

Clinical Trial Considerations: Ethics Perspective

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Disclosures

- Site PI, co-I for NIA-industry sponsored trials: Lilly, Novartis and Biogen
- Intellectual property: none
- Paid consulting: none

Why enroll....

- Clinical trial is a personal decision/preference: no inherently right or wrong decision (*"In matters of taste....."*)
- The decision to enroll is multi-attribute: trust, altruism & expectation of benefit
 - trust is contextualized and involves more than one component: research, the researcher, the institution, the sponsor
 - altruism is contextualized: my kin, kith, people like me, humanity
 - benefits: health and/or at least no harm, money, fun, a pleasant event

The Research Attitudes Questionnaire

1. I have a positive view about medical research in general.
2. Medical researchers can be trusted to protect the interests of people who take part in their research studies.
3. We all have some responsibility to help others by volunteering for medical research.
4. Society needs to devote more resources to medical research.
5. Participating in medical research is generally safe.
6. If I volunteer for medical research, I know my personal information will be kept private and confidential.
7. Medical research will find cures for many major diseases during my lifetime.



Figure 1: Model predicted willingness to participate by research attitude score (within the observed range of values). The graph depicts the relationship between a score on the Research Attitudes measure and the probability of a person endorsing whether he or she would endorse one of the four measures of willingness to participate.

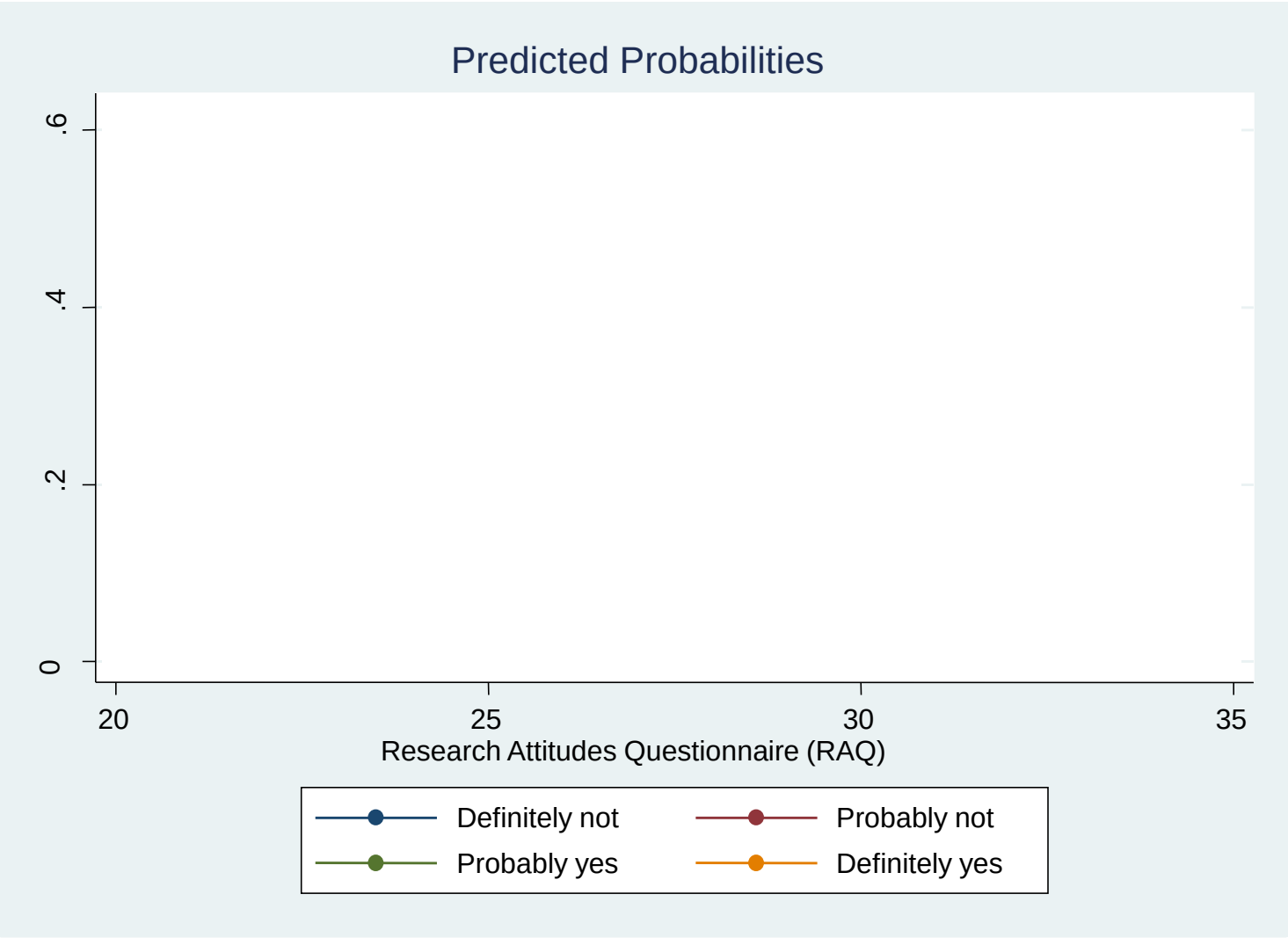
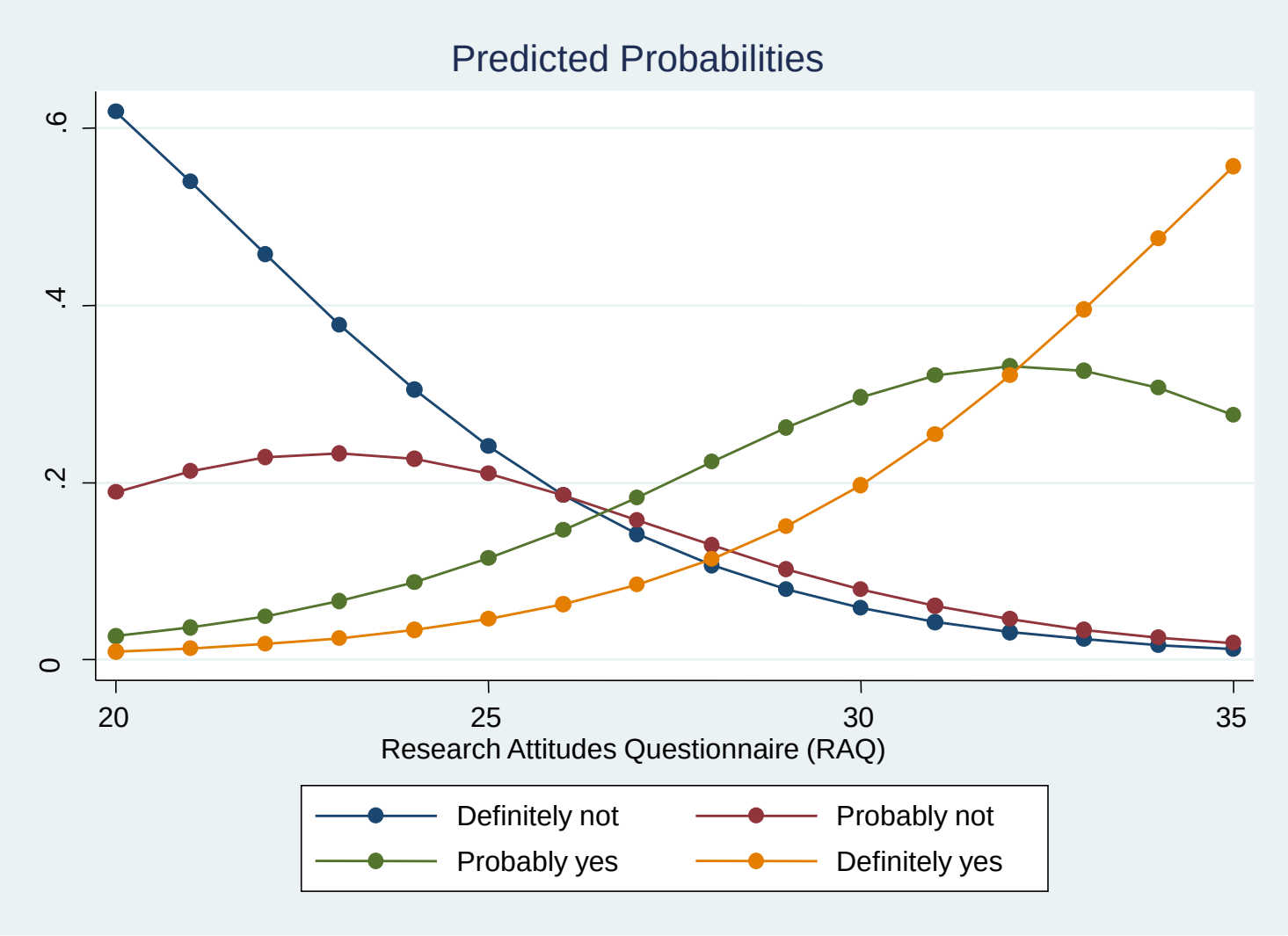


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Some more thoughts on benefit...

- Research is work. That's why we pay people.
 - the work includes travel to the study site and time at the study.
- As a result of physical and cognitive impairments, older adults, especially persons over 75, may experience inefficiencies or disabilities in performing IADLS
 - travel and being in research are IADLS
 - someone else may need to help out: care partner or care giver
- H: Can modifying attributes of a clinical trial adjust people's willingness to participate?

How to redesign an AD clinical trial...

- The location of study visits
- Transportation
- Potential risk
- Chance of receiving the experimental treatment



How to redesign an AD clinical trial...

- Attribute
- The location of study visits
 - All ten visits at Penn
 - Initial and final at Penn, eight intermediate at home
 - Transportation
 - A transportation (car) service is provided ← Levels of the attribute
 - Caregiver is responsible
 - Potential risk
 - Basic risk level
 - Basic, plus small risk of heart inflammation
 - Chance of receiving the experimental treatment
 - 50-50
 - 67-33

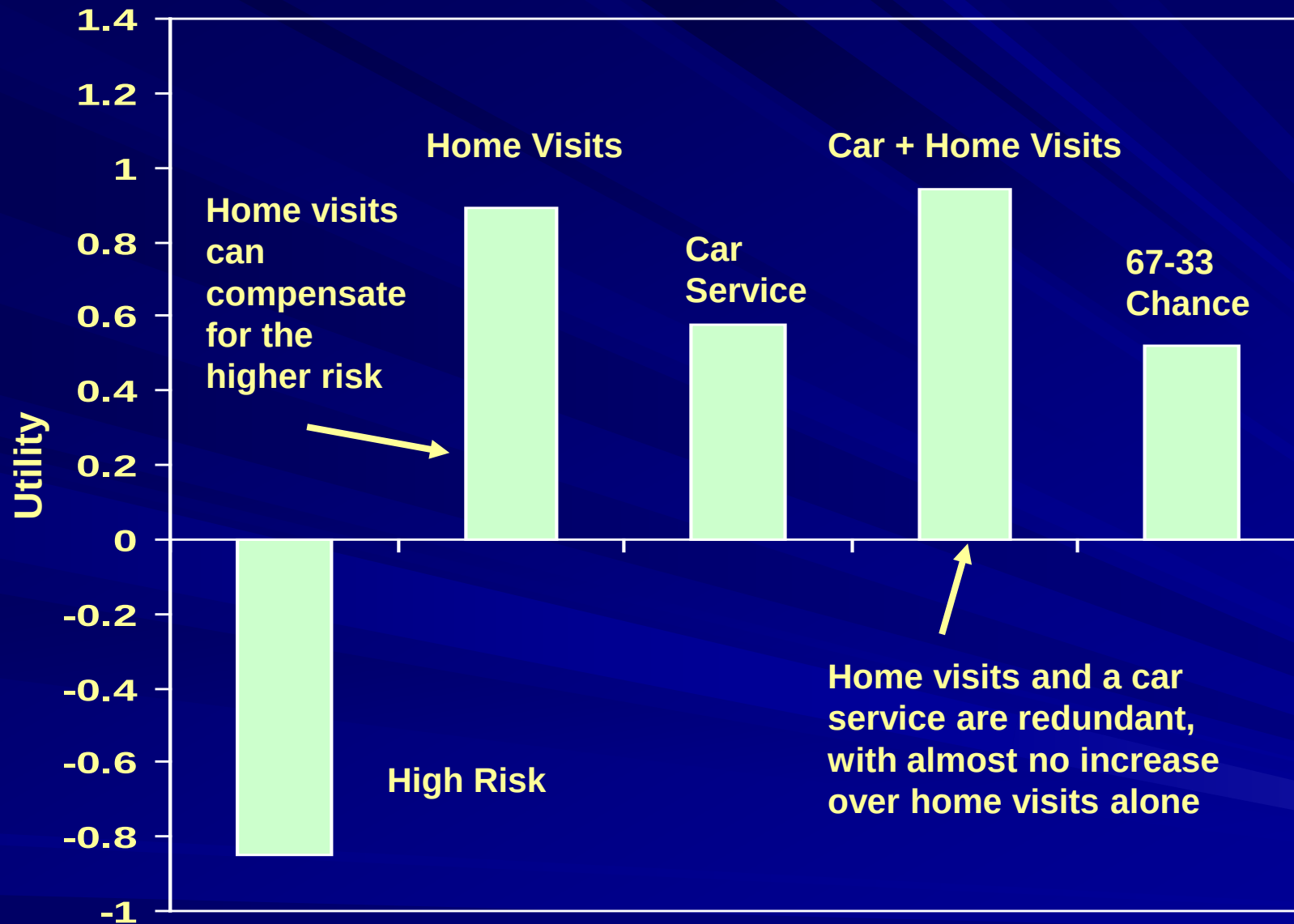
Karlawish et al. How redesigning AD clinical trials
Might increase study partners' willingness to
participate. Neurology 71(23):1883-8, 2008



The conjoint sorting task



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The potential impact of the intervention

- Home visits and a greater chance at research drug doubled willingness to participate in an AD clinical trial
 - reducing risk of the study drug as well nearly tripled willingness to participate
- Reducing the burden of travel was especially valuable to family members caring for sicker patients -- PTs with functional losses and behavior problems

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Some thoughts on solutions....

- Create messages to educate and empower about the value of research,
 - older adults may be more altruistic than younger adults
 - activities need to be framed to “feel good” and be attractive for a more present-moment timeframe
- Think carefully about the work being asked of a person
 - How long/far must they travel? How frequently?
 - Consider home visits, and other steps to reduce time & travel
- Consider the role of a “study partner”
 - a caregiver or a friend who helps drive the participant to study visits
 - these individuals should be compensated