

Supplement A: Surveys

A. Questionnaire for participants in controlled human infection trials

General:

1. In which study did you participate? Malaria/Schistosomiasis/Hookworm
2. Are you male or female?
3. What is your age? 18-24/25-30/>30
4. At the time of your participation in the trial were you: Student/Working/Unemployed
5. Had you participated as a subject in medical research before? Yes/No
6. Do you work in healthcare or do you follow a health-care related study? Yes/No

Motivation:

7. On a scale of 0 to 5 indicate how important the following factors were for your decision to participate (0=not important at all, 5=very important)

Curiosity 0 1 2 3 4 5
Contributing to science 0 1 2 3 4 5
Helping people who are less well-off than me 0 1 2 3 4 5
The financial compensation 0 1 2 3 4 5
I'm interested in the subject 0 1 2 3 4 5
Personal experience with the disease 0 1 2 3 4 5
Other, namely
8. On a scale of 0 to 5 indicate how much did you weigh the following factors before deciding to participate?

Severity of possible symptoms 0 1 2 3 4 5
Chance to get symptoms 0 1 2 3 4 5
How much time the study will cost 0 1 2 3 4 5
Easy to make money 0 1 2 3 4 5
Trust in the study team 0 1 2 3 4 5
The fact that this is a study about parasites 0 1 2 3 4 5
Reaction of people around you 0 1 2 3 4 5
9. Did you discuss your participation with people around you? Yes/No
 - a. If no: why not (open question)
 - b. If yes: with whom? Parents/partner/friends/roommates/class mates/colleagues/others.....
 - c. Did you receive positive reactions on your participation? Yes/No (space for open answers)
 - d. Did you receive negative reactions on your participation? Yes/No (space for open answers)
10. Did you feel pressurised to participate? Yes/No
 - a. If yes: why? Needed the money/did not want to say no after signing up/pressure from the study team/other.....

How was the infection experienced?

11. How did you estimate the risk of this study before participating? (0=very low, 5=very high) 0 1 2 3 4 5
12. Before the infection took place, were you afraid of getting symptoms? Yes/No
13. Has this changed during the course of the trial? Yes/No
 - a. If yes, has your fear of symptoms increased or decreased?

14. How did you experience the moment of the infection itself?
Positive/neutral/exciting/fearful/other
15. On a scale of 0 to 5, indicate how you experienced being infected for this study (0=not at all, 5=very much)
Exciting 0 1 2 3 4 5
Interesting 0 1 2 3 4 5
Fearful 0 1 2 3 4 5

Symptoms and trust in study team

16. On a scale of 0 to 5 how would you rate your symptoms during this trial? (0=no symptoms, 5=so bad I had to quit the trial)
17. Were the symptoms as you had expected before the start of the trial? Yes/No, space for open answer
18. Did you feel the symptoms and risks of this study weigh up to the possible benefits for you and for science? Yes/No, space for open answers
19. Do you think it is acceptable that a doctor might make you ill as part of research?
- Yes, I trust that I will be well taken care of and that the research is safe
 - Yes, if it contributes to science and to finding a cure or treatment for a severe disease the benefits outweigh the disadvantages
 - No, this goes against the principle that a doctor should do no harm
 - Other, namely.....

Informed consent

20. How important was the screening and presentation you received for your decision to participate? (0=not at all, 5=very important) 0 1 2 3 4 5
- What's the most important thing you remember from the screening? Possible symptoms/risks of participation/when and how often to visit the trial centre/rules surrounding life style during the trial/other
 - Did your opinion about the study change after talking to the trial physician about possible risks and symptoms?
 - Yes, afterwards I was relieved, I thought the symptoms would be more severe
 - Yes, I thought the complaints were less severe
 - No, the information in the letter was enough
 - Other
 - Can you briefly describe the purpose of the study you participated in? Open answer

Right to withdraw

21. An important part of a study protocol is that volunteers can always withdraw from a study.
- How important do you feel it is to be able to withdraw from a study at all times? (0=not at all, 5=very important) 0 1 2 3 4 5
 - In a controlled human infection trial it is often not possible to immediately withdraw from the study, because there needs to be a treatment and final check-up even after withdrawal, to ensure the safety of the volunteer. How do you feel about this?
 - That's logical: this is done for your own safety and you know this before participation
 - That feels as a restriction to my freedom to withdraw from the trial
 - Other, namely

Compensation

22. Would you participate in this trial if there was no financial compensation? Yes/No
23. How do you view the compensation?
 - a. As a compensation for time spent and travel costs
 - b. As a compensation for the risk and discomfort of participation
 - c. As motivation to participate
24. What did you do with the money you received? (multiple options) Holiday/Electronics/Paid debts/Used it in daily life/Gave to charity/I'd rather not say/Other.....
25. What did you think of the amount of the compensation? Alright/too high/too low
26. If the risk of severe symptoms was twice as high, but the compensation was also twice as high, would you participate? Yes/No
27. Other than the financial compensation, do you feel you have benefitted from your participation? Yes/No If Yes, how?.....

Concluding

28. Are you proud of your participation?
29. Would you advise others to take part in a trial like this? Yes/No space for open answer
30. Would you participate in another trial? Yes/No
 - a. If no: why? Takes too much time/symptoms too severe/compensation too low/other

B. Questionnaire – version for students

1. What is your age?
 - <18 years old
 - 18-25 years old
 - >25 years old
2. I am male/female
3. Would you participate in a study investigating a new drug? Yes/no

Malaria study:

Wanted: healthy volunteers for a study into the efficacy of a new vaccine against malaria. Earlier research has shown that this vaccine can be administered safely to humans. Now, the effect on protection against malaria will be studied. After three vaccinations, volunteers are exposed to bites of a malaria mosquito. After these bites volunteers visit the trial centre daily for 14 days for check-up visits. At each visit volunteers are checked if they have developed malaria. If a volunteer becomes positive he or she is immediately treated. Possible side effects include itching after vaccination and after mosquito bites and headaches, fever, myalgia and a flu-like syndrome if a volunteer gets malaria. Including vaccinations and all check-up visits volunteers have to come to the trial centre 25 times, for 15 minutes each. Compensation: €1200,-

Hookworm study:

Wanted: healthy volunteers for a study into hookworms. Hookworms are parasites measuring 1-2 cm that live in the intestine. In children this infection can cause anaemia, protein deficiency and impaired cognitive and physical development. In order to treat this infection and develop a vaccine more research is needed. For this study volunteers are infected with hookworm. This is done by placing a gauze with water containing the larvae on the skin. The larvae cannot be seen with the naked eye. Possible symptoms are itching and a rash on the site of infection and abdominal complaints, such as abdominal pain and diarrhoea. Volunteers have to come to the trial centre

weekly for 16 weeks for a check-up visit of 15 minutes and have to hand in a stool sample every week. After the 16th week all volunteers are treated so the worms go away. Compensation: €1500,-

4. Would you participate in (one of) these studies?
 - No, with neither of these → go to Q5, skip Q6
 - Yes, but only with the malaria trial → go to Q5, then to Q6
 - Yes, but only with the hookworm trial → go to Q5, then to Q6
 - Yes, with both studies → go to Q6
5. If you do not want to participate in this study or these studies, how important are the following factors in your decision? (0=not at all, 5=very important)
 - Takes too much time 0 1 2 3 4 5
 - I think the risk is too great 0 1 2 3 4 5
 - I'm afraid to get symptoms 0 1 2 3 4 5
 - Compensation is too low 0 1 2 3 4 5
 - The idea to be infected with a worm 0 1 2 3 4 5
 - The idea to be infected with a parasite 0 1 2 3 4 5
 - Other, namely
6. If you do want to participate in (one of) these studies, how important are the following factors for you? (0=not at all, 5=very important)
 - Curiosity 0 1 2 3 4 5
 - Contributing to science 0 1 2 3 4 5
 - Helping people who are less well-off than me 0 1 2 3 4 5
 - The financial compensation 0 1 2 3 4 5
 - I'm interested in the subject 0 1 2 3 4 5
 - Personal experience with the disease 0 1 2 3 4 5
 - Other, namely
7. When considering participation, how important are the following factors to you? (0=not at all, 5=very important)
 - Severity of possible symptoms 0 1 2 3 4 5
 - Chance to get symptoms 0 1 2 3 4 5
 - How much time the study will cost 0 1 2 3 4 5
 - Easy to make money 0 1 2 3 4 5
 - Trust in the study team 0 1 2 3 4 5
 - The fact that this is a study about parasites 0 1 2 3 4 5
8. Do you think it is acceptable that a doctor might make you ill as part of research?
 - Yes, I trust that I will be well taken care of and that the research is safe
 - Yes, if it contributes to science and to finding a cure or treatment for a severe disease the benefits outweigh the disadvantages
 - No, this goes against the principle that a doctor should do no harm
 - Other, namely.....
9. An important part of a study protocol is that volunteers can always withdraw from a study. How important do you feel it is to be able to withdraw from a study at all times? (0=not at all, 5=very important) 0 1 2 3 4 5
10. In a controlled human infection trial it is often not possible to immediately withdraw from the study, because there needs to be a treatment and final check-up even after withdrawal, to ensure the safety of the volunteer. How do you feel about this?

- That's logical: this is done for your own safety and you know this before participation
 - That feels as a restriction to my freedom to withdraw from the trial
 - Other, namely
11. Would you participate in this trial is there was no financial compensation? Yes/No
12. How do you view the compensation?
- As a compensation for time spent and travel costs
 - As a compensation for the risk and discomfort of participation
 - As motivation to participate
13. If the compensation was twice as high, would you participate in the trial? Yes/No
14. If the risk of severe symptoms was twice as high, but the compensation was also twice as high, would you participate? Yes/No

Room for additional remarks

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