

Reactions to Research Participation: Risks and Benefits

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**Presented at the 135th Annual American Public Health
Association Meeting
Washington, DC
November 5, 2007**

This study was supported through a contract with the
Florida Agency for Health Care Administration (Contract #M0308)

Background:

(Boothroyd, 2000; Jacomb et al., 1999; Jorm et al., 2007; Martin et al., 2001; Newman & Kaloupek, 2004; Newman et al., 1999; Turnbull et al., 1988; Walker et al., 1997)

- Minimizing risk of harm to participants is a basic principle of sound research practice.
- A systematic review of 46 studies found participant reactions to research range from reports of:
 - Depression / Anxiety
 - Embarrassment / Intrusiveness
 - Stressed Out / Annoyance
 - Regret for Participating

Prevalence of Distress:

- In trauma-focused studies participants report both:
 - “Unexpected upsets” - 57% of participants reported crying during interviews (Newman et al., 2004).
 - “Helpful” or “positive experience”
 - 26 - 99% report participating was both beneficial and valuable experience
- In both, patient studies of psychiatric disorder and community based (non-patient) samples:
 - Generally less than 10% report ‘distress’ (Jorm et al, 2007).

Gaps in the Literature on Risk:

- Limited literature exists on distress over time.
 - In both, psychiatric and trauma exposed populations:
 - Current evidence points to decreases in distress over time.
 - Follow up studies show that there is a range from 1-2 weeks to 4-6 years later of 'feeling better'.
 - One study of veterans with PTSD found an increase in medication and service use after participation (Halek et al, 2005).
 - In Children and Adolescents exposed to sexual abuse:
 - 25% remained symptomatic for weeks to months after disclosure (Putnam et al., 1996).
 - Clinical trials: no research found.

Purpose of this Study:

- To examine the positive and negative reactions of adult and adolescent research participants.
- Specifically:
 - Prevalence of adverse emotional reactions
 - Persistence of distress over time
 - Factors and questions associated with adverse reaction
 - Likelihood of future participation
 - Perceived benefits

The Research Questions:

- R1: What is the prevalence of adverse emotional reactions among participants?
- R2: What is the persistence of distress over time?
- R3: Which factors are associated with experiencing adverse reactions?
- R4: What is the relationship of understanding the study to experiencing adverse emotional reactions?
- R5: What is the likelihood of future participation?
- R6: What are perceived benefits of participation?

Overview of Methods/Procedures:

- A Mixed Method Four-Year Longitudinal Study
- Separate face-to-face interviews lasting 1-1/2 hours were completed with 125 adolescent girls (13-18 years old) and their mothers.
- After each interview, respondents were debriefed regarding their experience as a research participant.
- Each year protocols included questions on:
 - Health/Mental Health
 - High-Risk Behaviors: Sexual Activity /Substance Abuse
 - Perceived Social Supports and Self-Esteem
 - Hopes and Aspirations for the Future

Sample Demographics

Characteristic	Mothers (<i>n</i> = 125)	Daughters (<i>n</i> = 125)
Age: Mean	38.4	15.5
SD	4.99	.99
Range	30 to 53	13 to 17
Race/Ethnicity:		
White	40.7%	33.6%
Black/African American	38.2%	40.8%
Hispanic	21.1%	25.6%
Marital status:		
Married or living as married	12.8%	0%
Divorced, Separated, or Widowed	54.4%	0%
Never married	32.8%	100%
Education:		
Dropped out of school	50.4%	28.0%
Completed high school	49.6%	NA

Items for Reactions to Participation (Likert Scale)

1. To what extent do you think the informed consent procedures adequately described what this study was about and the kinds of questions you would be asked?
2. Did you feel pressured to participate in this study even though you did not want to?
3. To what extent are you aware of the purpose of this study?
4. To what extent do you think the questions you were asked intruded on you or your daughter's privacy? 4.a. Which questions that were asked do you feel were most intrusive ?
5. To what extent did any of the questions make you feel uncomfortable?
6. To what extent did the questions you were asked upset you or make you feel anxious?
6.a. Which questions made you feel upset or anxious?
7. How afraid are you that other people might find out about information you told us?
8. How would you describe your overall experience participating in this study?
10. How likely would you be to participate in a similar study in the future?
11. Do you have any comments you would like to share about your experience participating in this study?
13. Did you experience any uncomfortable feelings after you completed last year's interview?
13.a. If yes, about how long did these feelings last?

R1: What is the prevalence of “adverse emotional reactions” among participants?

■ Mothers:

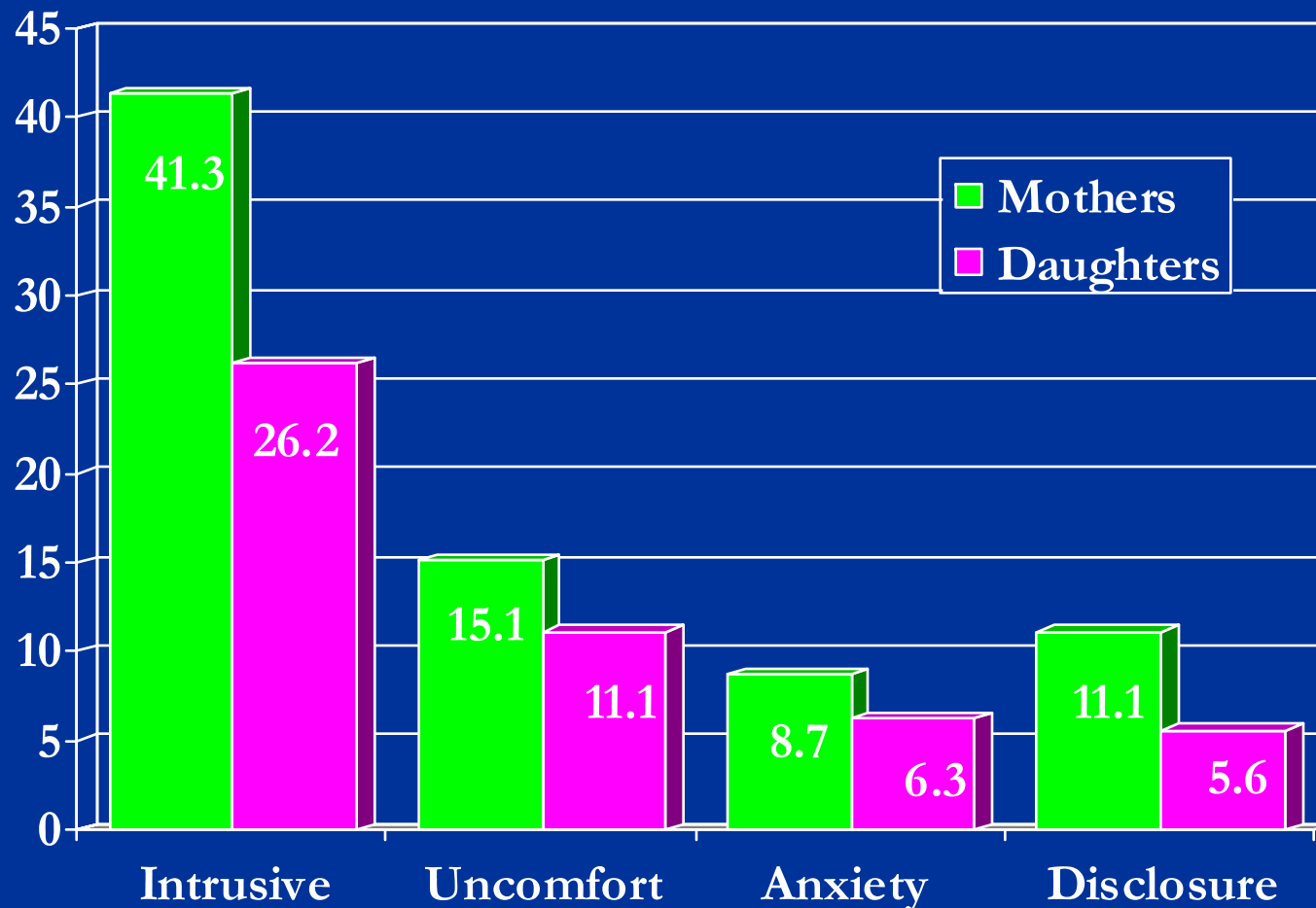
- 58.6% experienced at least one adverse reaction
 - 41.3% report questions as intrusive
 - 15.1% felt questions were uncomfortable
 - 8.7% report questions were upsetting or anxiety producing
 - 11.1% were fearful of disclosure
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- Over time there was decrease of reports of any adverse reaction:
 - Year 1 (32%) to Year 4 (12.8%)

R1: What is the prevalence of “adverse emotional reactions” among participants?

■ Daughters:

- 57.7% experienced at least one adverse reaction
 - 26.2% report questions intrusive
 - 11.1% felt uncomfortable.
 - 6.3% report questions were upsetting or anxiety producing.
 - 5.6% fearful of disclosure
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- A decrease in reports of any adverse reaction:
 - Year 1 (25 %) to Year 4 (16%)

Prevalence of Adverse Experiences



R2: What is the persistence of distress over time?

- Those reporting any persistence in distress across the four years of the study:
 - 4.0% of mothers
 - 2.4% of daughters
- The length of time reported for persistence in distress:
 - Mothers: from a few minutes to a couple of days.
 - Daughters: from a couple of hours to a couple of weeks.

R3: Which factors are associated with experiencing adverse emotional reactions?

■ Mothers:

- None of the characteristics we analyzed significantly contributed to adverse reactions:
 - Marital status, race/ethnicity, level of education, or exceeding the threshold criterion score for depressive symptoms

■ Daughters:

- Those meeting criteria for depressive symptoms were 2.6 times more likely to experience any adverse reactions.

Questions Identified by Mothers as Distressing

- Daughters' Sexual Activity
- Drugs and Alcohol Use
- Finances
- Religious Practices
- Mental Health
- Suicide
- Mother's "Personal" Life
- Regarding Being a Role Model

Questions Identified by Daughters as Distressing

- Sexual Activity
- Drug and Alcohol Use
- Finances
- Questions about Family
- Questions about Father
- Regarding Friendship
- Regarding Marriage

R4: What is the relationship of understanding the study to experiencing adverse reactions?

- Consent procedures were deemed adequate by:
 - Mothers (84.9%) / Daughters (75.4%)

- Reports of being unaware of study goals:
 - Year 1: Mothers (7.2%) / Daughters (18.5%)
 - Year 4: Mothers (.9%) / Daughters (5.4%)

- There was no significant relationship for mothers.
- In contrast, daughters were 3.9 times (p=.02) more likely to experience an adverse reaction.

R5: What is the likelihood of participation in future studies?

- Likelihood of future participation:
 - Year 1: Mothers (94%) / Daughters (92%)
 - Year 4: Mothers (98%) / Daughters (99%)
- Significantly, of those mothers (58.6%) with any negative reaction, 94% reported a desire to participate in future studies.
- Likewise, of daughters (57.7%) experiencing negative reactions 89% stated they would participate in future studies.

Question	Daughters					Mothers				
	2002	2003	2004	2005	Any	2002	2003	2004	2005	Any
Felt pressure to participate	0%	.9%	0%	.9%	1.6%	0%	0%	.9%	0%	.8%
Unaware of study goals	18.5%	14.7%	7.2%	5.4%	32.5%	7.2%	5.4%	4.7%	.9%	14.3%
Questions intrusive	13.5%	6.9%	10.8%	10.6%	26.2%	23.2%	11.6%	19.8%	10.7%	41.3%
Questions Uncomfortable	NA	5.3%	9.9%	7.0%	11.1%	NA	6.3%	4.7%	4.3%	15.1%
Anxiety producing	2.4%	1.7%	2.7%	.9%	6.3%	4.8%	3.6%	1.9%	2.7%	8.7%
Afraid of disclosure	.8%	2.6%	.9%	2.6%	5.6%	6.4%	5.4%	1.0%	0%	11.1%
Procedures inadequate	12.7%	6.4%	7.2%	8.2%	24.6%	7.9%	6.3%	2.8%	2.7%	15.1%
Persistence	NA	1.7%	2.8%	0%	2.4%	NA	1.8%	.8%	1.6%	4.0%
Any adverse reaction	29.4%	24.8%	23.4%	16.1%	57.7%	32.3%	21.6	27.2%	12.8%	58.6%

R6: What are perceived benefits of participation ?

Daughter's Perceived Personal Benefit

I think it's very good for someone to interview another person & show someone cares about them.

I think it's a good thing. I appreciate you checking up on us.

It was fun, it's nice to talk to someone.

Not like I thought it would be. Not as bad, I would participate again.

Happy that you chose our family to be in the study.

R6: Daughter's Perceived Benefits for the Future

They need a study like this, study needs to be continued so that us (teenage girls) can help the girls behind us/the next generation, to stay off of Welfare.

Glad someone would take time to find the needs of young girls and moms: The support system girls have when they have kids.

If it's a way to help others it's a good study.

It wasn't as bad as I thought based on the Informed consent - it was fine! It's more help for single mothers who are working & have children.

A good experience for teenagers. Learn how it is to be a teenage parent.

R6: What are Mother's perceived personal benefits of participation ?

Enjoyed the interview & the questions made me think about different issues.

It was very positive and informative. Some questions really dealt with me on a spiritual level. I really appreciate your concern for mothers/daughters.

It made me think about a lot of concerns and problems and my daughter's future. Very positive experience.

More comfortable than thought would be. Didn't find questions embarrassing.

This hour was like a psychiatric session for me.

Made me think I need to talk with my daughter more often.

Mother's Perception of Potential Benefit for the Future

I feel this is a good project for research to help mothers & young mothers to stay off welfare.

I hope that these types of programs improve actual circumstances of future generations, specially for Latin people, we really want to improve, not to be a problem to this country.

Thinks "It's a great thing you are doing here". The system & the situation for single parents is a nightmare. I have hope things will change & I would be very relieved to see help so my daughter doesn't wind up a single mom.

Mother's Perception of Potential Benefit for the Future (2)

Wish they could help out more with the transportation for people further away from businesses.

Tell children to stay in school & get education to stay off welfare.

Hope that this information will help someone else.

Problem w/ transition program is they withdraw assistance too soon once a person starts working. Questions should deal more w/ how program procedures & policies affect participants' lives.

I would like for my participation in this study to somehow create service for single parents & children. Such as better housing opportunities, more activity creations for children w/o a certain parent, etc.

Discussion:

- This study offers empirical evidence of participant's experiences of adverse emotional reactions, yet continued willingness to participate in future studies.
- Results suggests that participants value the experience of contributing to research that may benefit others and demonstrates the importance of being included in non-therapeutic research.

Recommendations:



- Establishing protocols for assessing reactivity and intrusiveness at the end of an inquiry not only alerts the researcher but also helps to contribute to our understanding of the potential risk and harm.

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