



PRINCIPLE

Platform Randomised Trial of Treatments in the
Community for Epidemic and Pandemic Illnesses

Information for participants

Thank you for taking part in the PRINCIPLE trial.

This information booklet will help guide you through what will happen during your time in the trial.

Please read on for more details about the trial medication and other key details.

Contact us

If you have any questions, please contact us on:

E-mail: principle@phc.ox.ac.uk

Telephone: 0800 138 0880

Summary

If provided with a swab through usual care, please take the swab as early as possible, before trial treatment begins.

Please take your medication (unless in Usual Care Group) for the *required number* of days and the dose specified. There is more detail in this booklet about how and when to take this.

During the trial period, we ask you to complete a short daily diary about your symptoms. If we do not receive your diary, we will call you and/or your trial partner to ask a few short questions.

Your participation will last for a total of 28 days.

Taking your trial medication (unless in Usual Care Group)

Please see the drug information card for guidance on how you should take your medication.

Completing the daily online diary

We ask you to complete a short daily symptoms diary for 28 days. This will take less than ten minutes of your time each day.

- You will receive a daily email with an internet link, which will take you to a secure online system to collect your diary entries confidentially.
- You will receive a text asking you to submit your answers on the same day; you may prefer to do this at a regular time for your own convenience and routine.
- You will be asked to record whether you are experiencing a few simple symptoms, and to rate the severity of these symptoms.
- Please ensure that you submit your diary to us at the end of the questions, so we receive all of your answers.
- If we do not receive your completed diary, or you are unable to access the online diary, we will contact you and/or your nominated trial partner on day 7, day 14 and day 28 of the follow up period to collect this information.
- Finally, we will also ask that you, or someone close to you notifies us if you are admitted to hospital.

Appendix: Pregnancy test

If randomised to certain medication, women of child-bearing potential must take the pregnancy test provided and confirm a negative test result with the trial team, prior to starting the medication. This requirement was indicated during the screening process and agreed to on your informed consent form. This is important to ensure your safety since there is limited human research for this medication for pregnancy and breastfeeding.

Please take the test as soon as possible and follow the instruction in the test kit provided. The trial team will contact you on Day 2 or Day 3 of the trial to confirm receipt of your trial pack and to ask for your test result.

You will also be asked confirm a negative pregnancy test result in your daily diaries. If we are unable to contact you or your Study Partner, with consent, we may contact your GP.

If you do have a positive test result, or do not wish to take a pregnancy test, please **do not** take any of the medication and we will arrange a free postal return to the trial team. Please do not discard the medication.

You will also be withdrawn from the trial. However, please note that this will not affect the standard of care you receive from the NHS in any way, now or in the future.