



Pitt

Nursing | Alzheimer Disease Research Center

# PERCEIVED PARTICIPANT BURDEN IN ADRD RESEARCH

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# PARTICIPANT BURDEN

*What is it to you?*



## PARTICIPANT BURDEN

- Human subjects protection involves minimizing the degree of burden that research poses to participants.
- Historically, efforts to address burden have focused on direct risks associated with intervention or data collection.
- There is a need to examine the broader construct of participant burden, including indirect burden.

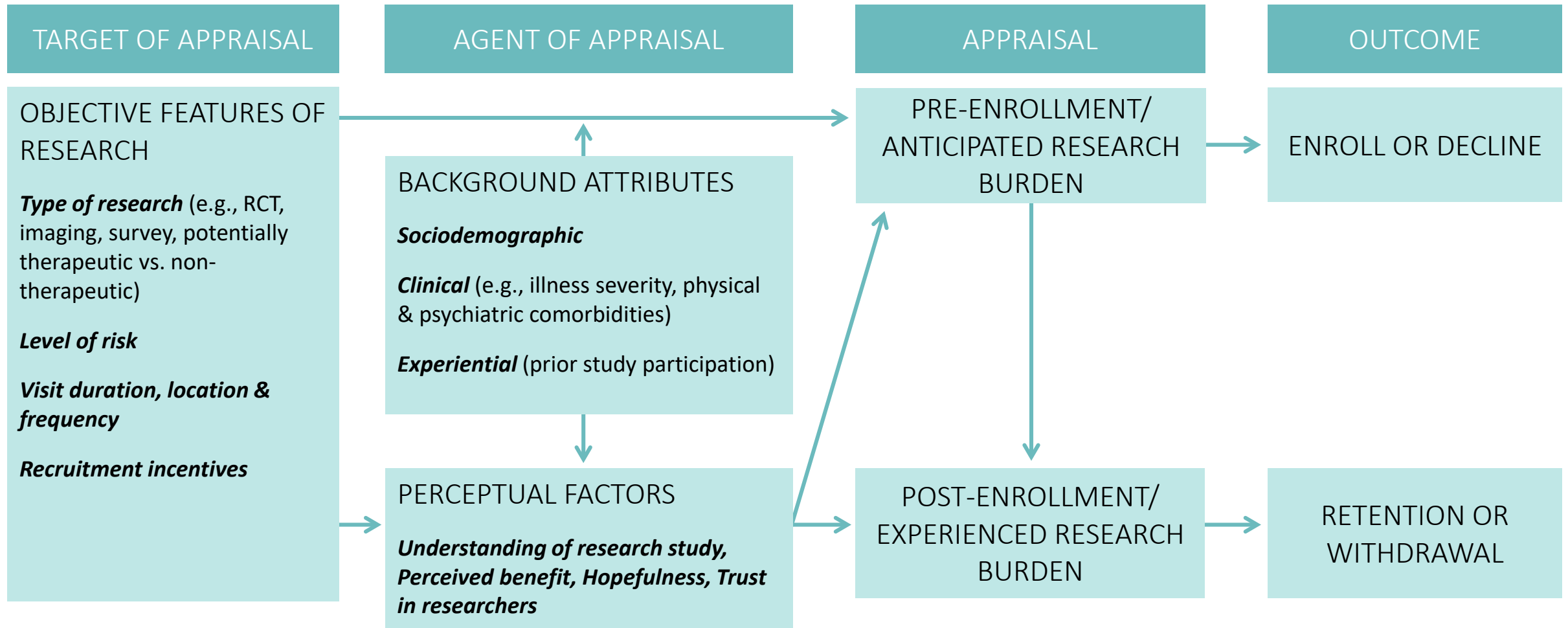


# PARTICIPANT BURDEN

- Indirect burden may include:
  - Time commitment
  - Travel inconveniences
  - Invasiveness of survey questions
- Common concern among research participants
- Plays a key role in explaining subject accrual and retention



# CONCEPTUAL FRAMEWORK



## PARTICIPANT BURDEN

- Research participants' perception of burden can be mitigated.
- A systematic assessment of participant burden could allow investigators to:
  - Better inform and prepare potential subjects for the experience of research participation;
  - Prospectively gauge participant burden during pilot studies; and
  - Modify their protocols so as to maximize subject participation while minimizing the associated burden.



## THE PeRBA PROJECT

- Pilot study
- Funded by the donations account of the U PITT Alzheimer's Disease Research Center (ADRC; Lopez: P50AG005133)
- Aims to examine the psychometric properties of a newly developed tool, the “Perceived Research Burden Assessment”
- Tests the hypotheses that the PeRBA will:
  - Produce reliable, consistent results; and
  - Demonstrate convergent and discriminatory validity.



## THE PeRBA INSTRUMENT

- Items were generated from literature review and input from a Community Advisory Council
- Measures 6 dimensions of participant burden
  - Time, invasiveness, accessibility, financial burden, psychological burden, physical burden
- 2 versions:
  - Patient version (21 items)
  - Family Member version (27 items)
- 5-point Likert Scale
  - Strongly disagree, Disagree, Neutral, Agree, Strongly agree





# PUBMED LITERATURE REVIEW

- Search terms, “burden” and “barriers”
- Paired with “human experimentation,” “research methodology,” and “research subjects”
- Search parameters
  - English language
  - January 1979–December 20012
- Screened 188 articles
- Excluded those focused on:
  - administrative burden of research, burden of research decision-making, or barriers to activities other than research participation
- In-depth review of 27 remaining articles



SAMPLE ITEMS FROM THE PeRBA: *FAMILY MEMBER VERSION*

SAMPLE ITEM	DIMENSION OF PARTICIPANT BURDEN	EXEMPLAR STUDY SUPPORTING INCLUSION OF DIMENSION
I feel that this study's visits might be too frequent.	Time	Resnick et al., 2003
I feel that the researchers might ask me questions that are too personal.	Invasiveness	Sherman et al., 2005
I feel that it might be inconvenient to get to the research center.	Accessibility	Arean & Gallagher-Thompson, 1996; Richardson et al., 1998
I feel that this study might take too much time away from my job.	Financial burden	Williams, Shuster, Clay, & Burgio, 2006
I feel that I may have to persuade or coax my loved one to come to the research center.	Psychological burden	Dowling & Wiener, 1997
I feel that my loved one may be physically harmed by the research procedures or study intervention.	Physical burden	Treschan et al., 2003; Tait et al., 2003

# STUDY PARTICIPANTS

- Recruited from the ADRC following an annual visit
  - 52 individuals with mild to moderate cognitive impairment
  - 52 family members
  - 30 healthy comparisons
- Eligibility criteria
  - Carry an ADRC consensus-based diagnosis of mild cognitive impairment or any dementia syndrome
  - Have an MMSE7 score of at least 18
  - Be community-dwelling
  - Live within a 50-mile radius of the University of Pittsburgh; and
  - Be willing to participate



# MEASURES

- Participants complete a one-time interview that includes:
  - 3 or 4 PeRBA surveys in which they rate their perception of the burden associated with 3 research hypothetical research scenarios (vignettes) for studies at differing levels of risk
  - Trust in Medical Researchers, Health Hope Index, Experience in Clinical Research, Motivation to Visit the ADRC, Social Support measures
- Clinicians complete a Clinical Insight Rating Form for each patient
- Sociodemographic and clinical characteristics are abstracted from the ADRC record

## SAMPLE VIGNETTE\*

The second kind of research involves the use of new medication that may help memory problems or even stop the progression of dementia. This new medicine is given through a vein in the arm and must be administered in a hospital setting. Its main side effect involves redness or irritation at the site of the injection. Less common, but more serious side effects include possible liver problems and brain swelling, which can be life-threatening. If these side effects should happen, the medicine would be stopped and you would be monitored with blood tests and brain scans until all symptoms went away. No one has

suffered any permanent damage as a result of this medicine, but several people have experienced life-threatening illness while taking a similar experimental medicine. Participating in this study would involve up to 10 visits to the research hospital over a 6 month period. Each visit would last for up to 4 hours and would include memory testing, interviews, and bloodwork. If the research procedures result in an injury, emergency medical treatment for injuries solely and directly related to participation in this research study will be provided by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you.

\*Adapted from Sachs et al., 1994

# SAMPLE CHARACTERISTICS (N=134)

	Controls n=30	Patients n=52	Study Partners n=52
	<i>mean (SD)</i>	<i>mean (SD)</i>	<i>mean (SD)</i>
Age in years	75.7 (10.3)	74.3 (9.8)	69.9 (11.5)
Education in years	15.9 (3.1)	15.4 (3.1)	14.9 (2.6)
Sex	<i>n (%)</i>	<i>n (%)</i>	<i>n (%)</i>
Male	<b>9 (30)</b>	<b>24 (46.2)</b>	<b>18 (22)</b>
Female	<b>21 (70)</b>	<b>28 (53.8)</b>	<b>34 (78)</b>
Race	<i>n (%)</i>	<i>n (%)</i>	<i>n (%)</i>
Caucasian	<b>21 (70)</b>	<b>48 (92.3)</b>	<b>48 (92.3)</b>
African American	<b>9 (30)</b>	<b>4 (7.7)</b>	<b>4 (7.7)</b>
	<i>mean (SD)</i>	<i>mean (SD)</i>	<i>mean (SD)</i>
Satisfaction with social support	2.7 (0.5)	2.6 (0.6)	2.2 (1.0)
Burden level, PerBA A	<b>28.2 (8.1)</b>	<b>32.6 (10.1)</b>	<b>43.9 (12.7)</b>
Burden level, PerBA B	40.1 (7.6)	37.7 (8.8)	53.9 (13.2)
Burden level, PerBA C	42.4 (9.9)	41.3 (9.9)	58.2 (13.2)

# PRELIMINARY RELIABILITY AND VALIDITY OF PERBA TO MEASURE ANTICIPATED RESEARCH BURDEN (N=134)

<i>Scenario/Analysis</i>	Internal Consistency: Cronbach's alpha		Correlation with related construct: likelihood of participating ( <i>r</i> )		Correlation with unrelated construct: social support ( <i>r</i> )	
	<i>P</i>	<i>F</i>	<i>P</i>	<i>F</i>	<i>P</i>	<i>F</i>
Study A: Venipuncture to develop a diagnostic test	0.95	0.96	-.523***	-.486***	-.289*	-0.131
Study B: Early phase investigational drug trial	0.87	0.94	-.496***	-.623***	-0.167	-0.257
Study C: Investigation of neurosurgical procedure	0.88	0.92	-.497***	-.421**	-0.284	-0.112

PeRBA mean scores ranged from 30.7 (Patient, Study A) to 58.2 (Family member, Study C)

# PeRBA SCORES IN THREE SCENARIOS (N=134)

	PeRBA 21-item Patient version (n=82)		PeRBA 27-item Family member version (n=52)	
	<i>M</i>	<i>(sd)</i>	<i>M</i>	<i>(sd)</i>
Scenario A: Venipuncture to develop a diagnostic test	30.7	(9.5)	43.9	(12.7)
Scenario B: Early phase investigational drug trial	38.7	(8.4)	53.9	(13.2)
Scenario C: Investigation of neurosurgical procedure	41.8	(9.8)	58.2	(13.2)
<b><i>P</i> value for paired t test within each group</b>				
A-B: comparison between scores for scenario A & B	<i>P</i> (A-B) < 0.001		<i>P</i> (A-B) < 0.001	
A-C: comparison between scores for scenario A & C	<i>P</i> (A-C) < 0.001		<i>P</i> (A-C) < 0.001	
B-C: comparison between scores for scenario B & C	<i>P</i> (B-C) = 0.001		<i>P</i> (B-C) < 0.001	



# NACC COLLABORATIVE STUDY, PI: MORRIS

## *Retaining participants in longitudinal studies of Alzheimer's disease*

- Multisite (Wash U, Wisconsin, U PITT, UC Irvine) telephone survey study to learn the research experiences of a random sample of:
  - 440 current ADRC patient participants nationally and
  - 240 current ADRC study partners nationally
- Eligibility:
  - All participants must currently be enrolled in a longitudinal study
  - Patients: age  $\geq 45$  years, CDR  $< 1$
  - Study partners: can be partners of participants in this study, partners of patients with CDR  $\leq 1$ , excluding those whose patient participant has passed away.
- Local sample size:
  - 110 Patients, 60 study partners



# NACC COLLABORATIVE SURVEY: DEMOGRAPHICS (N=170)

	Patients n=110		Study Partners n=60	
	(range) mean	SD	(range) mean	SD
Age, years	(53-91) 71.46	7.97	(27-91) 66.17	13.63
Years at ADRC	(0-27) 5.89	6.02	(0-24) 4.10	4.74
Sex	<i>n</i>	%	<i>n</i>	%
Male	47	42.7	15	25.0
Female	63	57.3	45	75.0
Race	<i>n</i>	%	<i>n=59*</i>	%
White	101	91.8	55	91.7
African American	8	7.3	4	7.7
Pacific Islander	1	.9	0	0
CDR of patient	<i>n</i>	%	<i>n</i>	%
0	58	52.7	13	21.7
0.5	52	47.3	31	51.7
1.0	0**	0.0	16	26.7

Relationship to Patient	Study Partners n=60	
	<i>n</i>	<i>Percent</i>
Spouse/Partner	32	53.3
Child	14	23.3
Friend or	5	8.3
Other***	9	15

\*\*\*Other relationships include  
 6 siblings,  
 1 cousin-in-law,  
 1 niece, and  
 1 parent.

Eight patient/study partner participants are a linked dyad, the remainder are independent.

\*One study partner did not report race.

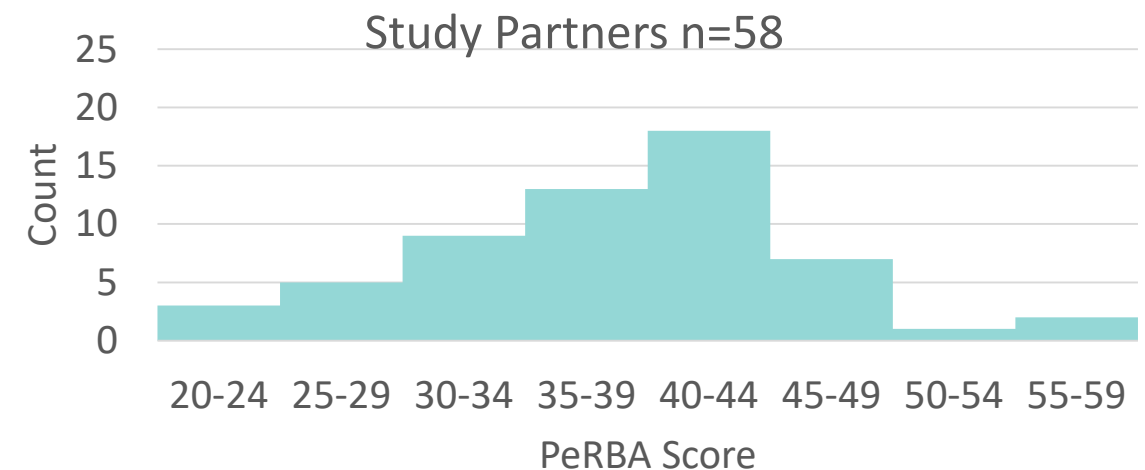
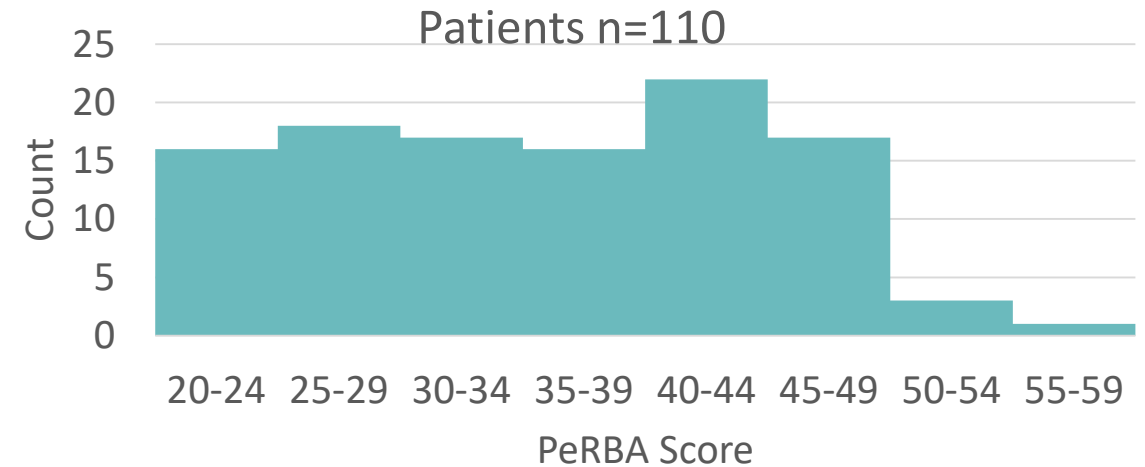
\*\*Patient participants with CDR > .05 were excluded from participating in the survey.

# NACC COLLABORATIVE SURVEY: PeRBA SCORES (N=168)

	PeRBA Score			
	<i>mean</i>	<i>SD</i>	<i>range</i>	<i>median</i>
Patients n=110	35.4	8.97	21-55	35.5
Study Partners n=58	38.5	7.84	20-58	39.0

Total PeRBA scores (the sum of 21 items) can range from 20 (low perceived burden) to 105 (high perceived burden).

Study partners, on average, reported higher perceived research burden than patient participants,  $Z = -2.02, p = .043$



## NACC COLLABORATIVE SURVEY: QUALITATIVE ITEMS

Of the 110 participants, 93 made comment(s) in response to either the two open-ended questions below:

1. What is the most important thing that ADRC researchers could do to enhance your experience in ADRC studies?
2. Do you have anything else you would like to share about your experience as a research participant?



# NACC COLLABORATIVE SURVEY: QUALITATIVE ITEMS

1. What is the most important thing that ADRC researchers could do to enhance your experience in ADRC studies?

## Praise

1. **ADRC Experience:** Keep it up!  
Positive experience, comfortable, smooth procedures
2. **Staff:** Kind, competent, accommodating
3. **Research:** Valuable work

## Advice

1. **More information: AD/Education/Preventative measures**
2. **More personalized testing feedback/communication/follow-up**
3. **Improvements to ADRC appointment/procedures:** location, longer business hours, better communication, waiting time, cater testing to the participant, etc.
4. **Study partner:** evaluate memory, exclude requirement

Other responses included providing: more information on alternative treatment options, compensation for transportation or lunch, more access to other research studies.

**Highlighted** responses indicate a comment repeated by over 10% of those responding. The 60 study partners also participated in this survey and their responses were similar, but more study partners volunteered the advice of providing more access/eligibility to more research studies.

# NACC COLLABORATIVE SURVEY: QUALITATIVE ITEMS

2. Do you have anything else you would like to share about your experience as a research participant?

## Praise:

- 1. ADRC Experience:**  
Positive, valuable, interesting, happy and fulfilling experiences, keep it up!
- 2. Staff:** Accommodating, professional, informative, bend over backwards

## Advice:

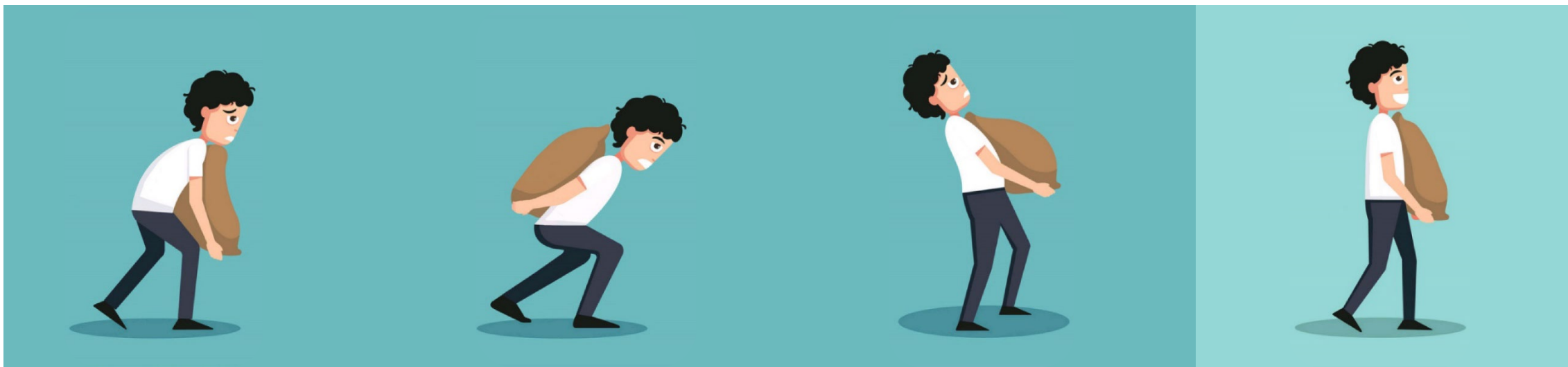
- 1. Improve ADRC appointment/procedures:** change cognitive tests, cognitive testing too long, mixed feelings (positive & negative), expand inclusion criteria, more time to get to the MRI/CT, update facility aesthetics, focus less on negatives
- 2. AD Information/Education/Preventative measures:** guidelines for prevention (AD/memory issues), share research study findings, more educational opportunities
- 3. Testing feedback/communication/follow-up:** more comprehensive feedback, better contact/follow-up with medical professionals, more communication throughout the year
- 4. More funding needed for AD research**
- 5. Negative experiences with staff:** arrogant, condescending

# REDUCING PARTICIPANT BURDEN

- Carefully consider assessment points
  - Are they scientifically justified, or mere convention?
- Consider providing participants with options
- Be mindful of participant burden during pilot testing
  - track refusal reasons
  - consider a formal assessment
- Follow the IRT literature, Patient-Reported Outcomes Measurement Information System (PROMIS)
- Offset burden with incentives/accommodations where possible
- Take advantage of technology (e.g., remote data collection)
- Engage staff in strategizing to minimize burden (U PITT Participant Experience Task Force)

# SUMMARY

- Participant burden is
  - Significant to participants, their study partners, and often noted by grant reviewers
  - Measurable
  - Controllable





# ACKNOWLEDGMENTS

## PERBA STUDY TEAM

- Lauren Terhorst, PhD
- Karen Schmidt, PhD
- Amanda Gentry, PhD, MSW
- Lu Hu, MSN
- Trevor Nissley, BSN
- Catherine Toth, BSN

## NACC COLLABORATIVE STUDY TEAM

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