Transforming blood pressure control in primary care through a novel Remote Decision Support Strategy based on wearable blood pressure monitoring:

The NEXTGEN-BP randomised trial

NEXTGEN-BP

This is an information sheet about a research trial called NEXTGEN-BP. Research involves finding out how people experience new treatments or ways of doing things and using that information to help other people.

Who is doing the research?

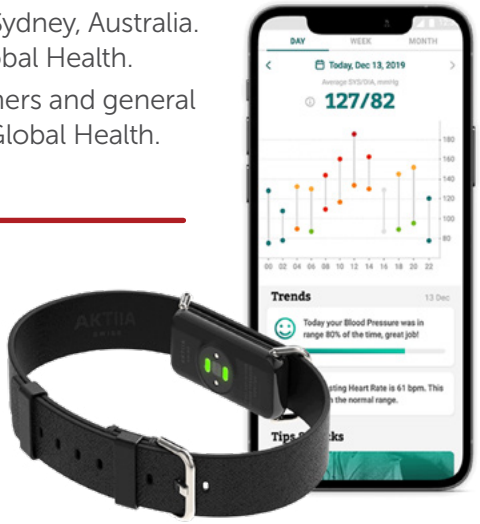
The person in charge of this trial is *Professor Alta Schutte*

I am a hypertension expert and Principal Theme Lead of Cardiac, Vascular and Metabolic Medicine at the University of New South Wales in Sydney, Australia. I am also a Professorial Fellow at The George Institute for Global Health.

The trial is being carried out by myself and a team of researchers and general practitioners and is coordinated by The George Institute for Global Health.

Email: *nextgenbp@georgeinstitute.org.au*

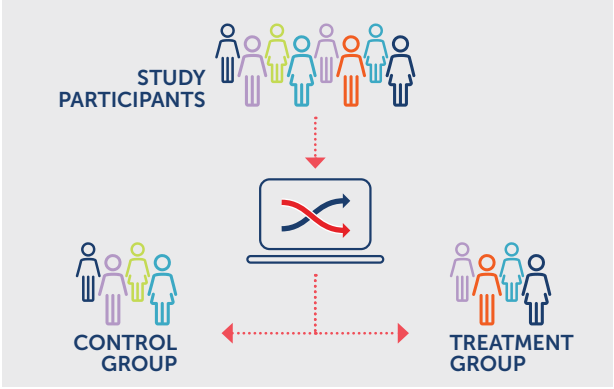
What is it about?



The NEXTGEN-BP trial is looking at the benefits of using a wearable blood pressure monitoring device (called the *Aktiia device*) that looks like a Fit-Bit to monitor your blood pressure remotely.

We want to compare this approach to the usual care that patients receive with their GP, to treat and manage high blood pressure (hypertension).

The research is funded by an Australian government grant called the Medical Research Futures Fund (MRFF).



What does taking part involve?

If you decide to participate in this research, you will be participating in a *randomised controlled trial*.

This means that, just like the flip of a coin, you will have an equal chance of being assigned to either of two groups:

- CONTROL Group: 'usual treatment' with your GP

OR

- TREATMENT (Intervention) Group: you will be monitored by the study team using the Aktiia device that you will wear 24/7 and receive treatment with your GP.

A computer will decide which group you are assigned to.

Over a 12-month period, we want to find out how well the *Aktiia device* works; as well as how safe, cost effective, and acceptable it is in helping to lower high blood pressure.

Later, you may be invited to be part of a small group to provide feedback on the trial via an interview.

If you participate:

- You will be asked to attend three (3) face-to-face clinic visits with a study team member, at the general practice that you attend.
- Each visit will be approximately 1 hour.
- There is no cost to you to attend these visits.
- If you want to, you can bring someone you trust to help you.

If you are in the TREATMENT group, you will also be:

- Contacted in between the clinic visits by phone on two occasions to calibrate your Aktiia device.
- Required to attend two (2) telehealth appointments with your usual GP.

At the end of the 12 months of your participation in the trial, we will give you a $100 gift card to thank you for your time.

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We will ask you:

- About your hypertension history, medical history, your age, ethnicity and gender as well as your lifestyle (smoking/alcohol).
- How frequently you are using your medication, using a questionnaire.
- If you have had any negative effects and if any of your other medications have changed.
- To complete a Quality-of-Life Questionnaire called EQ-5D-5L.

Results of past pathology tests

We will check your blood and urine test results collected over the last 12 months.

We will *measure* your height and weight and calculate your Body Mass Index (BMI)

We will check your heart rate and blood pressure each time we see you at the clinic visit. If you are in the TREATMENT group wearing the Aktiia device, your blood pressure will be monitored and recorded 24/7 for the 12 months of the trial.

Do I have to take part?

Your participation in this trial is voluntary. If you do not want to take part, you can say NO at any time without saying why and it will not affect your treatment with your GP.

Even if you say yes, you can change your mind later and stop taking part.

Ethics Committee Approval

Our research trial has ethics approval. This means it has been checked over to make sure we are doing it right and safely. The ethics committee that approved our research is University of New South Wales Human Research Ethics Committee (HREC). If you think we are not doing the research right or safely you can contact the HREC with this number: HC220617. Phone: (02) 9385 6222 or Email: humanethics@unsw.edu.au

What will happen to my information?

All your information we collect will be securely stored in locked files, folders and cabinets. The data will be kept on a secure computer server that is restricted and has a password. Only authorised research team members will see the data and analyse it at the end of the trial.

Your information will be stored for 15 years, in compliance with National Health and Medical Research Council (NHMRC) requirements.

We will keep your information private by giving you a unique study number and not using your name.

We will not tell anybody your name or where you live. No one will know it was you who took part.

At the end of the research we will send you a Summary report about what we find out.

Questions OR I want to participate

If you have any questions about this research and if you want to participate, please contact a study team member:

Ph: _____ Email: _____