# SNAP2 - FAQs

1. **Is there any funding per recruit?**

Yes, there is a combination of service support costs, research costs and treatment costs.

2. **How many blood pressure monitors will we get and when will they be sent?**

We will discuss with you how many monitors to send your site. We will have enough monitors for all women in the study. Different cuff sizes will be available.

We will send a package to your site which includes a bag to provide to women, depending on intervention group. Those in the intervention arm will receive a BP monitor, urine test sample (for the 6 week follow up) and instructions. Women in the control arm will receive the BP monitor and instructions only.

3. **How will women receive the ambulatory monitor?**

The central study team will organise shipment and collection of the ambulatory monitors at the 26-week time point.

4. **Can a midwife be a Principal Investigator?**

Yes. PI's need to have up to date GCP.

5. **If a midwife can be PI, how do you get instructions to participants in the intervention arm to titrate their medication?**

In the first two weeks, this would need to be someone in the clinical team who can prescribe. If the medication review is identified by a midwife who can't prescribe, she would communicate this with the clinician who can. It is not a drug trial but clearly medication is important so it would be a case of working with you to understand what those clinical flows in your particular Trust would be.

6. **When can women be approached?**

Women can be approached antenatally or postnatally. If approached antenatally, they will not be randomised until they meet the eligibility criteria, i.e. within 7 days after birth.

7. **Can consent be obtained from women before birth?**

Yes. However verbal re-consent should be re-affirmed post birth and documented in the woman's notes.

8. **How much following up do we do as a team if women aren't compliant with self-monitoring?**

If women miss readings, the App will initially send reminders. Women can be chased by the clinical team until it becomes apparent that she didn't want to use the intervention. We would encourage her to still attend the follow up appointments and the App will record what she has and hasn't done. In general, in primary care, usual compliance is about 80% of participants will continue to monitor for a year. In our feasibility work, there has been some suggestion that this may be higher in obstetric studies as women value having communication with the clinical team.

9. **Do monitors need to be returned?**

No, the participants in both groups can keep their blood pressure monitors.

10. **Do the BP monitors need calibrating at all during the course of the study?**

No, they will be calibrated before they are given out to participants. If the monitor is faulty and needs replacing the central study team will send a new machine directly to the patient. We are

responsible for the monitors for the period that the Woman is on study but beyond this we will not provide any maintenance or replace monitors.

11. **What if there is a discrepancy between the self-monitoring blood pressure and the clinic blood pressure if the woman, for example, attends the GP for an appointment?**

In terms of monitoring, we will encourage participants to take their blood pressure each morning so that if action is needed, it happens during working hours. We're going to ask that care is based on the self-monitored blood pressure reading. This is quite common in primary care where about 40% of general hypertension in primary care is managed via self-monitored blood pressure. Ultimately, it will be up to the clinician to decide. For these women most medication changes will be in the first 2 weeks where attending an appointment with a clinician may be more difficult so we anticipate a lot of this care will be done remotely. In cases where they are seen, if a clinician wishes to use their own blood pressure to guide management, that is completely reasonable.

12. **What gestation can you approach them antenatally?**

We haven't specified antenatally when they can be approached, but generally it would be in the last trimester. Women can consent to take part antenatally, for example, if she were an inpatient, so that initial data can be collected. This would make sense to do if she looked like she was definitely going to go home on medication. You cannot randomise until after delivery.

13. **Is randomisation within 7 days of birth or within 7 days of discharge?**

Within 7 days of birth. Most women will likely be randomised whilst they are still on the postnatal ward but if they did go home, perhaps earlier than expected, randomisation can happen remotely.

14. **When a participant gets a high reading, is the onus on the woman to seek medical care or will they be expecting it to be flagged to an obstetrician?**

The messaging prompts the woman to make contact (e.g. to MAU or GP) but you as the clinical team will have access to the dashboard and so will be able to look and see if there are women with raised blood pressures that haven't had any action taken. The women are not being told that a clinician will contact them if they have a high reading. If you see someone with a high blood pressure and you're able to contact them, then there's nothing stopping you from doing that.

15. **Do you have any participant information leaflets in other languages?**

No. The reason we haven't is because around 95% of women in this age group have got working English. If someone does not speak any English unfortunately this trial may not be for them at this stage. Nine out of the 11 women who were involved in developing the intervention were from ethnic minority groups so we have made sure that the language is simple, but it has not been translated.

16. **When women have the ABPM at 6 weeks, can they drive?**

They would be advised to take off the monitor for long drives. However, we would try as much as possible to organise to do it on a different day.

17. **Do the women receive anything for taking part?**

For the trial, women will be able to keep the monitor. If women take part in an interview as part of trial, participants will be offered a voucher to thank them for their time.

18. **Can the consent be taken electronically?**

Yes.

19. **Are all the follow ups remote?**

We anticipate that most of the recruitment will be in person and the rest of the follow up visits can either be in person or happen remotely, whichever works best for the team and the woman. It is up to the site staff to organise the follow up appointments and communicate this to the woman.

20. **How does the transition to primary care work?**

When women are recruited, the GP will receive a letter informing them of their participation in the study and information about the intervention and adjusting medication that is based on existing guidelines. Most GP practices will have a central email address and contact. The email triggers prompted by low or high readings will be sent to this contact. We anticipate that their GP will be informed when the woman is prompted to make contact with her practice and explains that she is measuring her own blood pressure and they need a medication adjustment. This is something that often happens in primary care. We conducted a large survey prior to designing the trial to find out existing care pathways and found that GPs usually took over care for most women after the first two weeks of birth. This has helped inform the design of the intervention. Part of the trial is to find out how this transition works when women move from maternity care to primary care teams.

Women will be prompted to contact her maternity team if any abnormal readings in the first two weeks and then her GP practice thereafter which will also help to reorientate her care appropriately.

**21. What personal data will you be collecting?**

All personal data will be collected within the RedCAP database which a secure platform. Personal information is not extensive and all required to take part in the study. This includes, name, date of birth, address, phone number to arrange study procedures as well as information about their prior pregnancies and medical history. Consent will be obtained prior to obtaining any personal information and will be kept confidential as per the University of Oxford procedures and the trial protocol.

**22. Do they have to use the study monitors?**

Yes, all participants should be provided with a study blood pressure monitor. Participants in the intervention arm should be encouraged to use this for self-monitoring and all participants should be encouraged to use the study monitor for the follow up visits.

**23. Do you have large cuff sizes?**

We can supply the following cuff sizes:

Medium Cuff- 22cm-32cm

Large Cuff- 32cm-42cm

Large/ XL Cuff- 32 cm-52cm

**24. Can women who do not speak English take part?**

Unfortunately, if the woman speaks no English, she would not be able to take part in the trial itself. However, these women should still be approached, and we would offer them an interview about the intervention (with a translator). Women with limited English may still be able to take part - this would require some judgment around being sure of understanding to consent to the study and to be sure they understood how to monitor and act on high or low readings. Again we are keen to interview these women about their experience of using or not using the intervention.

25. **Can women who only start medication in the postnatal period take part?**

Yes, as long as they have had a diagnosis of pregnancy hypertension, either chronic/essential hypertension (predating current pregnancy or requiring treatment before 20/40), or gestational hypertension (new-onset hypertension from 20/40 of index pregnancy) or pre-eclampsia (hypertension (GH or with proteinuria or metabolic changes), prior to their discharge from hospital post-delivery.

26. **How can women adjust their medication promptly?**

When women are discharged from hospital, we have some suggestions of the medication regime to be prescribed so that it is easy for them to titrate up or down. You can access that information here.

27. **What should secondary care site staff do if they notice a high blood pressure reading on the dashboard beyond 14 days?**

After 14 days the participants readings will be greyed out on the dashboard to signify that they have moved to primary care oversight. The lead Research Midwives will have oversight of all women on the study and can intervene if they are concerned for the patient's safety.