Another vast trial is on the cards for Apple’s ECG, and ought to yield more meaningful data.

The Apple Watch turns out to be pretty good at detecting atrial fibrillation. Without a control group, though, data reported this weekend from the Apple Heart Study cannot definitively answer questions about the real-world value of the device. But Apple is hoping to address these issues with a new study, which will have two comparator groups.

Even more crucially this new trial, Heartline, will look at the Apple Watch’s potential to prevent stroke. This is a far more clinically important endpoint than anything the Apple Heart Study showed, and could finally make consumer ECGs a serious prospect as medical devices. Still, the Apple Heart Study was a useful first step towards this, with the data largely quelling fears that the watch might cause unnecessary warnings in healthy people.

Shining a light

The trial might have enrolled the best part of half a million people, but in the end it was data in just 450 that mattered. This was the number of patients who wore a confirmatory ECG patch monitor to which the performance of the Apple Watch as a means of detecting AF could be compared.

The watch detected arrhythmia using photoplethysmography – intermittently shining a light onto the wearer’s skin to detect the pulse. This is distinct from the FDA-approved ECG feature available on newer versions of the Apple Watch, which the user has to activate deliberately in order to take a measurement.

These periodic light-based measurements are called tachograms. If one is positive for AF, the Watch performs five more tachograms in a short period. If five of these six show AF, the watch alerts the wearer.

In the 450 patients with both watch and patch, 2,089 AF-positive tachograms were seen. 1,489 of these were confirmed as AF via the patch, giving a positive predictive value of 71%.

Also in this group, 86 notifications of uneven heartbeat were sent to the watch users. 72 of these coincided with positive detection of AF by the ECG patches, giving a positive predictive value of 84%. By these terms the study can be considered a hit (Detection vs diagnosis: Irhythm and the Apple Watch, March 14, 2019).

Future
These results indicate that the Apple Watch’s algorithm can identify people with previously unsuspected AF. Beyond that, however, few conclusions can be drawn. How applicable are the data to the general population? What kind of impact might wearable technologies have on health systems? And most importantly, do these alerts save lives?

This last point ought to be addressed by the new trial that Apple will conduct in collaboration with Johnson & Johnson. The Heartline study will evaluate whether use of the Apple Watch’s ECG app can improve outcomes including stroke, heart attack and death.

The study will sign up 180,000 patients aged 65 and older who will be randomly assigned to the Apple ECG, a different app, or nothing. The trial will start in late 2019, and bearing in mind the endpoints will likely take longer to yield data than the 15-month term of the Apple Heart Study.

“There are two things it’s going to have to show,” Mark Link, professor of medicine at the University of Texas Southwestern, told Vantage. “If you could show that not only you were accurate in diagnosis, but you prevented a stroke, that would be huge.”

If the Heartline trial can show that the watch reduces stroke risk, this would almost without doubt lead to doctors recommending that their patients buy one. “There’s already a movement out there for physicians to recommend more close monitoring of AF,” he said.

There would even be an argument that the watch be reimbursed as a medical device, Dr Link contended. How much this would boost the sales of Apple Watches is open to conjecture – Apple does not release unit sales for the product, but these are already estimated at around 12 million units per year.

But a hit in Heartline would be a major vindication of wearable monitoring technologies, and could revolutionise the way arrhythmias are screened for at the population level.