

Information sheet for participants in a medical scientific study

MOPHAR study

Monitoring the somatic effects of psychological disorders, including side effects of medication at the outpatient clinics of mental health service providers (GGZ) in the Netherlands.

Introduction

Dear Sir/Madam,

We would like to invite you to take part in a medical scientific study. Participation is entirely voluntary. If you wish to take part, we need your written consent. You have received this letter because you are being treated by a mental health service provider (GGZ organisation), and may be taking medication for the treatment of a psychiatric disorder. We would like to study the somatic effects of your disorder and the side effects of any medication you are taking.

Before you decide whether you want to take part in this study, you will be given an explanation of what the study involves. Please read this information sheet carefully and ask the researcher to answer any questions you may have. If you wish, you can ask the independent psychiatrist listed at the end of this information sheet to provide you with additional information. You can also discuss possible participation with your partner, friends or family.

1. General information

This study has been designed by GGZ Drenthe and is being carried out by healthcare practitioners and researchers at various GGZ organisations, the psychiatry department of University Medical Center Groningen (UMCG) and general practitioners. The study has been approved by the medical-ethical committee of the Medical Center Leeuwarden. If you would like to have more general information about participating in scientific research, please consult the website [Medisch-wetenschappelijk onderzoek | Rijksoverheid.nl](https://www.wetenschappelijkonderzoek.nl).

2. Purpose of the study

The purpose of the MOPHAR study is to understand the somatic effects of psychiatric disorders, and which risk factors determine that some people experience far more effects than others. We also intend to specifically monitor the side effects of medication to better understand why certain side effects are found much more often among some people than among others. We want to examine what can be done to reduce the side effects and to improve the physical health of people with psychiatric disorders in general. The results of this study will be shared with you as well as with healthcare practitioners and

other researchers, and will be described in scientific journals so that others can also benefit from the study's findings.

3. Background to the study

People with psychological problems often also suffer from physical health conditions. Physical problems can negatively affect the way someone feels or acts. Conversely, psychological problems can have a negative effect on a person's physical health. People with mental health conditions, for example, may eat less healthy food, exercise less and sleep less well, often causing them to feel tired or exhausted.

Therefore, when treating psychological problems, it is important to have a good understanding of someone's physical health, medication use and lifestyle so that this can also be addressed during their treatment. This is the case in the MOPHAR study. MOPHAR (pronounced 'mofar') is short for Monitoring Outcomes of Psychiatric PHARmacotherapy, which means measuring the effects of medication use for psychological problems.

It has also been found that people with psychiatric disorders may suffer from poor physical health. A better lifestyle, more exercise and a healthier diet could help in these cases. This is also something we want to study. And lastly, we want to find out more about possible hereditary factors that could affect the risk of developing physical problems.

4. What participation involves

Many aspects of this study, such as monitoring your general state of health, are part of the standard healthcare you receive if you are being treated for a psychiatric disorder. We may only use this information for our research if you have given us your consent. In addition, we would like to collect other data that would help us better understand why some people are more likely to experience physical problems than others. This information could, for example, enable us to examine why some people experience certain side effects and others don't. We will also ask your consent and cooperation to collect these data.

When you visit one of our outpatient clinics, it is standard practice to assess your state of health, including any side effects of the medication you use (if any). We monitor parameters like changes in weight, waist circumference and blood pressure, and take a blood sample, which is sent to a laboratory for analysis. We will also ask your pharmacy or dispensing physician to provide us with details of the medication you are on now or have used in the past. If you decide to take part in the MOPHAR study we will ask your consent to use these standard healthcare data. This includes information you yourself have provided in the standard questionnaires used by GGZ mental health service providers to establish whether you suffer from psychological problems. We will also ask you to complete several additional questionnaires, or to answer the questions together with a nurse, to be able determine why a given treatment works for you and others don't. Issues addressed in these questionnaires include your medication use, physical health and lifestyle (such as smoking, alcohol consumption and physical exercise), any changes in the psychological problems you experience and

quality of life. You will also be asked about events in your childhood that could influence the problems you are now facing. You will be asked to complete the questionnaires at the start of your treatment, and some will be repeated after a year, or if your treatment changes. Completing the questionnaires will take about 60 minutes first time round and about 30 minutes for any repeat questionnaires.

At the start of your treatment we will also ask your consent to collect an extra blood sample (10 ml) for the purpose of this study, in addition to the two samples we draw as standard practice. Where possible, the additional sample will be collected at the same time as the standard blood samples. The additional blood samples will be used for DNA analysis to determine your hereditary disposition for side effects and physical problems. We hope that this DNA analysis will, in the future, contribute towards the development of medication for psychiatric disorders that is tailored to a person's genetic make-up.

5. What can you expect?

Apart from the extra time you will need to spend on completing the questionnaires (possibly together with a nurse) and having an additional blood sample taken (see details above), you are not expected to do anything else for the purposes of this study.

6. Possible adverse effects

Taking a blood sample can be painful or cause some bruising, but as we will draw a blood sample during our standard blood sample collection procedure, this will not cause any additional inconvenience.

7. Possible benefits and drawbacks

It is important that you carefully weigh the possible advantages and disadvantages before you decide whether you want to take part in this study.

You might find it difficult to answer some of the questions. Other possible drawbacks are that participation will take up some of your time, and that we will collect an extra blood sample.

As for the possible benefits, participating in the study could help better identify the side effects you are experiencing. You can discuss this with your healthcare practitioner. The healthcare practitioner can then adjust your medication, treat the side effects or invite you to take part in a lifestyle programme, for example. While you will not benefit personally from the collection of an extra blood sample for this study, it will contribute to a better understanding of the occurrence of side effects and the success of certain treatments.

8. If you do not want to participate or want to withdraw from the study

It is up to you to decide whether you want to take part in the various elements of this study. You will be asked separately on the consent form whether you wish to give your consent for any additional

elements. Participation is voluntary. If you do not want to take part, your condition will be treated in the usual way.

If you do participate, you may always change your mind and choose to stop at any time during the study, and your condition will be treated in the usual way. You do not have to say why you want to withdraw from the study, but we do ask you to immediately inform your healthcare practitioners. The data we have collected until that time will be used for the study. If you wish, the blood samples collected can be destroyed.

If any new information about the study becomes available that could be important to you, the researcher will let you know. You will then be asked whether you want to continue participating.

9. End of the study

Your participation in the study will end once your treatment at a GGZ health service provider has been completed, or if you choose to withdraw yourself, unless you have explicitly informed us that you would like to take part in a follow-up study. The full MOPHAR programme will continue in the years ahead. Participants will be informed of the results of the study in an annual newsletter.

10. How we use and store your data and blood samples

For this study we collect, use and store your personal data and blood samples. Personal data includes your name, address, date of birth and data concerning your health. We will also take blood samples for this study in order to analyse your DNA. Collecting, using and storing your data and blood samples is needed to be able to answer the research questions in this study and to publish the results. We will ask for your consent to use your data and blood samples.

Confidentiality of your data and blood samples

To protect your privacy, your data and blood samples will be coded. Your name and any other information that could directly identify you are omitted. The data can only be traced back to you with the key to the code. The key to the code will be stored safely at the research location. The data themselves are stored in RoQua, a data system of the University Medical Center Groningen, where the codes that can be traced back directly to an individual have been removed. Only researchers who have been given the explicit consent of the lead researchers of the MOPHAR study have access to the stored data. The data and blood samples that are sent to the laboratory can only be identified with a code, they are not linked to your name or other data with which you can be identified. Nor can the data be traced back to you in reports and publications about the study.

Access to your data for control purposes

Some people at the research location will have access to your data, including data that have not been coded. This is necessary for them to check whether the study is being conducted in a proper and reliable manner. People who are given access to your data are a controller/monitor working for the researcher, and national and international supervisory authorities such as the Health and Youth Care Inspectorate, all of whom observe strict confidentiality. We ask your consent for these people to

access your data.

Retention period of data and blood samples

Your data will be stored at the research location until 15 years after the end of the study. Your blood samples will also be kept and are not destroyed immediately after they have been analysed. Your data are kept to be able to conduct other scientific studies into mood and anxiety disorders in the future should new questions arise. When we collaborate with researchers from other universities, research institutes or companies, your data may be stored in a shared database. By teaming up, we can cut costs *and* answer research questions that require large numbers of participants. The data are aggregated in a non-identifiable way and can therefore not be traced back to individuals. Also, we may in the future want to link your data with the data of healthcare providers or from registration systems, such as data that Statistics Netherlands collects about public health in the Netherlands. Your identity will be protected at all times and will not be revealed to third parties. We therefore ask your consent to use your research data for other studies and to store your data in shared research databases such as the ones described above. You can indicate on the consent form whether you give your permission for this. Should you choose not to consent to this, you can still take part in this study.

Information about unexpected findings

The study may yield chance findings, for example when collecting blood samples, that are not relevant to the study itself but that *are* relevant to you. If the findings are important to your health, you will be informed by your GP or psychiatrist. You can then discuss with your GP or specialist what needs to be done. We also ask your consent for this.

Withdrawing your consent

You are free at any time to change your mind and withdraw your consent for the use of your personal data – not only for this study but also for any future studies. The research data that have been collected up to the time that you withdraw your consent will, however, be used for the purposes of this study. Your blood samples will be destroyed after you withdraw your consent. Any measurements on your blood samples that have already been performed, can still be used.

Sharing data with countries outside the European Union (EU)

In this study, we regularly work with international researchers from different universities, for example when an international research team has specific expertise that is not available in the Netherlands. This means that your coded data and blood samples may be shared with countries outside the European Union where the EU's regulations for the protection of personal data do not apply. Your privacy will, however, enjoy the same protection.

More information about your rights in relation to the processing of your data

For general information about your rights in relation to the processing of your personal data, please see the website of the Dutch Data Protection Authority.

If you have any questions about your rights, you can contact the organisation responsible for the processing of your personal data. See Appendix A for contact details.

If you have any questions or complaints about the processing of your personal data, we recommend that you first contact your research location. Alternatively, you can get in touch with the data protection officer of GGZ Drenthe or the Dutch Data Protection Authority.

Registration of the study

Information about this study is also registered in an overview of medical scientific studies, the Netherlands Trial Register (NTR) (<http://trialregister.nl>, under number NL4779). The register does not include data that can be traced back to you. After completion of the study, the NTR website may contain a summary of the results of this study.

11. Insurance for participants

As participation in the study does not pose any additional risk, the GGZ organisation is not required by the medical-ethical committee of the Medical Center Leeuwarden to take out additional insurance.

12. Payments and expenses

Collection of the additional blood sample for this study is free of charge. You will not be paid to take part in this study. Any travel expenses you need to make for the study will be reimbursed.

13. Questions?

If you have any questions, feel free to get in touch with the research team. For independent advice about participation in this study, you can contact the independent psychiatrist. She is in no way involved in this study, but does know a lot about it.

If you have a complaint about any aspect of this study, you can ask to speak to the researcher or your treating doctor. If you would rather not discuss this with them, you can contact the [complaints officer/complaints committee of your hospital/ institute/other]. See Appendix A for contact details.

14. Signing the Participant Consent Form

If you give your consent for participation in the study, we will ask you to confirm this in writing on the enclosed consent form. By providing your written consent, you confirm that you have understood the information provided and agree to take part in the study. Both you and the researcher will receive a signed copy of the consent form.

Kind regards,

On behalf of the MOPHAR team, Dr E. Visser, senior researcher

16. Appendices to this information

- A. Contact details
- B. Participant Consent Form

Appendix A: Contact details [GGZ Drenthe and University Center of Psychiatry (UCP), Groningen]

Lead researchers GGZ Drenthe:

Prof. Dr Danielle Cath, psychiatrist, Head of specialist training, GGZ Drenthe, senior lecturer
University Center Psychiatry, UMC Groningen; danielle.cath@ggzdrenthe.nl

Nicolette Moes, MSc, manager and lifestyle coach, MOPHAR project leader;
nicolette.moes@ggzdrenthe.nl

Dr E. Visser, senior researcher MOPHAR; visser03@umcg.nl

Lead researcher UCP:

Dr B. Haarman, psychiatrist, Head of Mood and Anxiety Disorders Program; b.c.m.haarman@umcg.nl

Lead researcher Lentis:

Dr. B. Doornbos, psychiatrist, head of training, senior researcher Lentis; b.doornbos@lentis.nl

Independent psychiatrist: Astrid Lugtenburg, MD, psychiatrist at GGZ Drenthe;
a.lugtenburg@ggzdrenthe.nl

Complaints: klachtenfunctionaris@ggzdrenthe.nl

Data protection officer of GGZ Drenthe FGespria@espria.nl

For more information on your rights see <https://ggzdrenthe.nl/privacy-statement>, or send an e-mail
to: privacy@ggzdrenthe.nl

MOPHAR research locations:

Assen: outpatient clinic Tripolis, Beilerstraat 177, 0592-324200

Emmen: outpatient clinic Stationsstraat 20, 0591-856111

Hoogeveen: outpatient clinic Amshoffweg 3, 0528-857777

Groningen: University Center of Psychiatry, Hanzeplein 1, 050-3618880

Groningen: Lentis, E 6, 9471 KA Zuidlaren, 088-1140000

Appendix B: Participant Consent Form

MOPHAR study

- I have read the information sheet. I also had the opportunity to ask questions. My questions have been adequately answered. I had enough time to decide whether I want to participate.
- I understand that participation is voluntary. I also understand that I can decide at any time to not participate after all or to withdraw from the study. I do not have to give a reason for my decision.
- I consent to my GP being informed that I am taking part in this study, and about any unexpected findings that are important to my health.
- I understand that for control purposes in the context of this study, some people may be given access to all my data. These people are listed in this information sheet. I give permission for such access by these people.
- I consent to the collection and use of my data which form part of the GGZ's standard healthcare and those that are needed for this study.
- I consent to the collection and use of my data for the purpose of answering the research questions in this study.
- I **consent/do not* consent** to my personal data and blood samples being stored and to use these data/samples for future research into my disorder.
- I **consent/do not* consent** to an additional blood sample being taken for the purpose of genetic (DNA) analysis.
- I **consent/do not* consent** to being contacted again after this study for the purpose of scientific research.
- I agree to take part in this study.

***Please delete where not applicable.**

Name of participant:

Date of birth: __ / __ / __

Signature:

Date: __ / __ / __

(to be filled in by the researcher)

I certify that I have fully informed this participant about the study described.

If, during the study, information becomes available that could influence the participant's consent, I will inform them thereof in good time.

Name of researcher (or his/her representative):

Signature:

Date: __ / __ / __