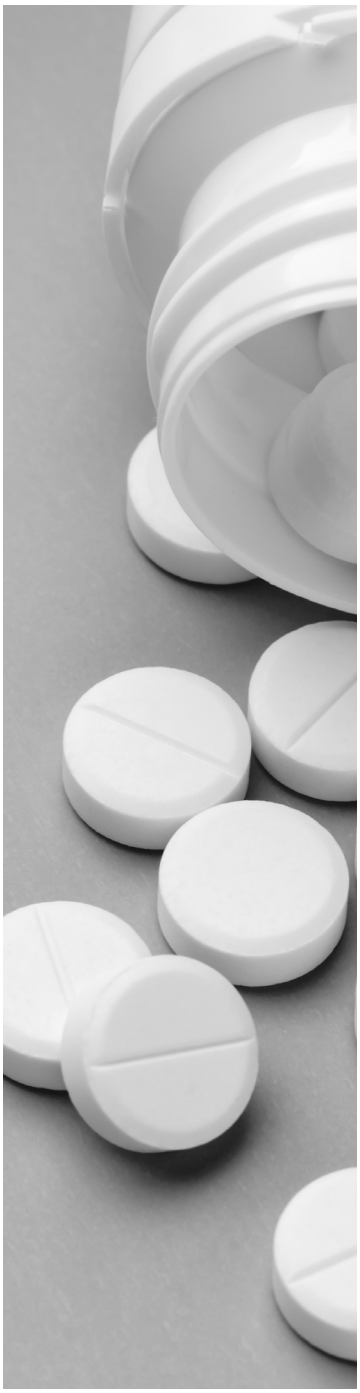
A longer follow-up time may have resulted in different outcomes. Because the study was virtual, there was a larger than usual missingness of patient-reported information that may have impacted the dose switching and discontinuation data.

WHAT'S NEXT?

The ADAPTABLE team will continue to analyze the results with consideration of dose switching, age, sex, and presence of disease such as diabetes. Stay tuned to the ADAPTABLE website to learn more.

ADAPTABLE provides a model where patients partner with researchers to design research studies that answer questions of importance to patients.

Participants who are interested in taking part in future research can share their insights and experiences from ADAPTABLE to continue to improve the clinical trial process for both researchers and participants.



WHERE CAN I LEARN MORE?

Read the published paper of the main results.

Visit clinicaltrials.gov and search for ADAPTABLE using this number: NCT02697916

Visit the website at www.theaspirinstudy.org

@ADAPTABLEStudy on Twitter

@ADAPTABLEStudy on Facebook

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The ADAPTABLE study is funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (Contract Number: ASP-1502-27079).

This summary was completed in May 2021. Since this summary was written, newer information may exist.