

**COLLEGE OF  
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FLORIDA STATE UNIVERSITY



# Psychological Issues in Screening, Enrollment and Retention in Trials

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# Presentation Overview



- Psychological Issues in Screening
  - Cognitive, Emotional, Behavioral
  - Study population effects
- Psychological Issues in Trial Enrollment and Retention
  - Cognitive, Emotional, Behavioral
  - Study population effects

# Screening: Psychological Impact



- Most studies have been conducted with mothers of children screened for T1D
- Most studies have focused on emotional impact
  - These have used the State component of the State Trait Anxiety Inventory





# Emotional Impact: Maternal SAI scores over time



Genetically at-risk	Country	Pre-test	Post-test	4-6 mos post-test	1 year post-test
Johnson (2004)	US		37	31	28
Carmichael (2003)	US		36	32	30
Johnson (2007)	Finland		36	32	
	Germany		38	39	
	Sweden		40	36	
	US		41	39	
<b>ICA+</b>					
Johnson (1995)	US		55	39	
Hummel (2004)	Germany	43	51		

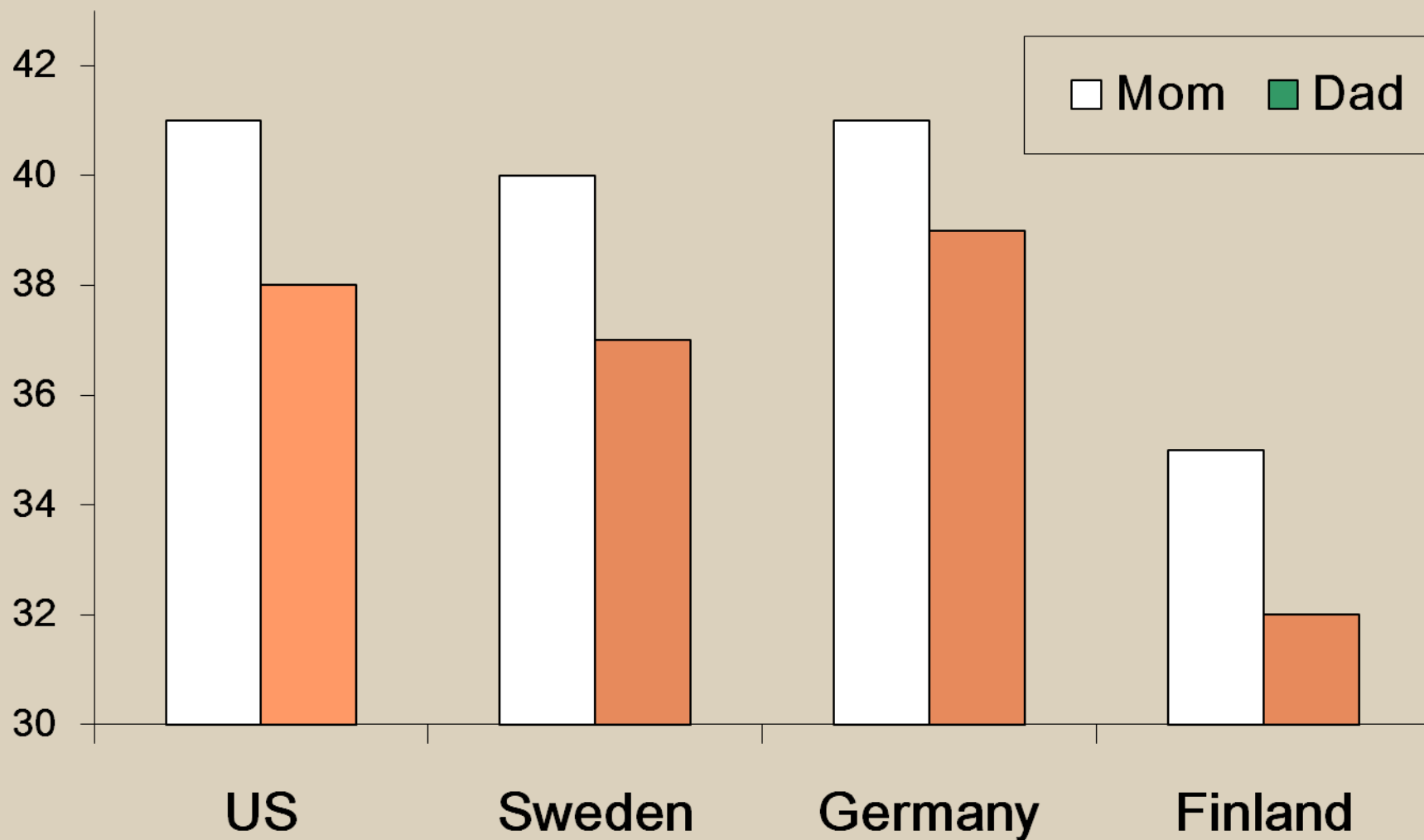
# Emotional Impact: SAI scores differ by study population



- Country
- Child versus adult
- Parent versus child
- Mother versus father
- General population versus first degree relative (FDR)



## Initial SAI Anxiety Scores of Parents with Genetically At-Risk Children by TEDDY Country





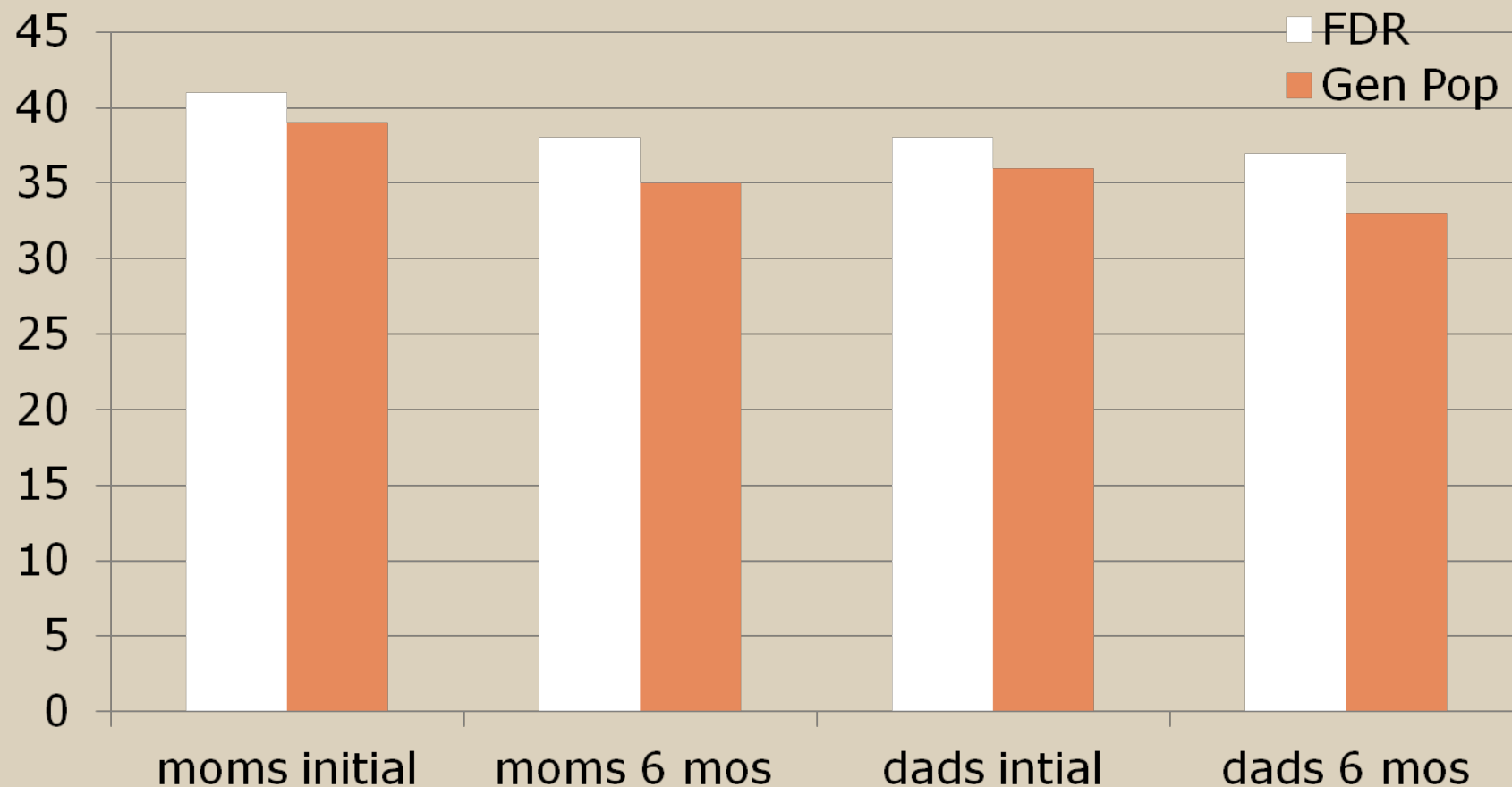
# Emotional Impact: SAI scores for ICA+ children and adults and their parents



ICA+ adults	Country	Pre-test	Post-test	4-6 mos post-test
Johnson (1990)	US		52	35
Johnson (1995)	US		45	34
ICA+ children				
Johnson (1990)	US		44	33
Johnson (1995)	US		42	32
Mothers				
Johnson (1995)	US		55	39
Hummel (2004)	Germany	43	51	
Fathers				
Hummel (2004)	Germany	39	44	



# Emotional Impact: SAI scores for FDRs versus general population TEDDY parents





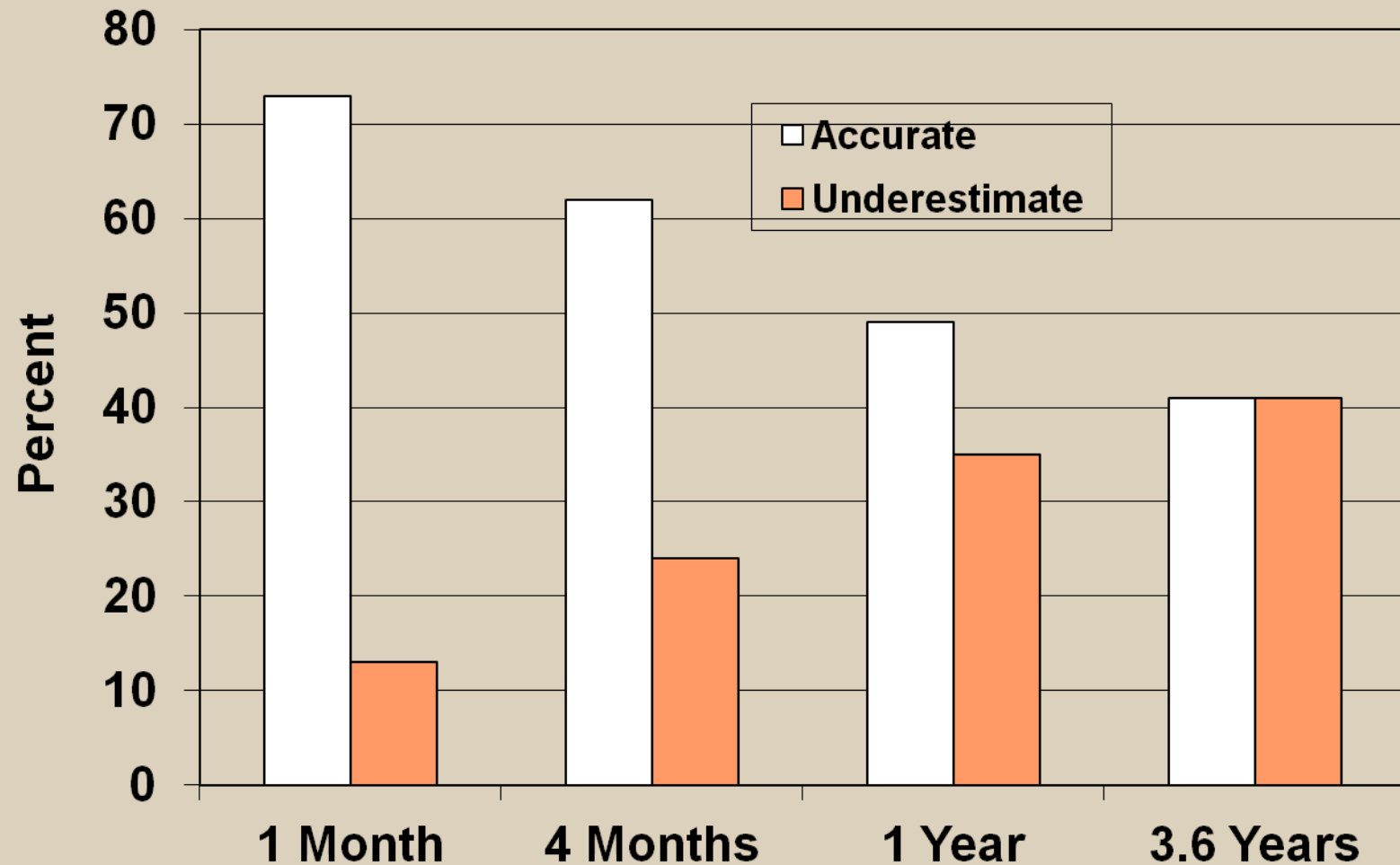
# Screening: Cognitive Impact



- Some studies have examined whether participants understand the risk information provided
- Most have been conducted with parents, usually mothers



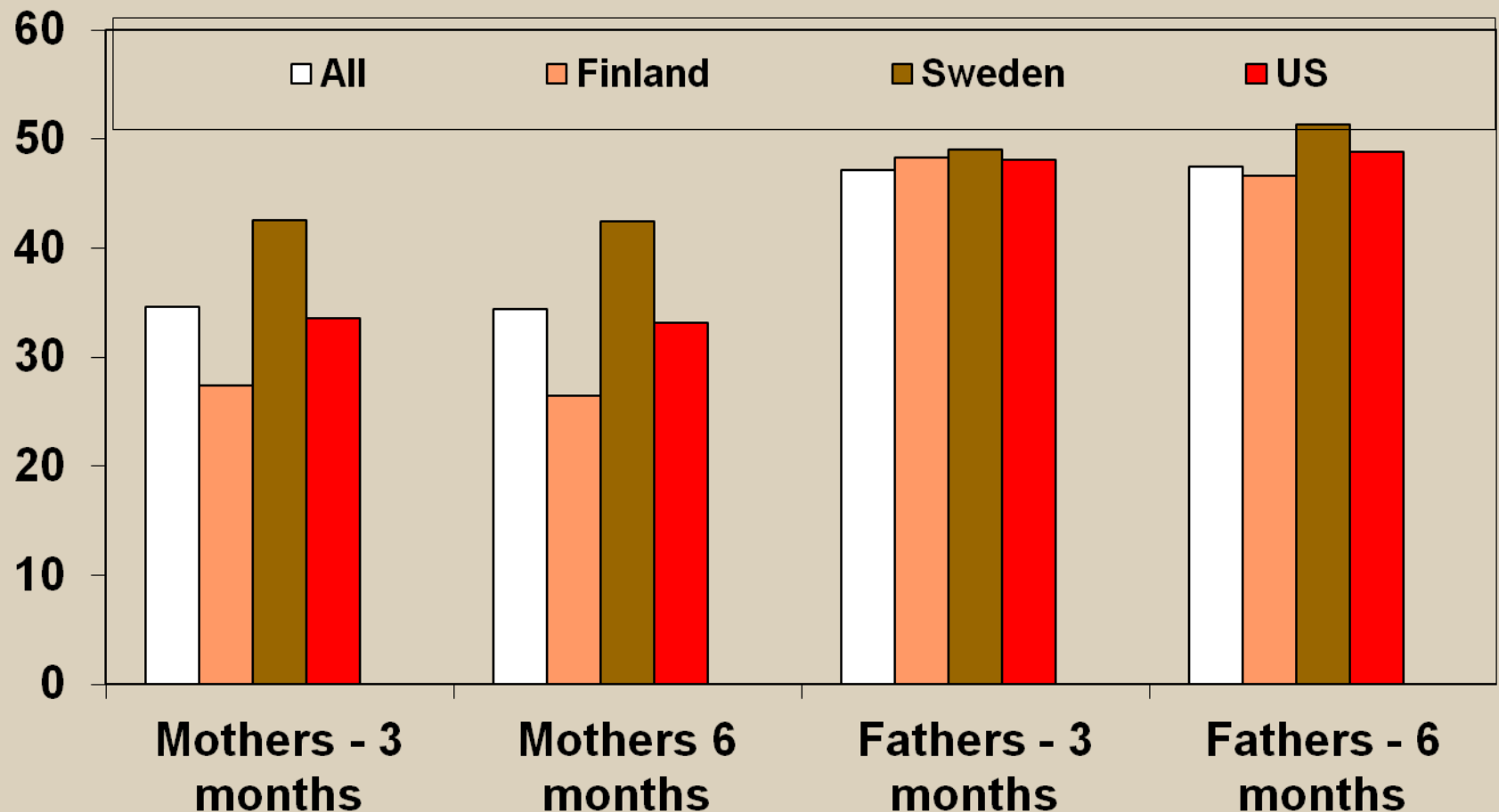
# Cognitive Impact of Screening: Maternal Risk Perception Accuracy Over Time



(Johnson, 2006; Baughcum, Johnson et al, 2007)



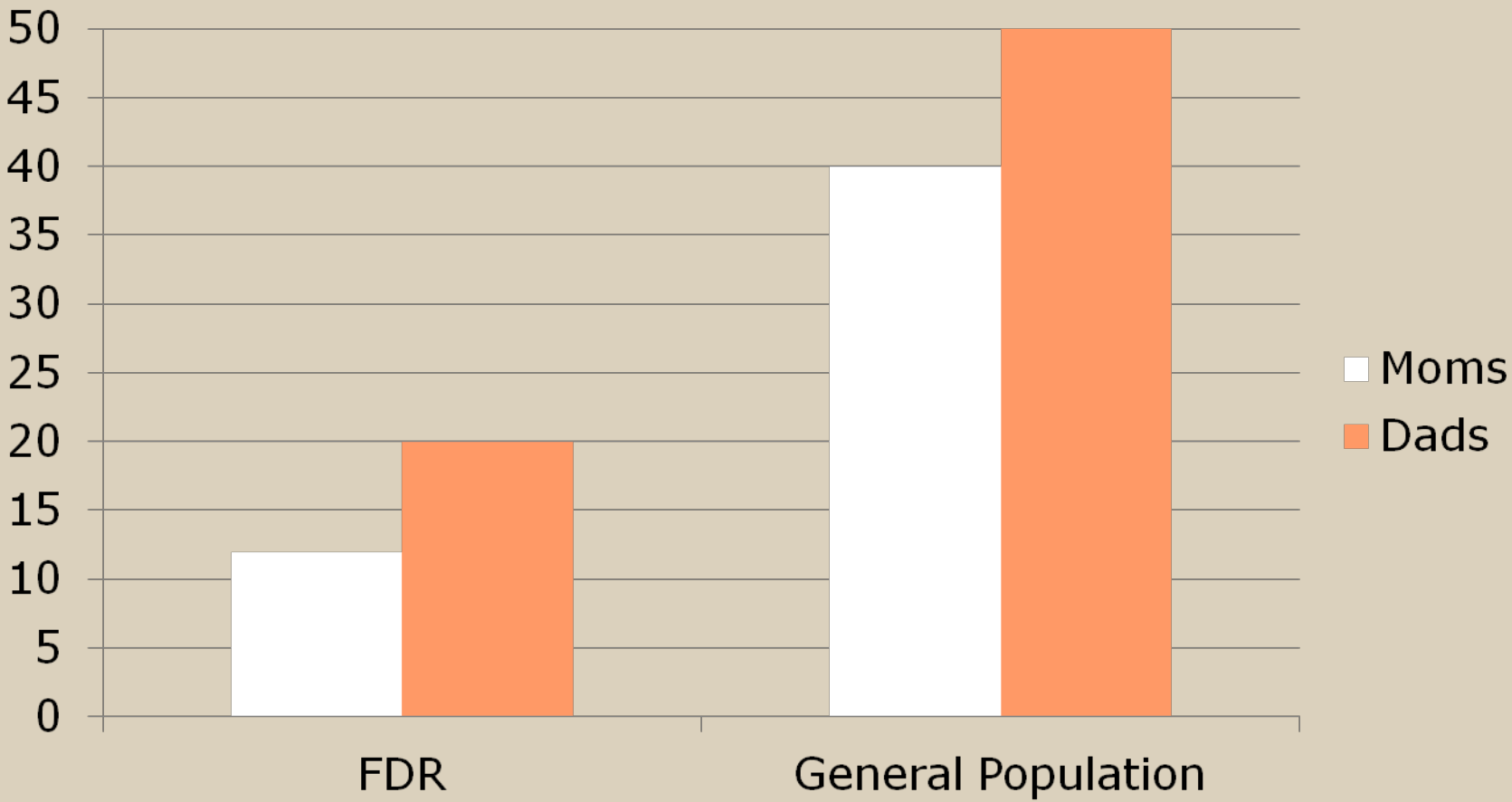
# Cognitive Impact: TEDDY Parent Percent Underestimation by Time and Country







# Cognitive Impact: TEDDY Parent Percent Underestimation by FDR/General Population Status



# Screening: Behavioral Impact



- A small literature suggests that many with positive screening results report behavior changes in an effort to prevent T1D
- T1D monitoring behaviors, changes in diet and exercise are common
- Potentially harmful behaviors (limiting contact with other children, delaying immunizations) are rare **FSU COLLEGE OF MEDICINE**



## Behavioral Impact: Many Mothers Report Behavior Change in Response to Child's Increased T1D Risk

- 67% mothers reported behavior changes
- Most common behaviors reported:
  - Monitoring behaviors (59%)
  - Dietary changes (34%)
  - Physical activity changes (14%)
- If the at-risk child was a FDR, mother was 19 times more likely to report behavior changes to prevent T1D
- Mothers who were more anxious and who had accurate perceptions about the child's T1D risk were more likely to report behavior changes

(Baughcum, Johnson et al, 2005)





# Trial Enrollment & Retention: Psychological Issues



## ➤ Enrollment

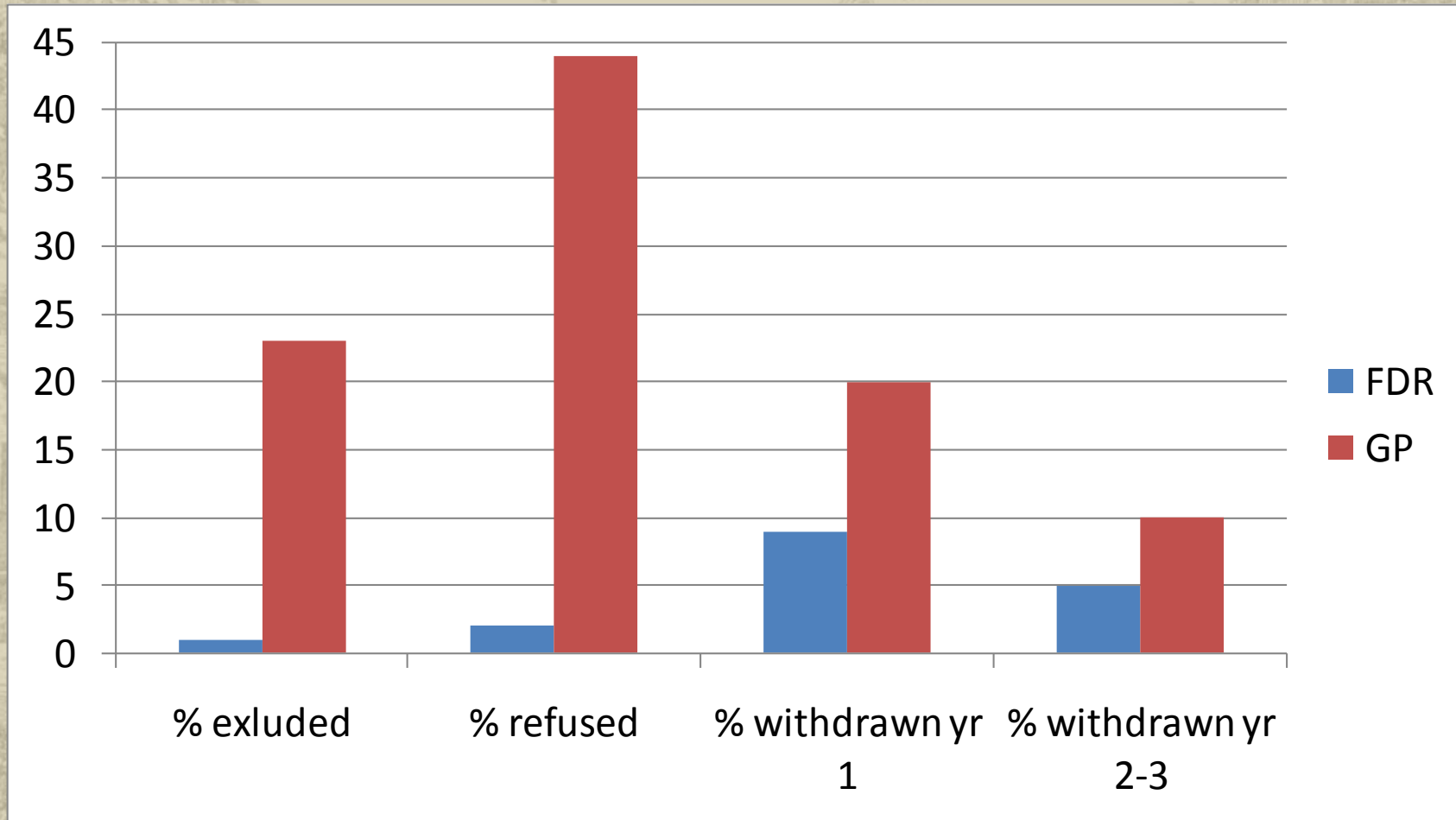
- Psychological issues difficult to study
- Study population clearly important

## ➤ Retention

- Psychological issues understudied but clearly important
- Study population clearly important

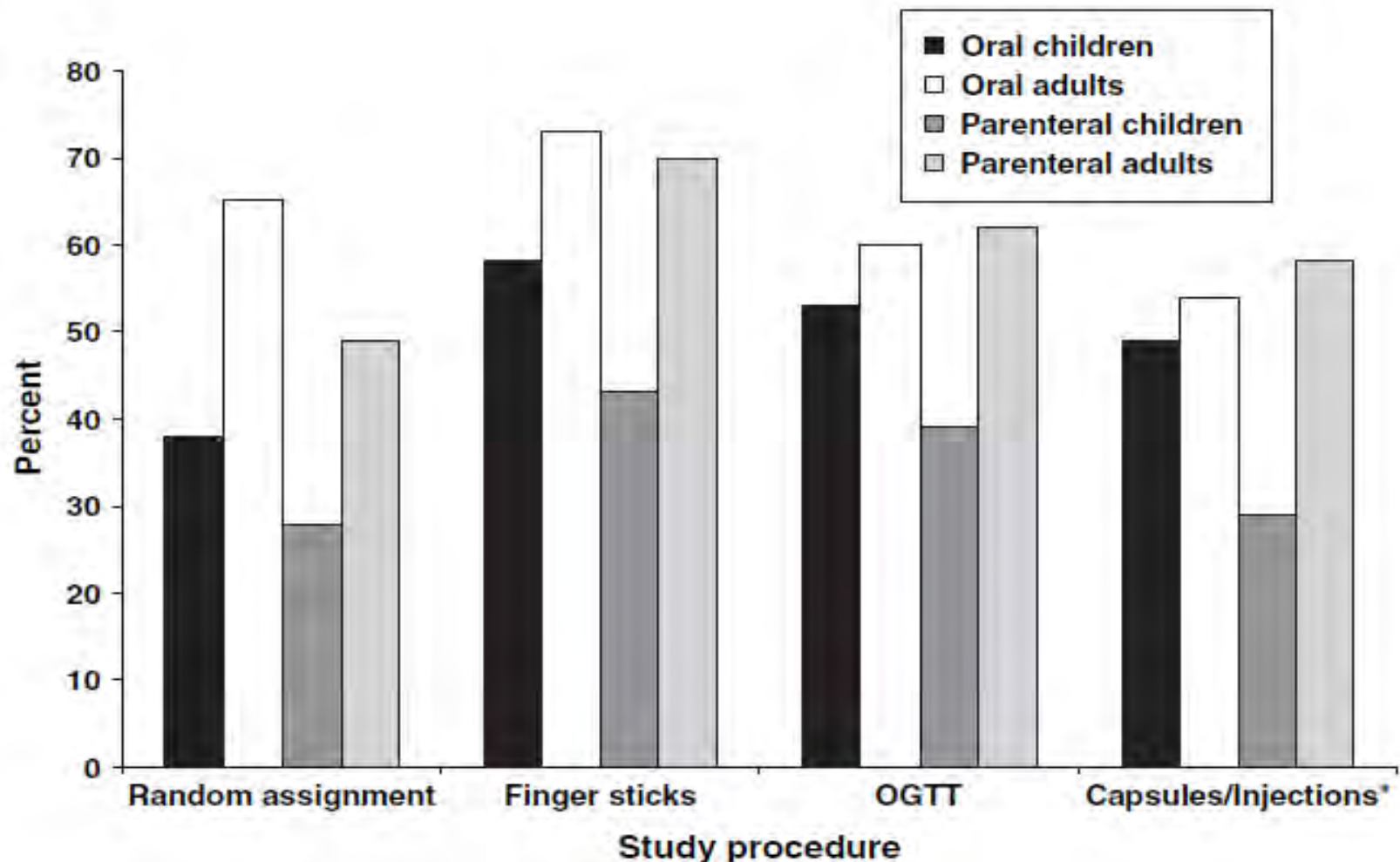


# FDR versus General Population: TEDDY Enrollment and Retention





# DPT-1: Percent of Children versus Adults Willing to be in another Study with Similar Procedures

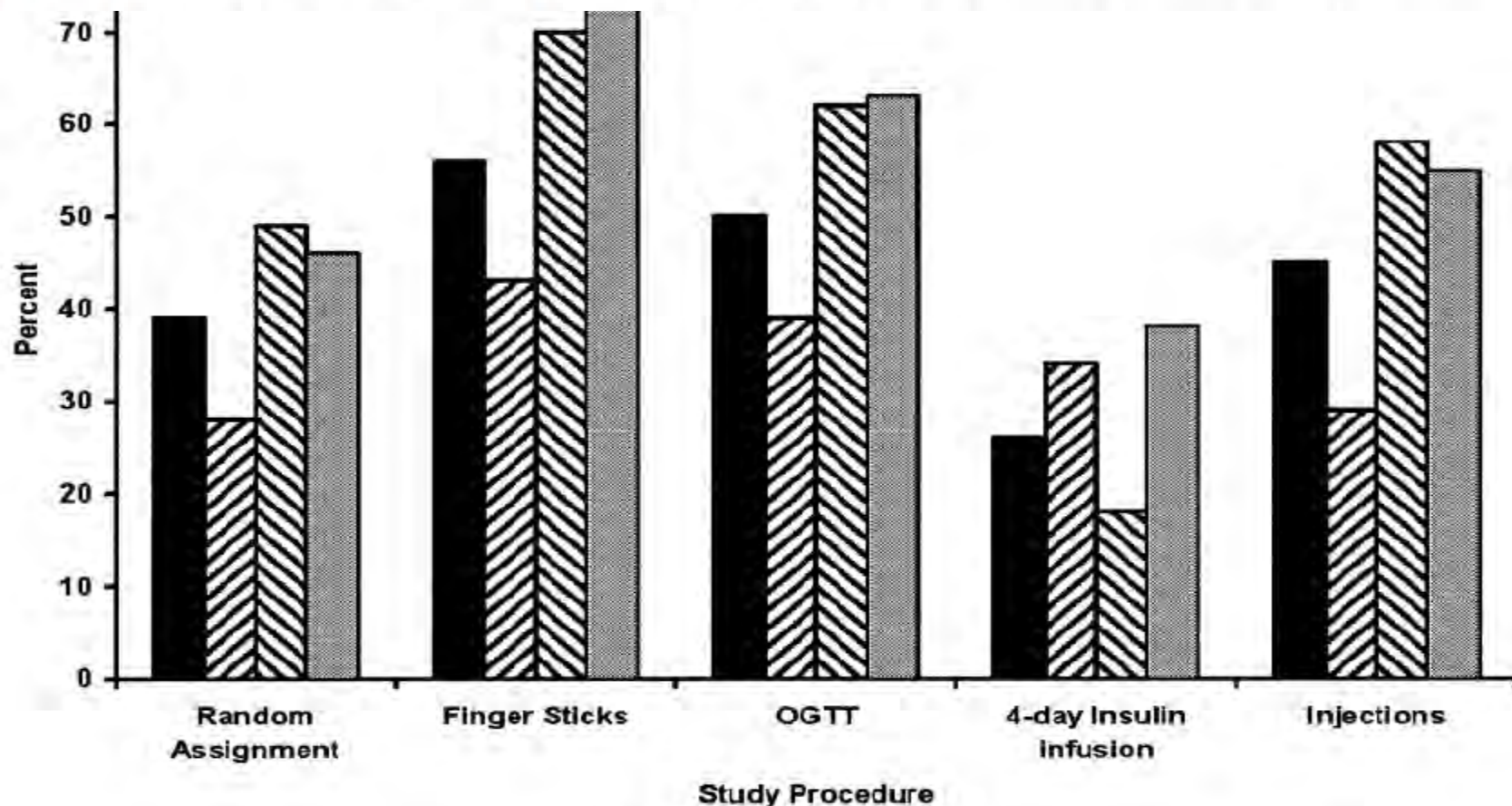






# DPT-1: Percent of Parenteral Child & Adult Participants & Parents Willing to be in another Study with Similar Procedures

■, all participants; ▨, child participants; ▩, adult participants; ▤, parents.





# Demographic Predictors of TEDDY GP Withdrawal

Predictor	% withdrawal: year 1	% withdrawal: year 2-3
Country	Finland: 16% Germany: 25% Sweden: 18% USA: 25%	Not significant
Child sex	Male: 19% Female: 22%	Not significant
Only child	Not available	Yes: 13% No: 11%
Child ethnic minority	White: 17% Hispanic: 33% Black: 33% Other: 29%	Not significant
Maternal age	Withdrawals younger	Withdrawals younger
Maternal education	Not available	Primary: 16% Trade/some college: 15% Graduated college: 10%
Crowding	Not available	Withdrawals more crowded



# Emotional/Cognitive Predictors of TEDDY General Population Withdrawal



Predictor	% withdrawal: year 1	% withdrawal: year 2-3
Maternal Risk Perception	Accurate: 16% Underestimate: 23%	Accurate: 9% Underestimate: 15%
Maternal State Anxiety Score	High anxiety in moms with accurate risk perceptions more likely to withdraw	Not significant
Maternal Study Satisfaction	Not applicable	Extremely satisfied: 7% Very satisfied: 13% Somewhat satisfied: 15% Somewhat dissatisfied: 23%



# Behavioral Predictors of TEDDY GP Withdrawal

Predictor	% withdrawal: year 1	% withdrawal: year 2-3
Maternal Employment Status During Pregnancy	Worked all trimesters: 15% Reduced work or did not work at all: 23%	Worked all trimesters: 10% Reduced work or did not work at all: 15%
Maternal Smoking	Yes: 37% No: 16%	Yes: 20% No: 11%
Maternal Drinking	Yes: 13% No: 21%	Not assessed
Maternal Reports of Child Illness	Not applicable	More child illnesses, less likely to withdraw 0-2 illnesses: 18% >10: 7%
Dad Participation	Yes: 18% No: 43%	Yes: 10% No: 20%
Study visits missed	Not applicable	Yes: 33% No: 10%



# Behavioral Impact: Percent Reporting Efforts to Prevent T1DM in DPT-1 and TEDDY



Study/Respondent	Percent Reporting Behavior Change to Prevent T1DM
DPT-1 Oral Insulin Trial	
Parent	38
Participant	48
DPT-1 Parenteral Insulin Trial	
Parent	57
Participant	48
TEDDY year 1	
General Population Parent	40
FDR Parent	51

# Summary

- Diabetes risk is difficult to communicate
  - Risk underestimation is common, may increase over time, and is associated with study withdrawal
- Anxiety is a common response to learning that you or a loved one is at increased risk for T1D
  - Anxiety usually dissipates over time
  - High anxiety may be associated with early study withdrawal



# Summary

- Many other emotional and behavioral factors have been associated with study withdrawal
  - Unfortunately these are rarely measured
- Many individuals informed of their or the loved one's T1D risk, engage in behaviors in an effort to prevent T1D
  - This occurs in response to screening, as well as in natural history and intervention trials - threatening study validity

# Summary

- Psychological impact varies across populations
  - Children may have more negative views of invasive study procedures than adults or parents
  - Mothers are more likely to be anxious and to accurately perceive the child's risk than fathers
  - FDR populations are more likely to be anxious, have accurate risk perceptions, to join and stay in a trial, and engage in behaviors outside the trial in effort to prevent T1D

# Recommendations



- Psychological impact of screening should be monitored in at-risk individuals and families
- Psychological variables are important predictors of study withdrawal and should be routinely collected and utilized to develop strategies to reduce drop-out



# Recommendations

- Participants commonly engage in behaviors outside of the trial in an effort to prevent T1D; unless measured – these threaten the validity of the study
- Characteristics of the target population are critical to all aspects of the study - screening, enrollment, retention, study compliance, and reactions to screening or study participation – and should be given greater consideration