



ALGEMEEN
Gebruikte link is een multipaginaal document (zie PDF).
Computervraaglijst-documenten van ZUS.

1. **What is the primary purpose of the study?** The primary purpose of the study is to evaluate the effectiveness of a new treatment for depression compared to a placebo. The study will also assess the safety and side effects of the treatment.

2. **Who is eligible to participate in the study?** Participants must be at least 18 years old and have been diagnosed with major depressive disorder. They must also be willing to take part in all study procedures and follow the study protocol.

3. **How long will the study last?** The study will last approximately 12 weeks, including a 4-week baseline period, 8 weeks of treatment, and a 2-week follow-up period.

4. **What treatments will be provided?** Participants will receive either the new treatment or a placebo. Both treatments will be administered orally once daily. The new treatment is a combination of two medications, while the placebo is a dummy pill.

5. **What are the potential risks and benefits of participating in the study?** The potential risks include side effects from the medication, such as nausea, drowsiness, and headache. The potential benefits include relief from symptoms of depression and the opportunity to contribute to medical research.

6. **Will participants receive feedback about their individual results?** Participants will receive feedback about their individual results, including how well they responded to the treatment and any side effects experienced.

7. **How will participant privacy be protected?** Participant privacy will be protected by using a unique study code instead of a name, and all data will be stored securely and confidentially.

8. **What happens if a participant decides to leave the study early?** If a participant decides to leave the study early, they will be free to do so without penalty. However, they will still be asked to complete all study procedures up to that point.

9. **What happens if there are any changes to the study?** If there are any changes to the study, participants will be informed and given the opportunity to withdraw from the study if they choose.

10. **What happens if a participant has an emergency?** In case of an emergency, participants should contact the study team immediately or seek medical attention as needed.

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