



3. The Insulin Injection Trial is an unmasked, controlled, randomized clinical trial. What are the names (or can you describe) the two treatment groups in the trial?

*[The person should be able to explain that there are two different treatment groups: One that receives the "Experimental" insulin treatment and the other which does not receive any insulin treatment, but is "Closely Monitored."]*

Rate their understanding:  Good  Fair  Poor  Unsure

4. (a) Can you tell me how insulin will be used in the Experimental Treatment Group of the Insulin Injection trial?

*[The person should state that Experimental Treatment consists of twice daily injections of insulin and insulin given in the hospital for four days every year.]*

Rate their understanding:  Good  Fair  Poor  Unsure

- (b) Can you tell me how the medication (insulin crystals or placebo) will be used in the Oral Insulin Trial?

*[The person should state that a capsule containing insulin crystals or placebo will be taken once daily.]*

Rate their understanding:  Good  Fair  Poor  Unsure

5. Can you tell me what is meant by randomization?

*[The person should state that randomization is the process that will be used to assign the subject to a treatment group. There is a 50% chance of being assigned to either of the two groups.]*

Rate their understanding:  Good  Fair  Poor  Unsure

6. (a) Do you have a strong preference for being assigned to one trial over the other? If so, which do you prefer and why?

- No strong preference.  
 Yes, strong preference for Insulin Injection Trial.  
 Yes, strong preference for Oral Insulin Trial.

Reason for preference: \_\_\_\_\_

- (b) Do you have a strong preference for being assigned to one treatment group over the other in the Insulin Injection Trial? If so, which do you prefer, and why?

- No strong preference.  
 Yes, strong preference for the Closely Monitored Group.  
 Yes, strong preference for Experimental Group.

Reason for preference: \_\_\_\_\_

7. Would you be willing to support the decision to be randomized into either of the treatment groups and to adhere to the assigned treatment group for the duration of the study?

No  Yes  Unsure

8. If you are enrolled in either DPT-1 trial, how often will you need to come in to the clinic for routine follow-up appointments?

*[The person should state that routine follow-up visits will occur every six months.]*

Rate their response:  Overestimate  Accurate Answer  Underestimate

9. If you are assigned to the Experimental Group of the Insulin Injection Trial, you will need to spend 4-5 days in the hospital right away. After this, how often will you need to be hospitalized?

*[The person should state that hospitalization will occur once a year]*

Rate their response:  Overestimate  Accurate Answer  Underestimate

10. Do you realize that sometimes you may have to give priority to this study, causing other family members and friends to change plans? Do you think this will cause problems?

Rate their response:

- They appear to understand the issues involved but do not believe that they will experience problems.
- They appear to understand the issues and agree that problems may arise.
- They do not appear to understand the issues.
- They do not think that they can deal with the problems.

11. Do you understand that you may have some expenses for transportation, telephoning the clinic (if long distance), or hiring a baby-sitter? Do you think this will cause problems because these expenses cannot be reimbursed?

Rate their response:

- They understand the issues but do not believe they will experience undue hardship.
- They believe this will cause significant problems.
- They do not appear to understand the issues.

12. Do you understand that you may need to miss school or work days in order to keep clinic appointments? Do you think this will cause problems?

Rate their response:

- They understand the issues involved but do not believe that they will experience undue hardship.
- They understand the issues involved and believe that a considerable amount of inconvenience may result.
- They do not appear to understand the issues and that problems may arise.

13. How do you feel about performing blood glucose monitoring at home, which will have to be done five times per day once every 3 months? Would you have problems with doing this?

Would not have a problem  Would have a problem  Unsure

14. Are there any circumstances in your family life, school life, work situation, etc. that could affect your participation in any aspect of this trial?

Yes  No If yes, describe\_\_\_\_\_

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15. Have you spoken with friends or family members about enrolling in the DPT-1?

Yes  No

If yes, who have you spoken with?

- parents  other relative  
 mother only  friends/roommates  
 father only  spouse  
 children  other, specify\_\_\_\_\_

16. Family members often have differences of opinion about the DPT-1. How about your family?

Yes  No

If yes, describe the conflict:

- Some disagreement but the family is working it out.  
 Serious disagreement between family members that needs to be followed by the DPT-1 Staff; describe:

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