PARTICIPANT INFORMATION SHEET (diabetic patients)

HREC Project Number:	HRE2023-0050
Project Title:	*Taking blood pressure (BP)-lowering medications at night to improve prevention of kidney disease in diabetic patients: What do Australian GPs and diabetic patients think?*
Chief Investigator:	*Dr Chau Ho, Curtin University*
Investigators:	*Jun Chih, Vivian Chiu, Dan Xu, Christopher Reid and Markus Schlaich.*
Version Number:	*2.0*
Version Date:	*24 Nov 2022*

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

- Taking blood pressure lowering medications at night may play a role in preventing the progression of kidney disease in diabetic patients (Moorthi et al 2004). Current evidence for such effect remains inconsistent (Hermida et al 2010, Rossen et al 2014, Povedano et al 2009). Australian GPs' and patients' perspectives on this novel and relatively simple approach are unknown, yet such pilot data are necessary for seeking future larger research funding.

Why have I been invited?

- You are 60 years or over and have been diagnosed with type 2 diabetes mellitus and you are taking once daily dose of BP lowering drug treatment.
- This study plans to recruit participants from now to November 2023.

Do I have to take part?

- No. Taking part in this study is entirely voluntary.
- You can withdraw if you later change your mind, without giving a reason.

What will happen to me if I decide to take part?

- You will be asked to complete a baseline survey to assess your eligibility via the study website. If you meet all of the criteria, you will need to electronically sign an informed consent form through the study website.
- Then, you can access the main survey to explore your perspectives toward changing the time of taking blood pressure lowering drugs. There are other questions relating to demographics, medical history, medications, sleep and mental health as these factors may contribute to explaining the observed results.
- The surveys for patients may take up to 30 minutes to finish.

What should I consider?

- You may not be eligible for the trial if you don't meet the study inclusion criteria. You will need to complete a questionnaire through our study website about your medical history to decide if you are eligible for the trial.

Are there any possible disadvantages or risks from taking part?

- You may have to give up some of your time to complete the online questionnaires.
- This survey will ask some questions about your mental health. If any of the questions listed in the survey bring up something sensitive or upsetting, you can choose not to rate it or you can discuss it with one of the researchers. The following resources are also available if you experience any distress or discomfort from the survey, including:
    - *Lifeline* on **13 11 14** or at https://www.lifeline.org.au/
    - *Beyond Blue* on **1300 22 4636** or at https://www.beyondblue.org.au/
    - MindSpot Clinic at https://mindspot.org.au/

What are the possible benefits of taking part?

- You will be updated on the results of the study once it is completed.

Will my taking part in the study be kept confidential?

- Yes. Data can only be accessed by responsible study staff, where it is relevant to your taking part in this research.

Will I be reimbursed for taking part?

- No.

What will happen to my data?

- We will be using information that you provide from undertaking this survey. Research is a task that we perform in the public interest. Curtin University is the data controller. This means that we, as Curtin University researchers, are responsible for looking after your information and using it properly. Data will be re-identifiable to match the DMP
- You can find out more about how we use your information by contacting the Curtin University Research Team on 1800 971 022 or email admin.ccre@curtin.edu.au.

What happens to the results of this study?

- The results of this study will be published in relevant medical journals and conferences. We will add in a link to the study website from which you could get the information. No identifiable information will be published. Some of the research being undertaken will also contribute to the fulfilment of an educational requirement (e.g. an honour project).

How have patients and the public been involved in this study?

- General practitioners helped develop the research topic and what research questions should be asked and some of them are team members of this project.
- Potential participants were involved in reviewing the Participant Information Sheet.
- Potential participants were involved in describing the inclusion and exclusion criteria for people taking part in this study.

Who has reviewed the study?

- Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2023-0050). Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au.

Participation in future research:

- On the consent form, you will be asked whether you agree to being contacted to participate in future research. If you agree, your contact details would be held separately from this study on a password protected computer in the Curtin School of Population Health.

Further information and contact details:

- Please contact the Curtin University Research Team on 1800 971 022 or email admin.ccre@curtin.edu.au.

Thank you considering taking part.