

# Clinical Research Discussion in Support Groups

Another important role for the  
HD Social Worker

TO HD5A 2008,  
CHDI, and all HD Social Workers . .



# Thanks for all you do . .

- Triage in times of crisis.
- Provide counseling and support for patients, families and caregivers.
- Support Groups
- Advise, refer, and advocate for services.
- Participate in activities and fundraisers.
- And much more . .

So . . . with all you already do . . .

Why this topic about clinical research?

Why in support groups?

And why me?

## Because . .

- Participation needs are huge.
- The time is right.
- The support group is a right place.
- Members want more discussion, and learn from it.
- AND bottom line, it is successful for recruitment.

# A Look at the Numbers

Nearly 800 needed now:

- 2-CARE: 600 participants at 43 study locations
- PRECREST: 80 in Boston
- Memantine: 60 participants at 3 study centers
- Citalopram: 36 in Iowa

# And within the next year . .

Nearly another 1000

- CREST: Will need another 650 participants.
- ACR-16: Will need another 100.
- Dimebon: May need several hundred more for PHASE 3.
- PREQUEST

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And . .  
that's just the beginning . .

Several CHDI drugs are anticipated ready for clinical trials in near future (2 to 5 years), . . with more to follow.

\*Bottom line: Long-term and on-going need for thousands, within and outside of usual trial centers.

# Not just Numbers . . Pace of Recruitment

- Minocycline: (118) 12 centers, almost 2 years
- Dimebon : (90) 15 centers, 10 months.
- Memantine (60), 3 centers, still recruiting after several years.
- Citalopram: (36) 1 center, still recruiting after several years.

Suggests that the message is not getting out far enough quickly enough.

To best succeed:

We need **every** willing hand, lay and professional at all points of contact . .

And engagement of “grass root” lay community efforts in recruiting process.

# Why the Support Group ?

- Most frequent community outreach.
- “Hands on” learning.
- Trusted supportive environment.
- Extended family reach.

# Why Add the Lay Community?

- Fewer restrictions: Not constrained by IRB regulations, or organizational liabilities.
- History of success in aiding recruitment and retention (Breast Cancer best example).

# The Northwest Project

- Grew out of my own (positive and negative) support group experiences.
- Modeled on successful community outreach in STAR breast cancer prevention trial.

# Project Design:

To attend Northwest support group meetings to survey 100 members (HD and caretakers) before and after clinical research discussions.

The Reality: Due to time constraints: Survey formats differed (time constraints) among the 6 groups.

# Survey Design

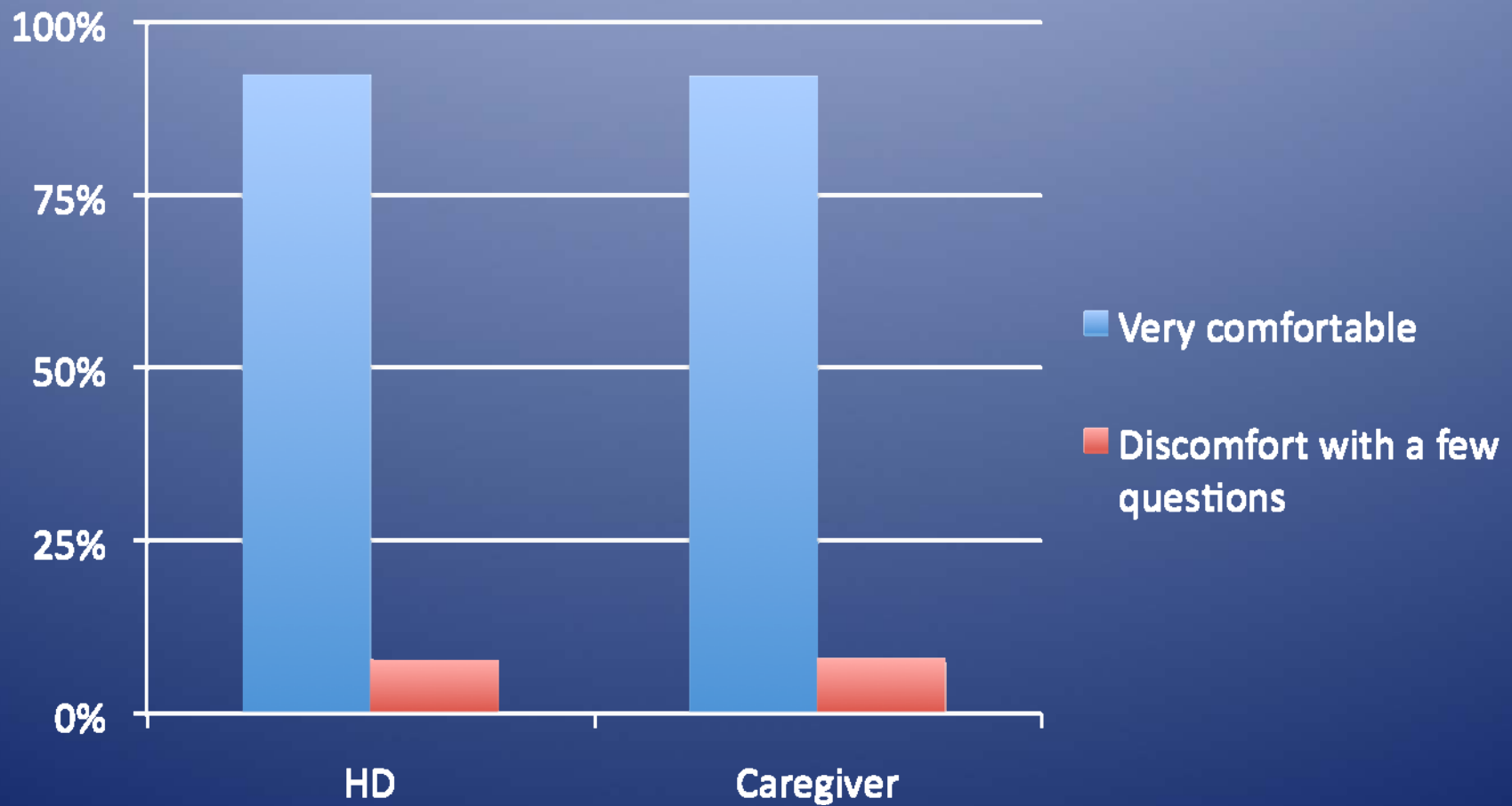
Assessment of clinical research:

- Interest
- Knowledge
- Factors influencing participation

Anonymous and voluntary.



# Comfort with the Survey



# Discussion Points

- Pace and description of drug development and introduced CHDI.
- Drugs in trial; drugs far along pipeline potentially near to trial.
- Mechanics of clinical studies and trials utilizing real-time examples; discussed criteria, informed consent, placebo, phases, safety, risk, personal issues.

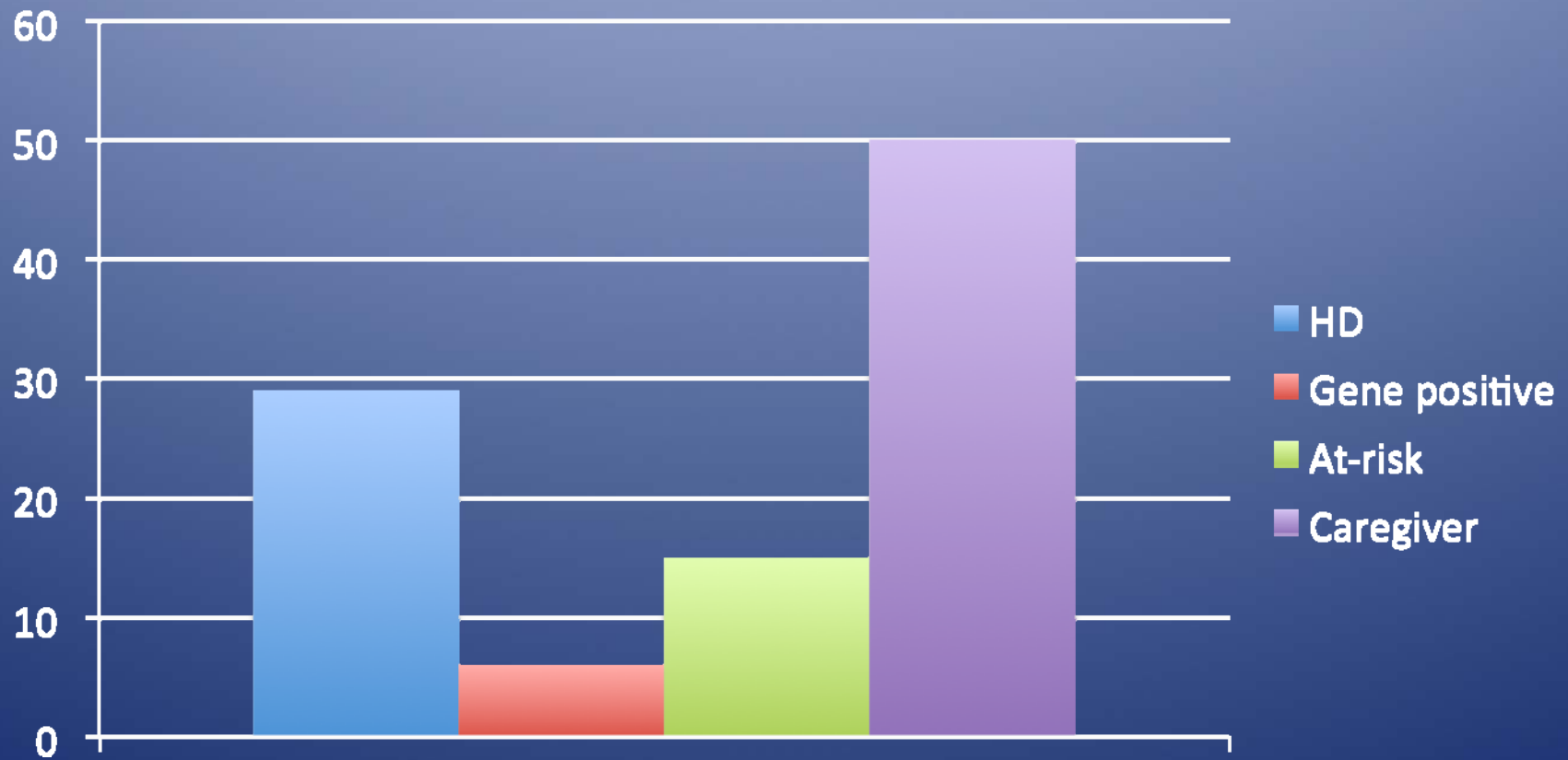
# The Results

The majority:

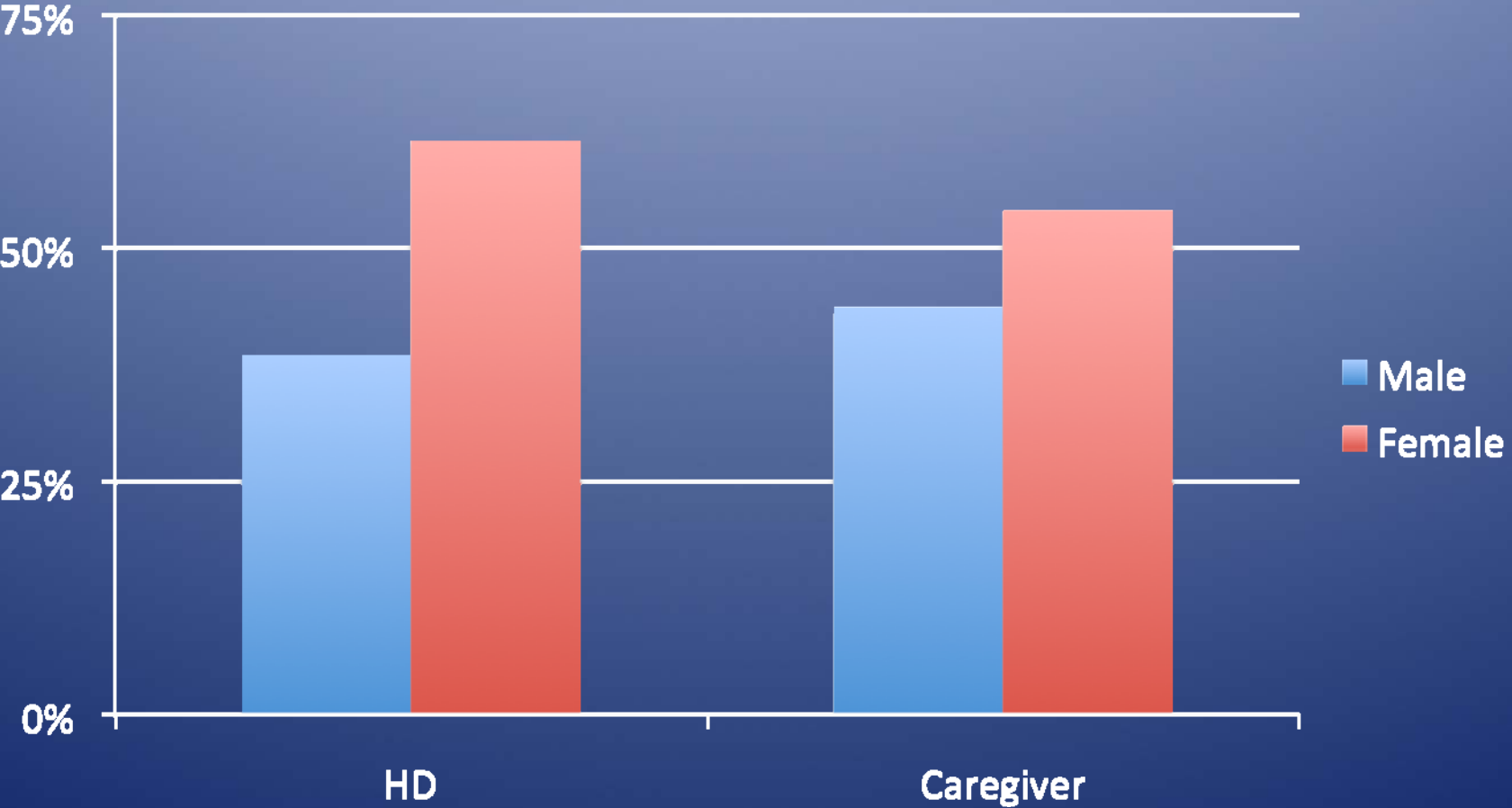
- Want more information
- Are interested in participation.
- Have little basic knowledge of clinical trials, but . .
- Learn many specifics of clinical trials.

Unanticipated Results: Recruits to TRACK-HD

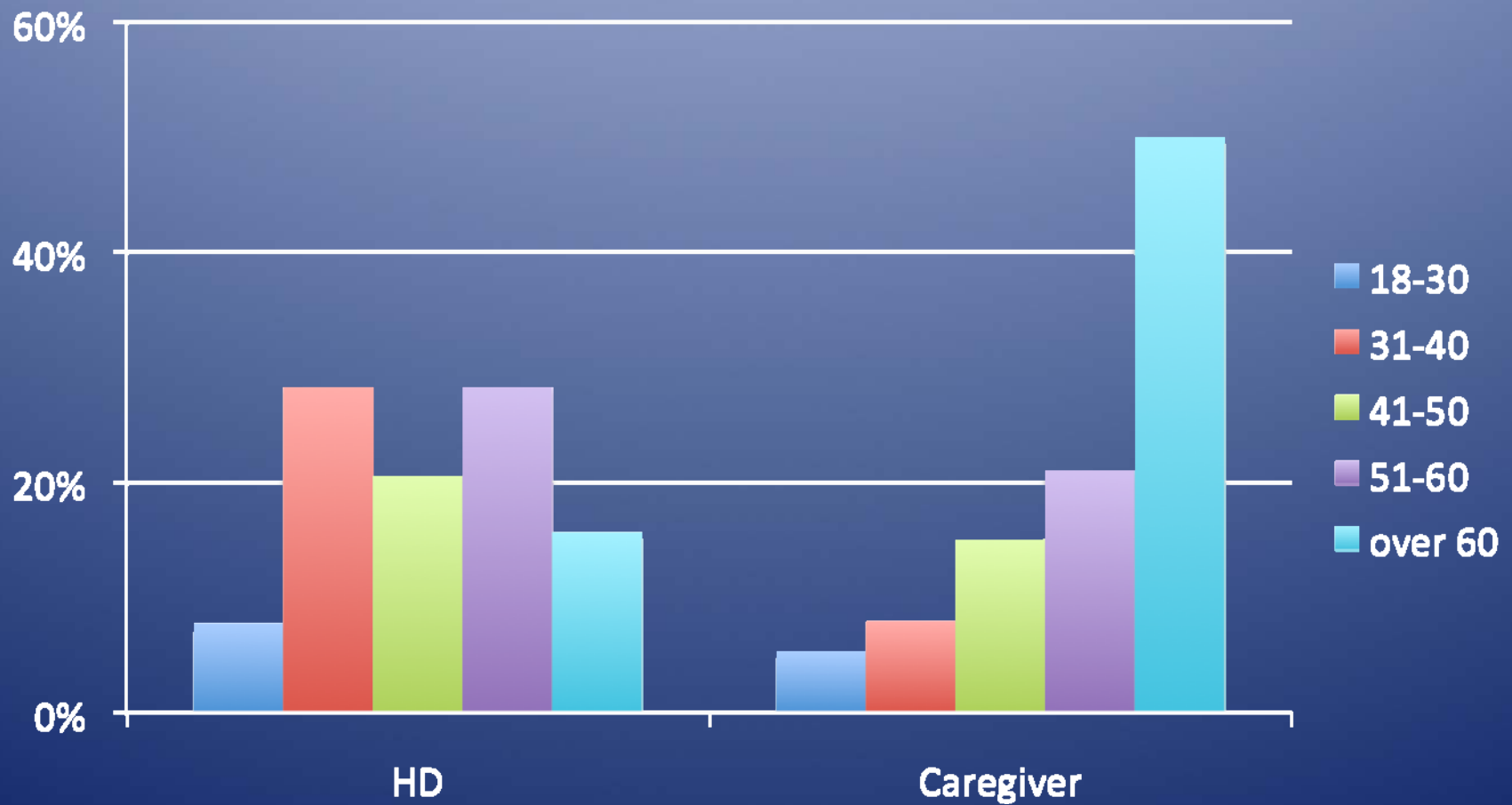
# HD Status



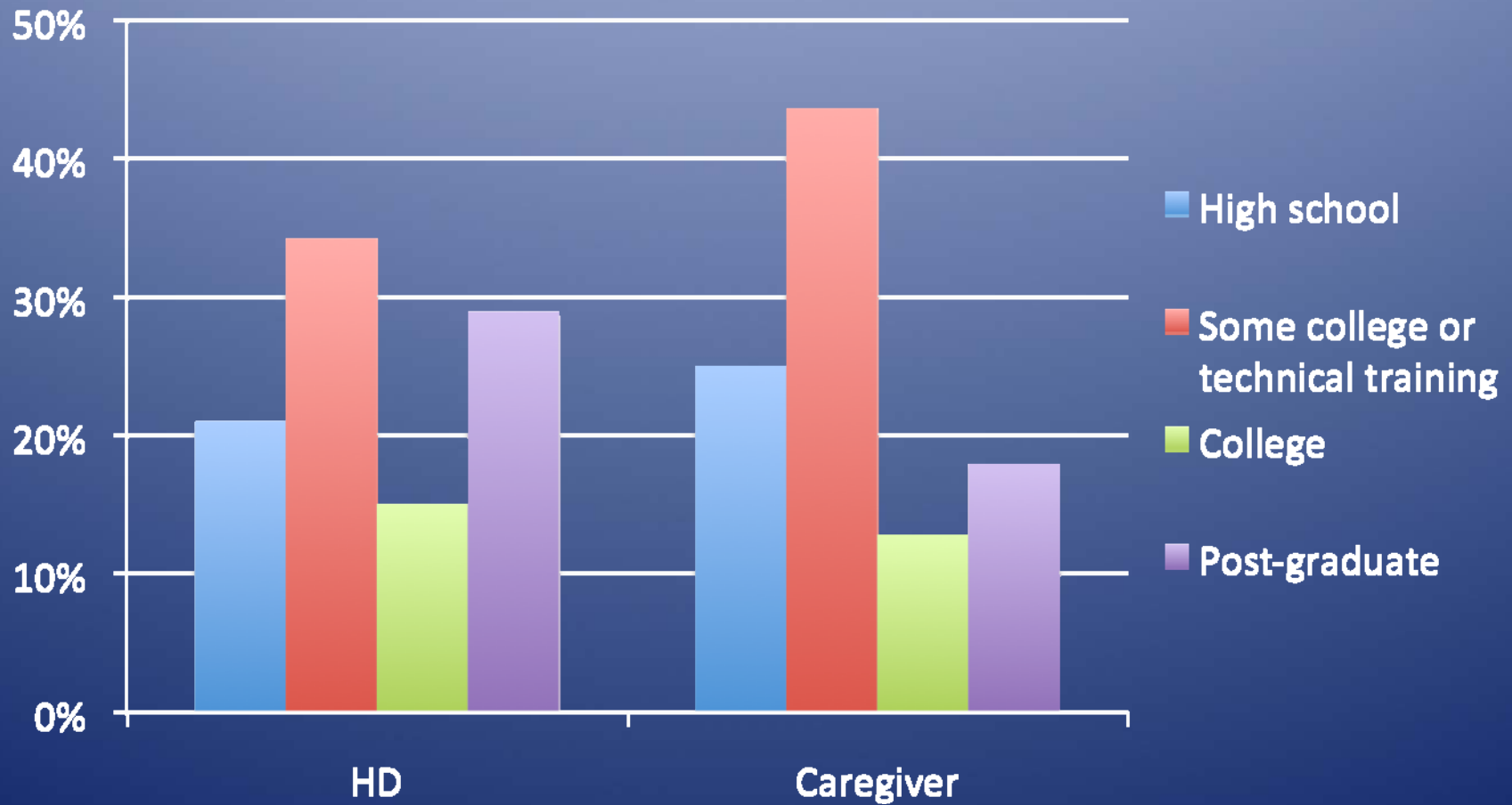
# Gender



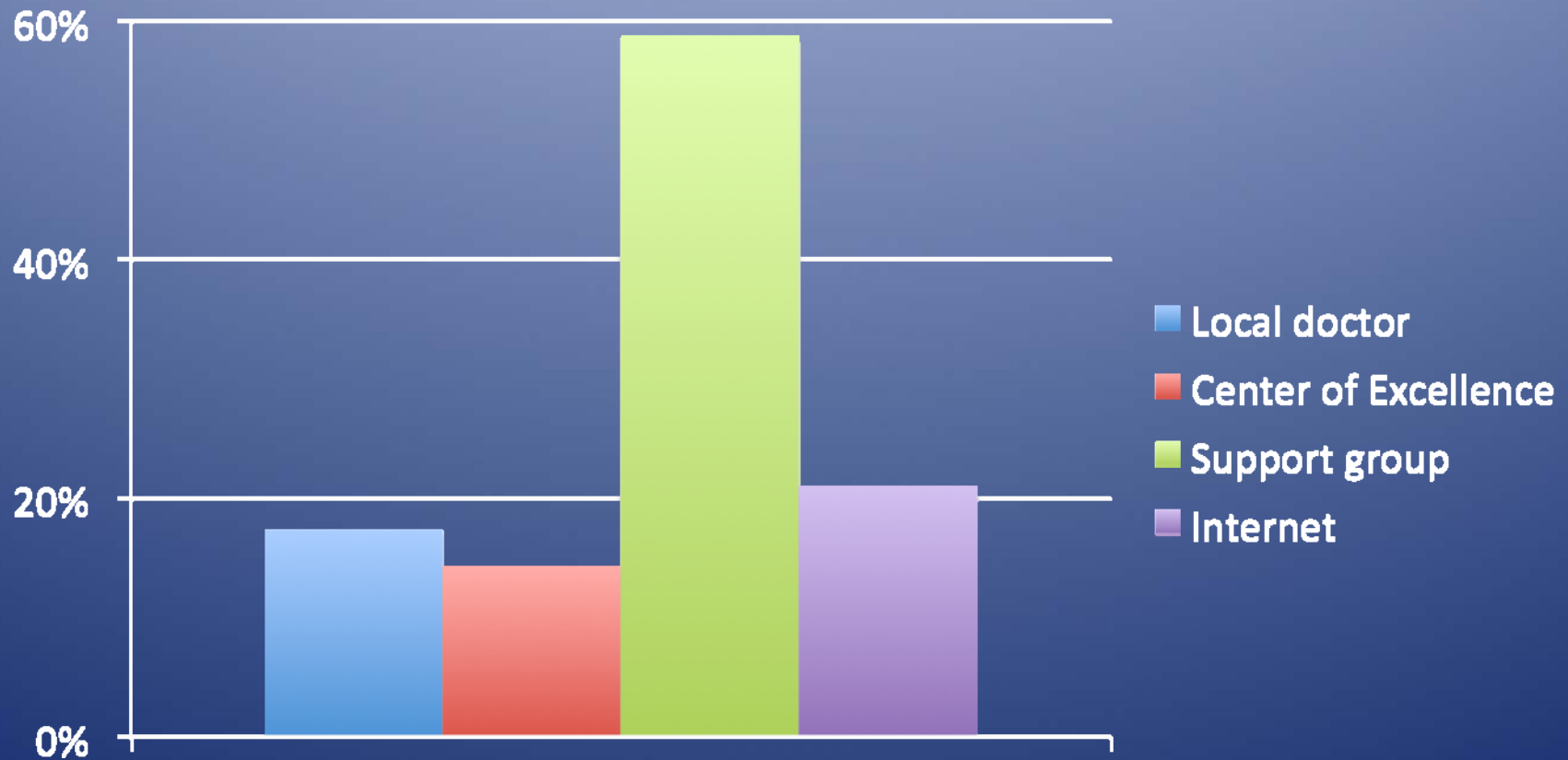
# Age



# Education

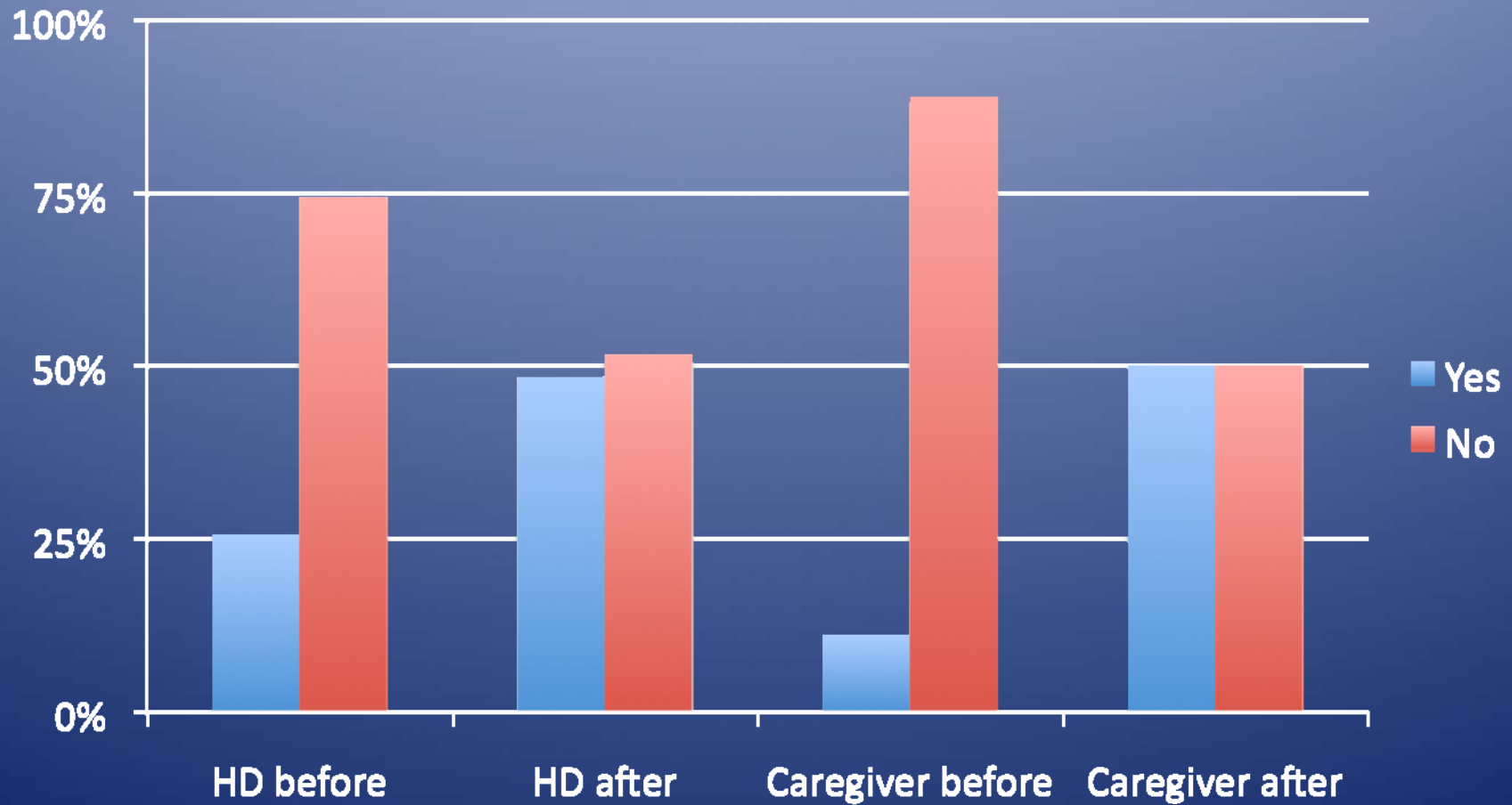


# Source of Clinical Trial Information

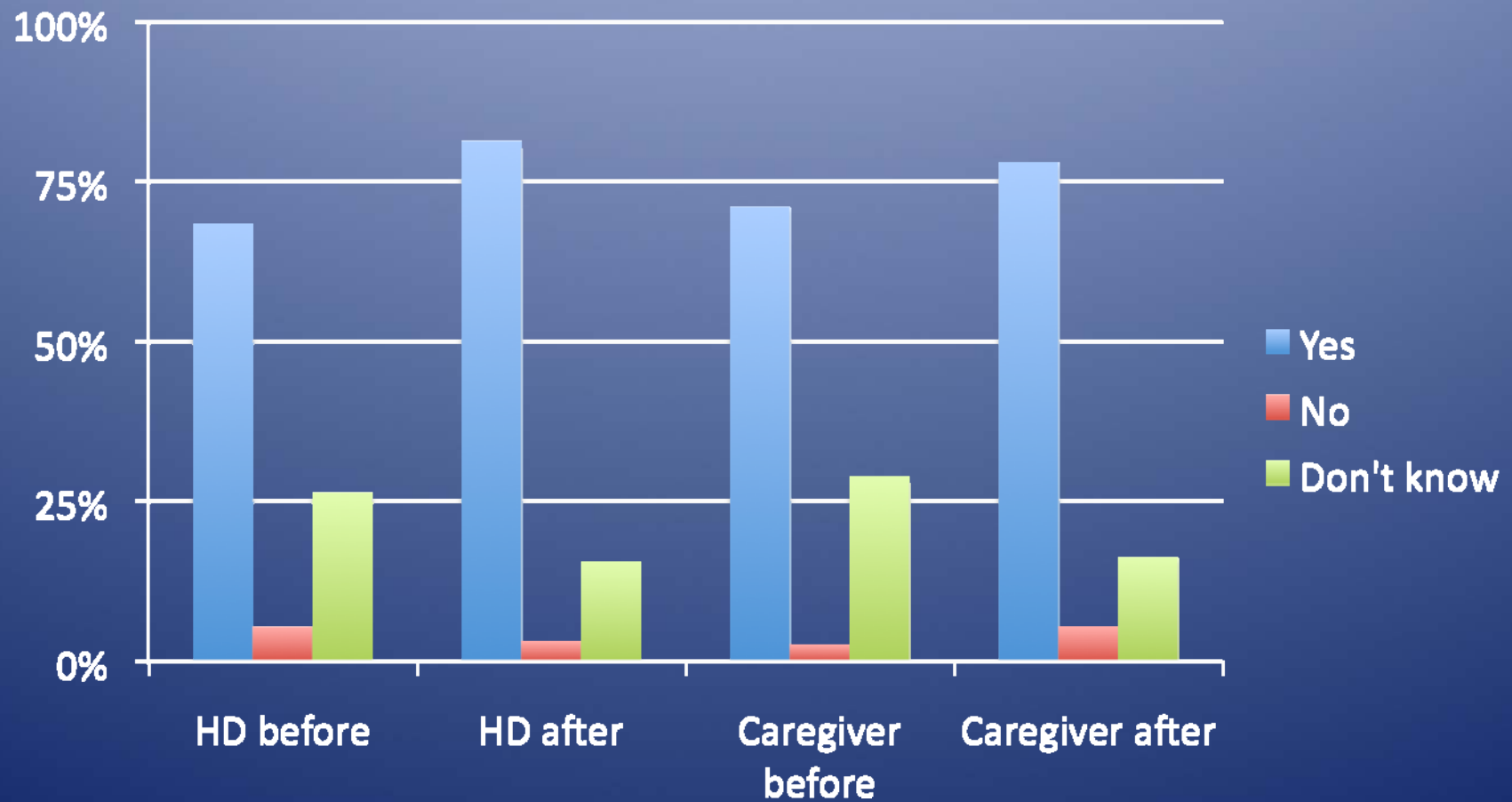




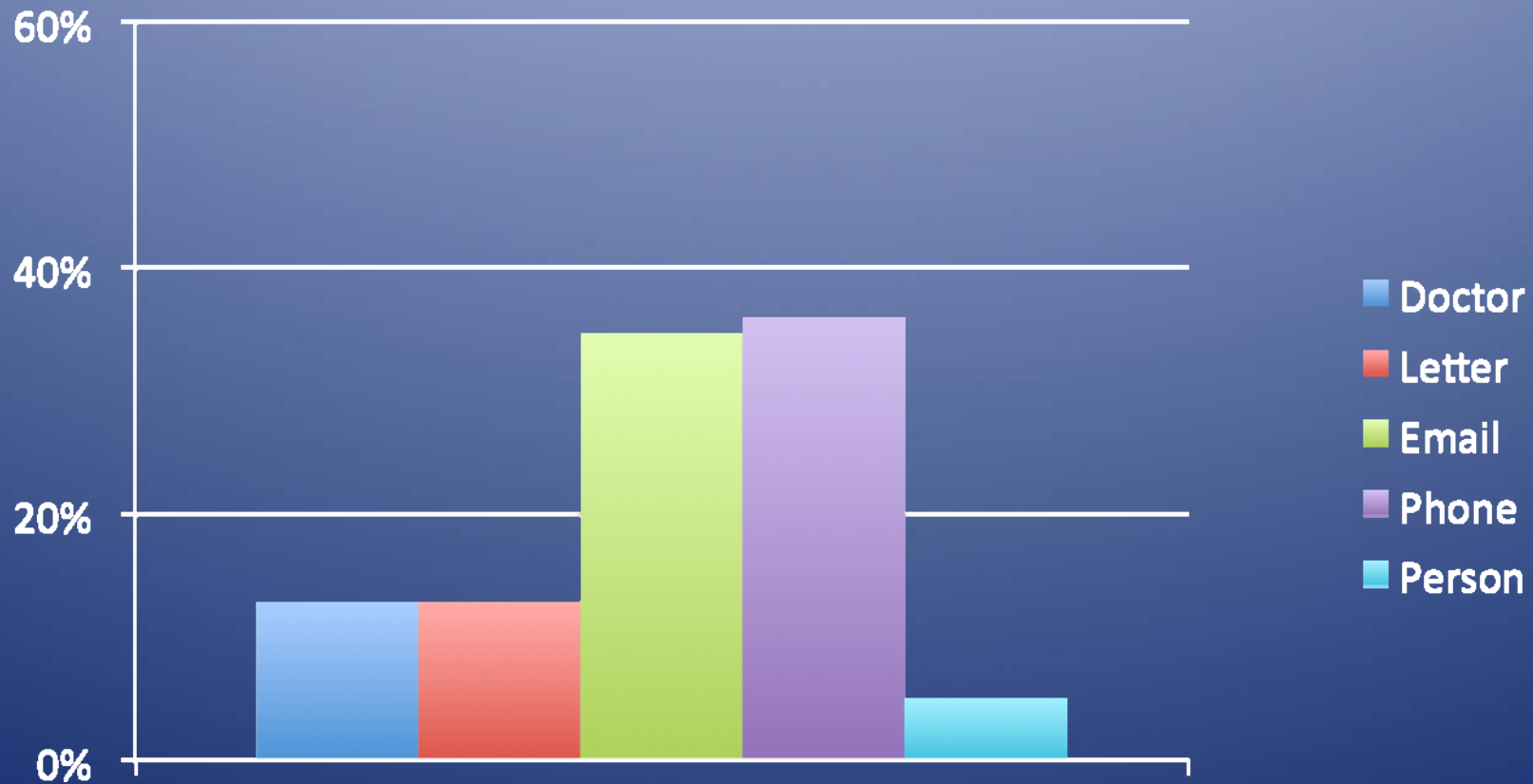
# Do You Have Enough Information?



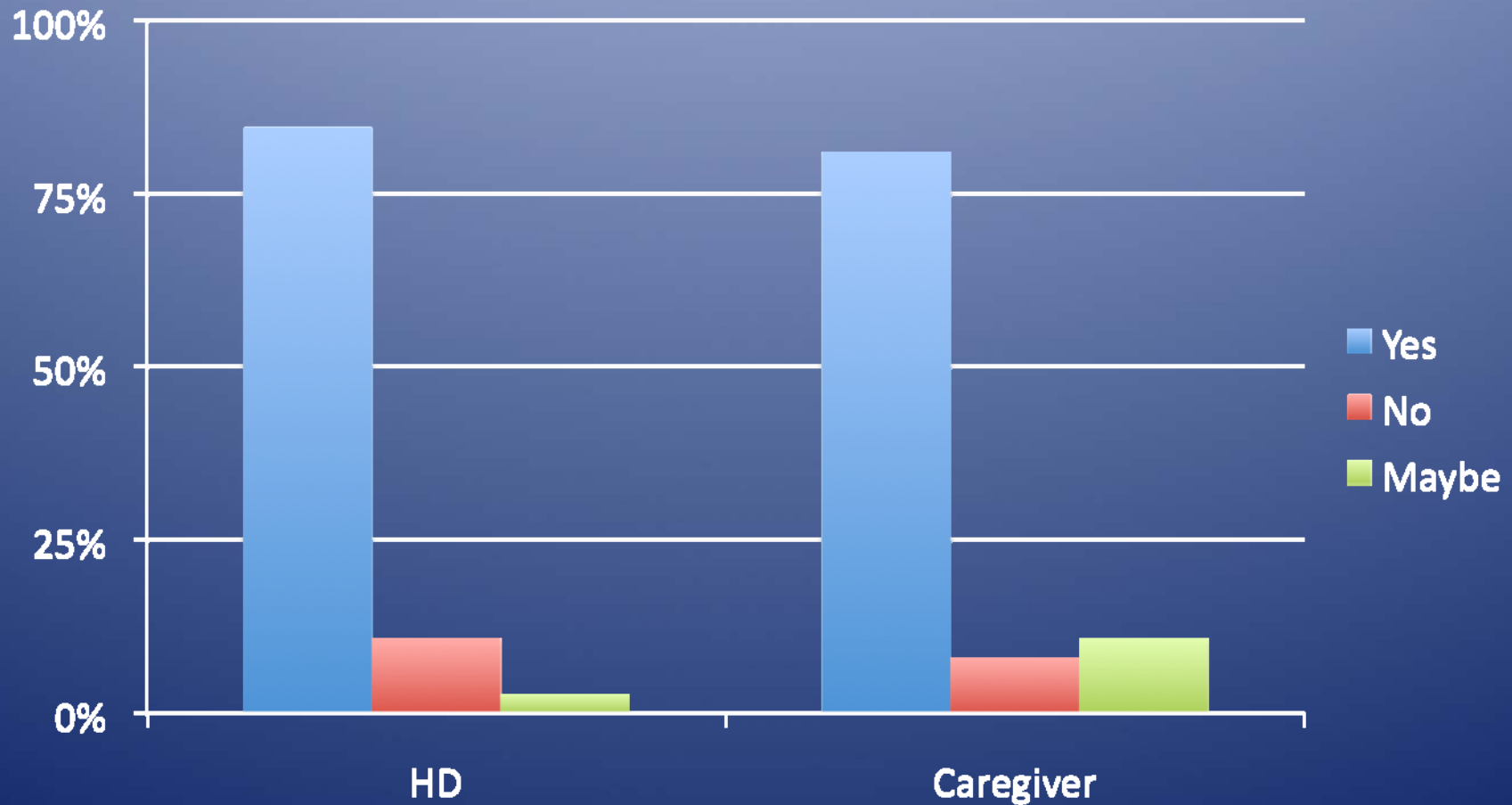
# Interested in Clinical Trial Participation?



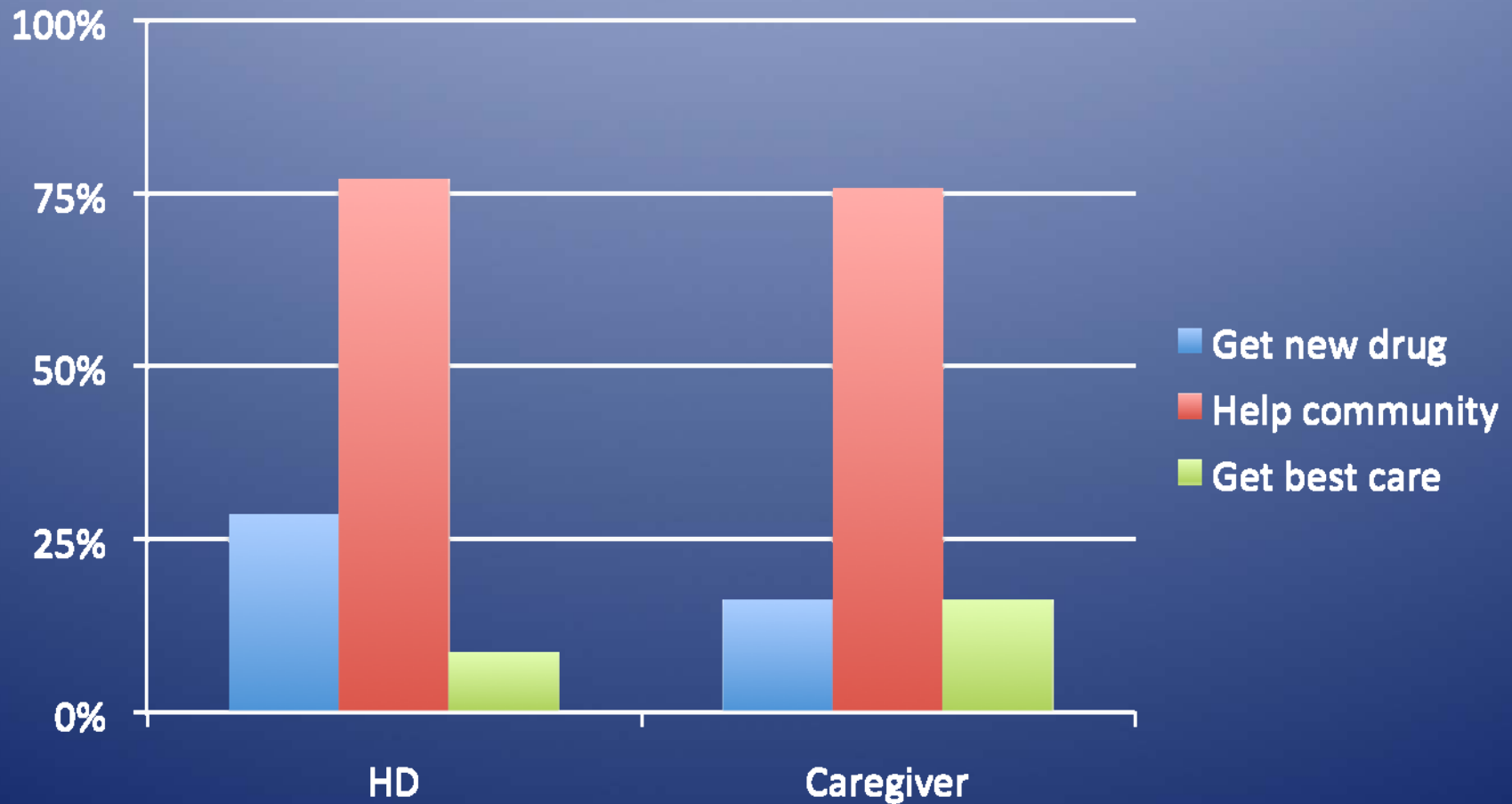
# Preferred Mechanism to Notify you about Clinical Trials?



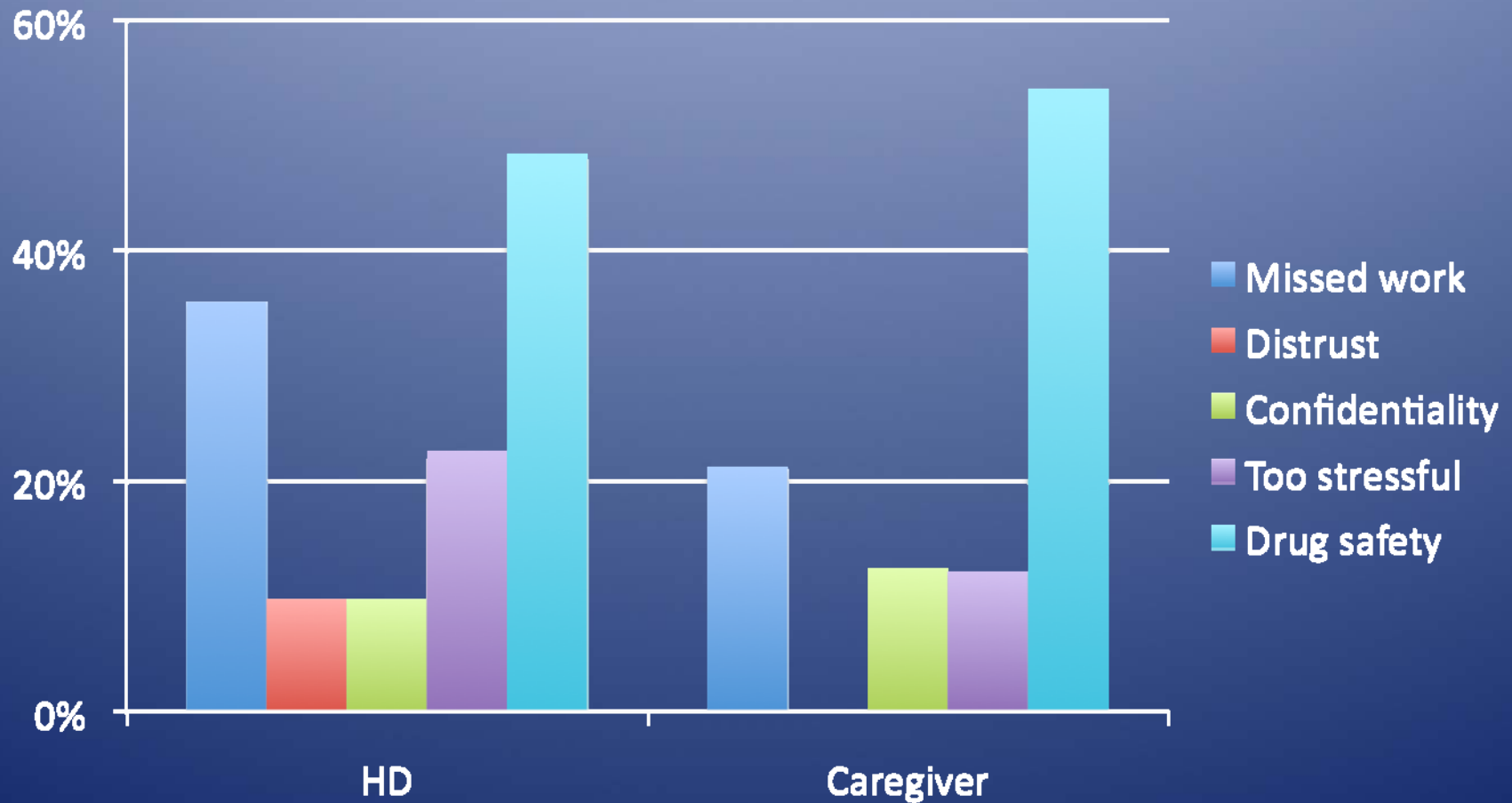
# Would you be Comfortable with Web Registry?



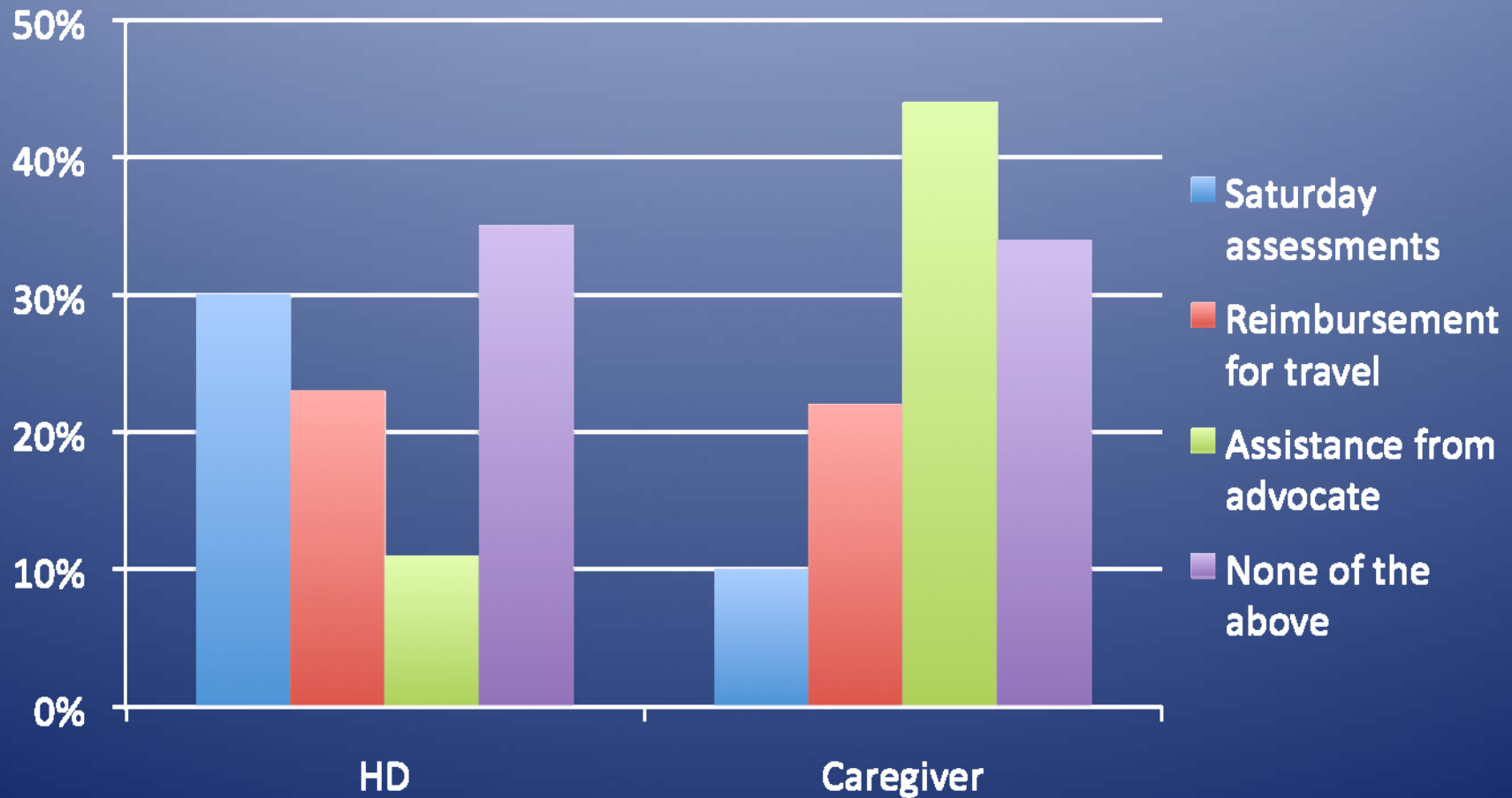
# Your Most Important Reason to Participate



# Your Most Important Reason Not to Participate



# Factors that would Influence a Positive Decision



# Can support group discussion be a successful part of recruitment?

For TRACK-HD:

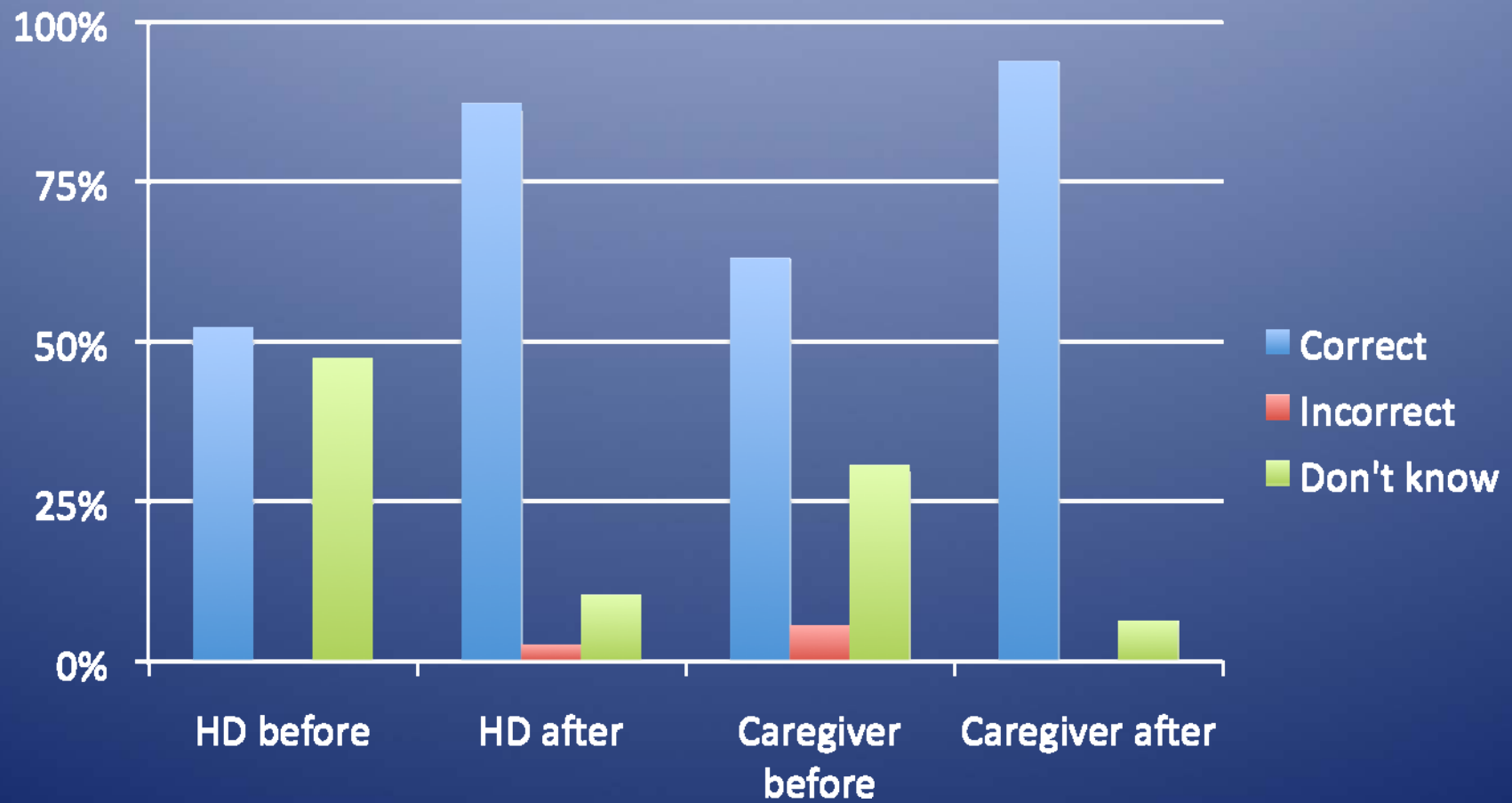
- Successfully recruited 4 (5 volunteered, but did not fit criteria: 4 pre-manifest volunteers too far from onset, 1 early symptomatic on antipsychotic).
- Arranged car pools and negotiated Friday afternoon/Saturday assessments.



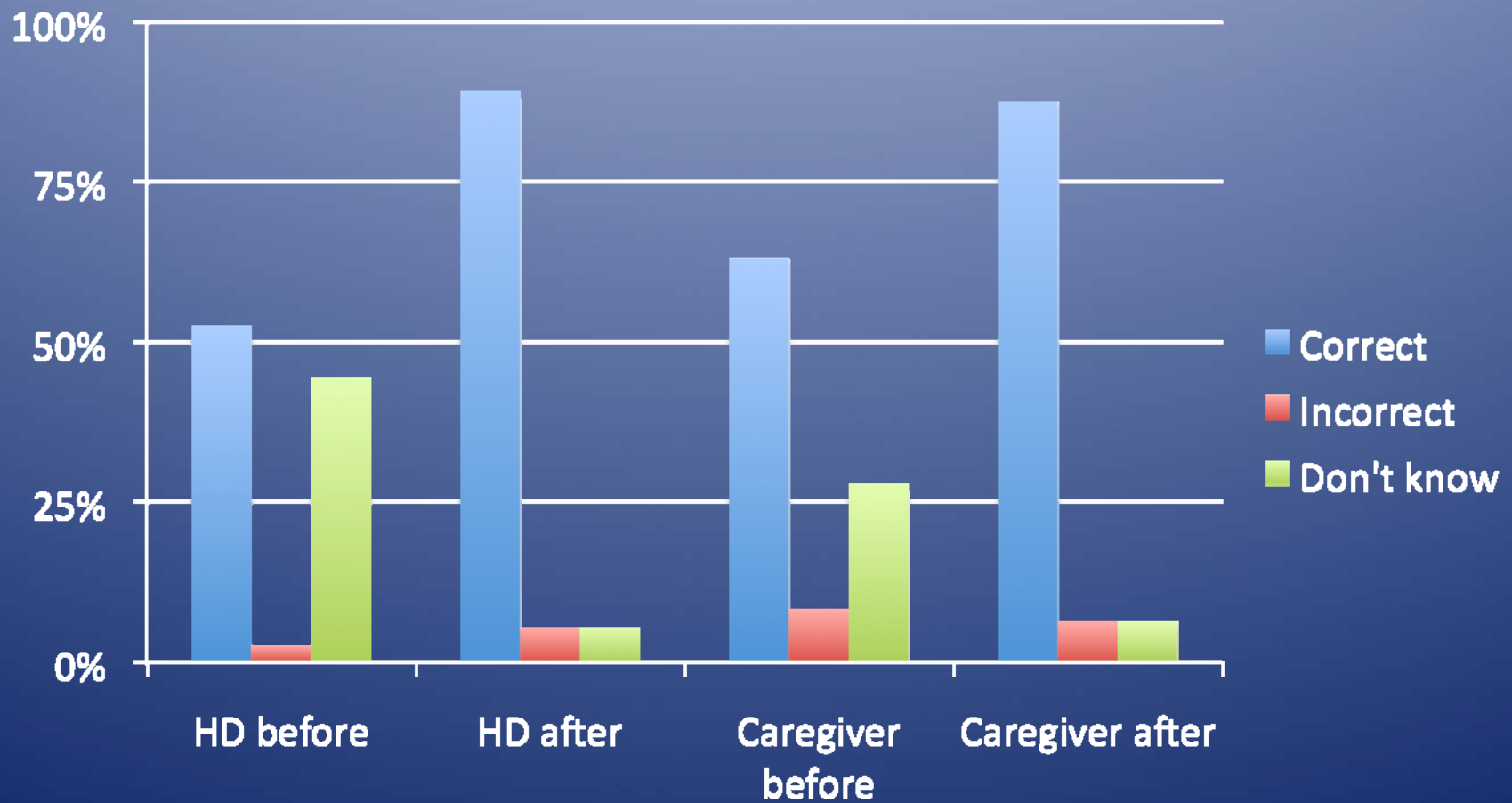
# Literacy Results

- Baseline clinical research literacy is very low.
- Substantial learning occurred in many areas: understanding criteria, consent process, participant rights, placebo and blinded concepts.
- Substantial confusion regarding trial phases and medical care within clinical trials.

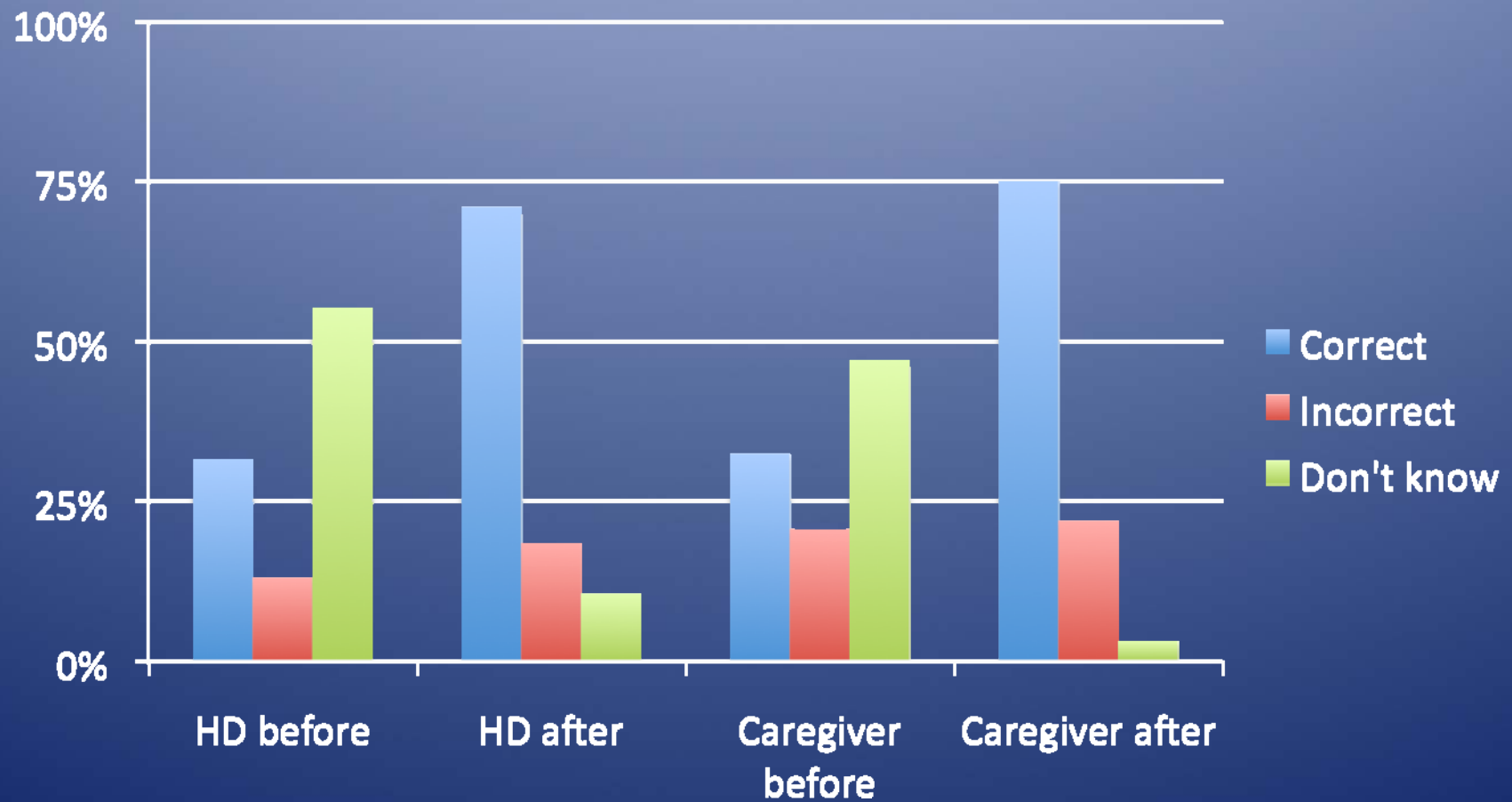
# Trial criteria



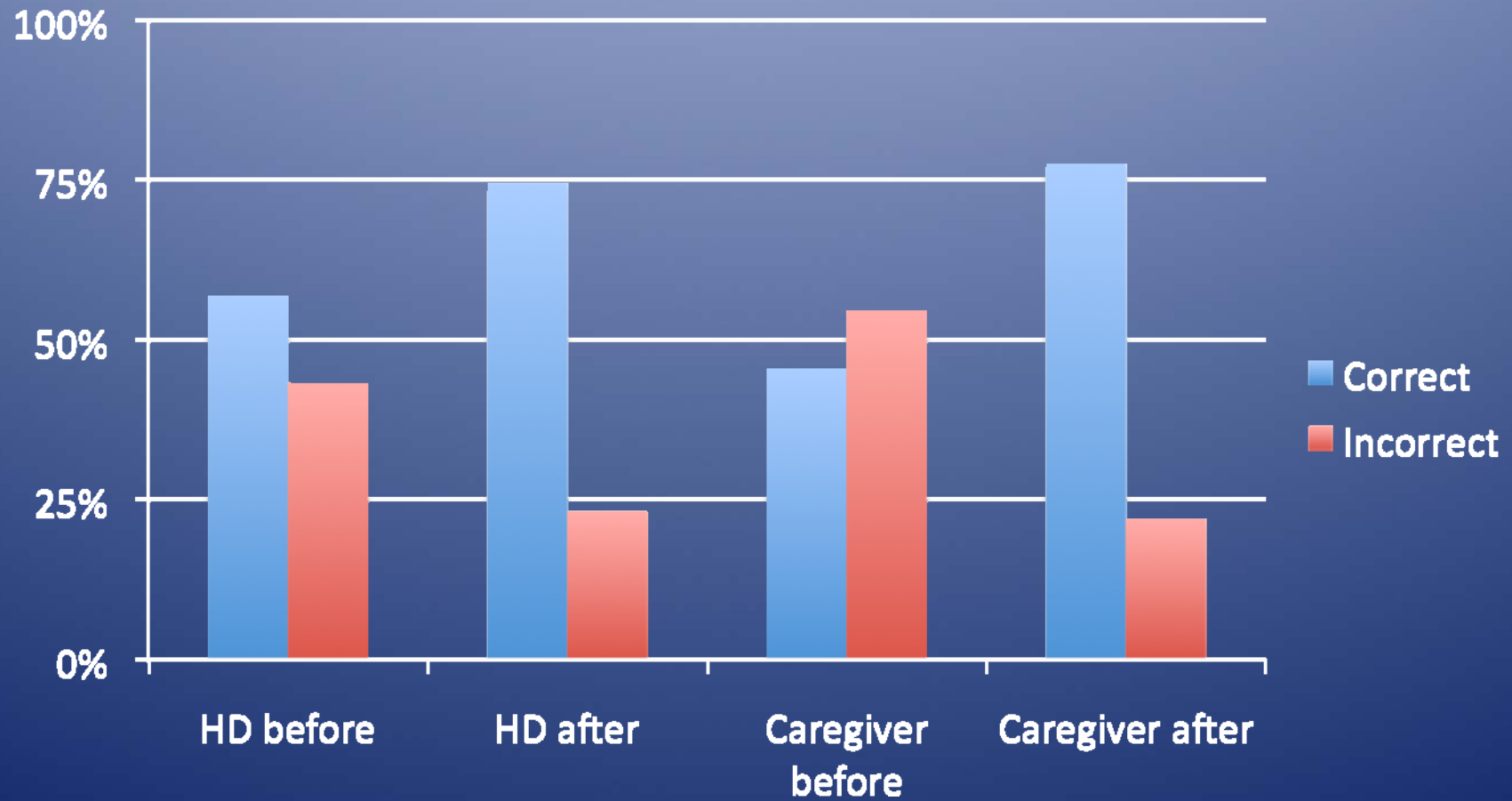
# Consent procedure



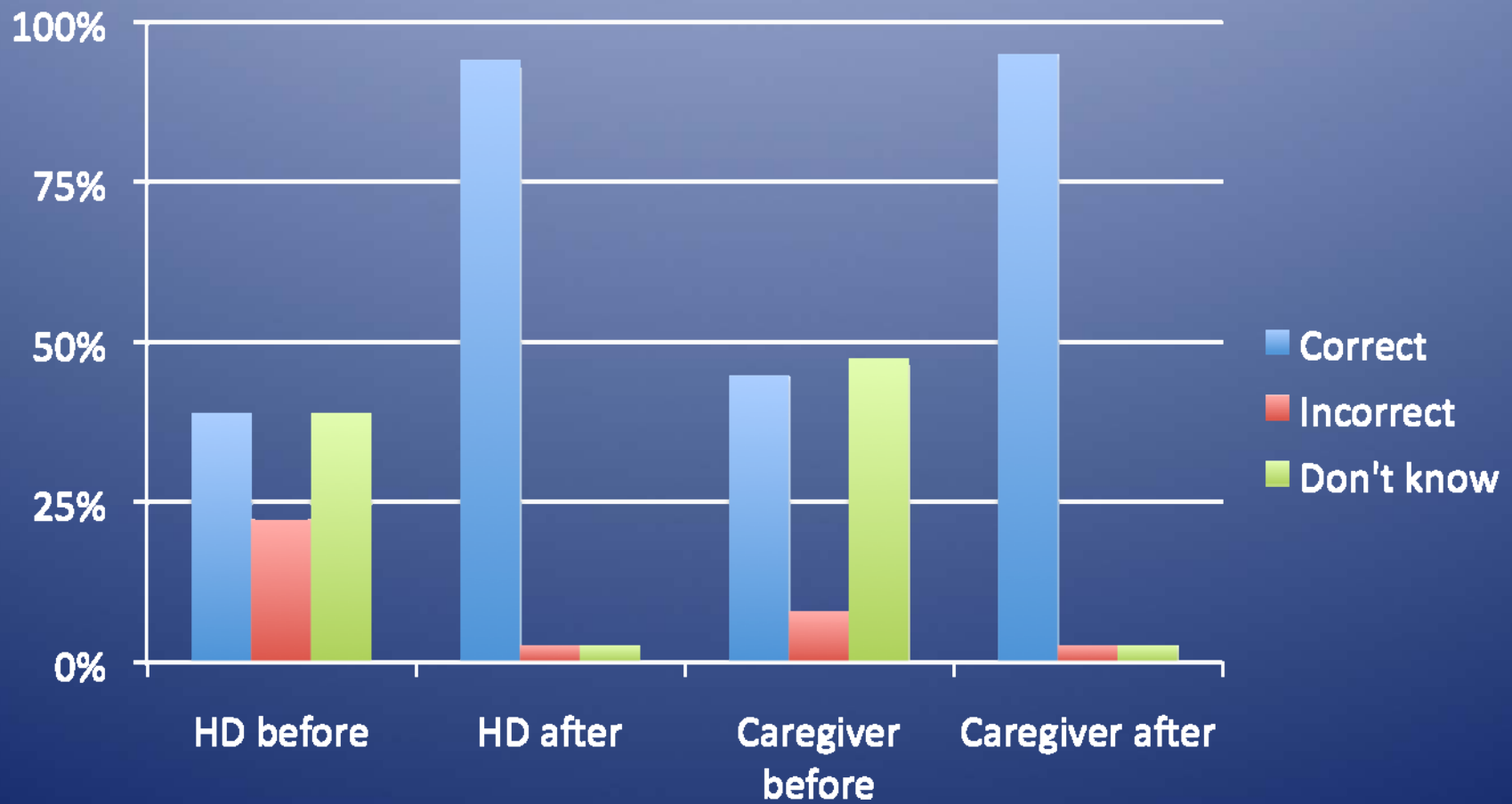
# Right to leave trial



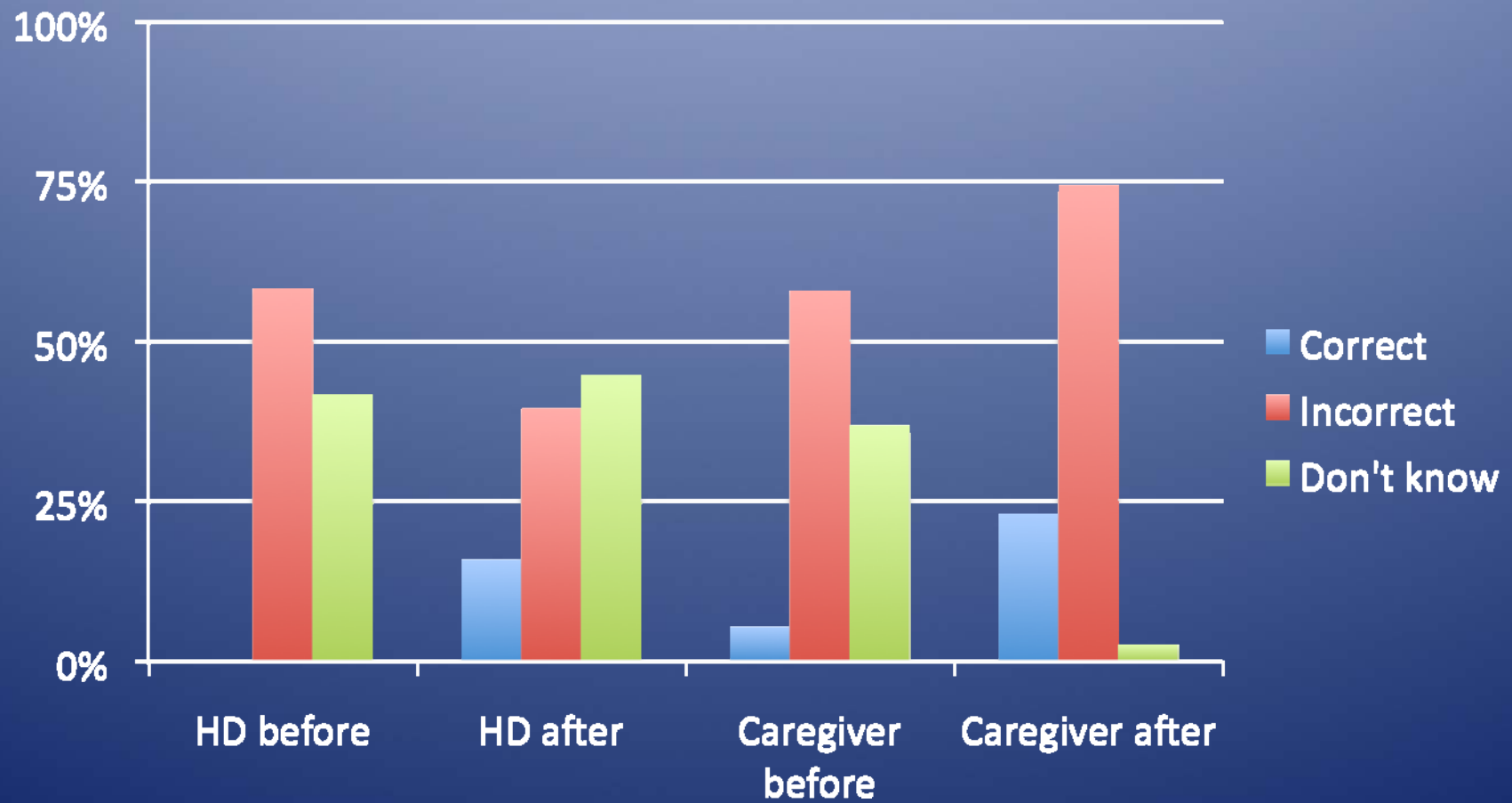
# Placebo



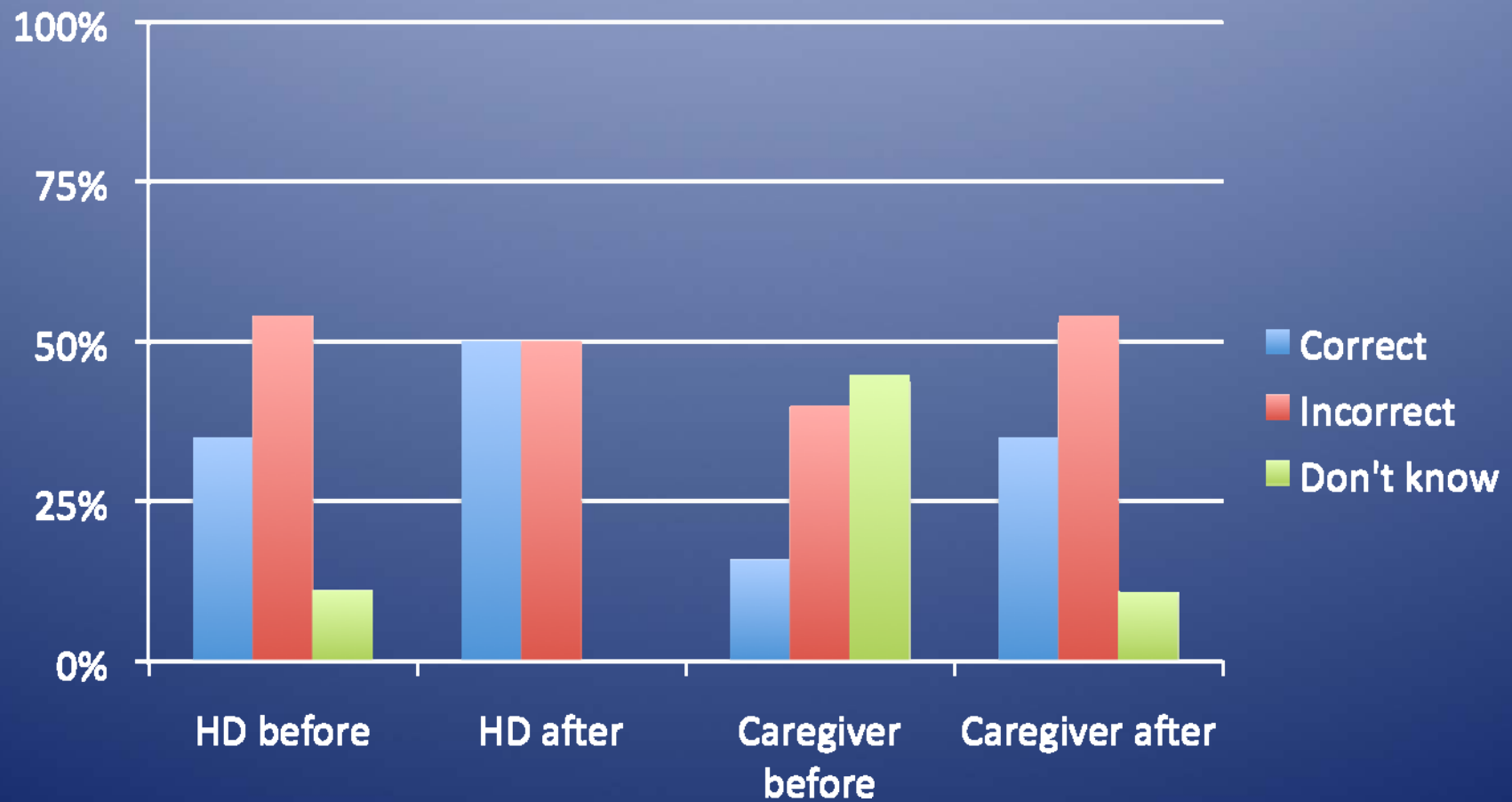
# Blinding



# Trial phases



# Medical care in clinical trials





# Northwest Support Group Project

- HDSA (D. Lovecky, B. Boyle) and CHDI (R Blumenstein, D. van Kamman, J, Guiliano)
- Support groups in Ballard. Boise, Olympia, Spokane, Yakima and Snohomish/Everett
- Cindy and Amy Crossman, Donna Ross, Anne Spencer and Lael Hinds