



Development and Validation of the PROMIS[®] Vulvar Discomfort with Sexual Activity Scales

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Domain Group

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Background

15%

Percent of sexually active U.S.
women who experienced
vulvar discomfort during
sexual activity in the past
month

*Lack of measures of
vulvar discomfort
during sexual activity*

PROMIS®
*Sexual Function &
Satisfaction*

SEXFS

Version 2.0



Methods

Development Summary

Task	#
Patient focus groups	11 groups
Clinician discussion groups	6 groups
Generation of candidate items	16 items
Cognitive interviews	48 patients
Psychometric analysis	1686 sexually active U.S. women
Final items	8 items



Low literacy

Chronic conditions

Lesbian, gay, and
bisexual

Older ages

Psychometric Analyses



Make sure item responses behave the way we expect

Determine how to combine item responses into a score

*Confidence Interval
Item Response*

score is $\hat{y} = b_0 + b_1x$
 $= t_{\alpha/2} \cdot se \sqrt{1 + \frac{1}{n} + \frac{n(x_0 - \bar{x})^2}{n(\sum x^2) - (\sum x)^2}}$
 $= 3.169 \cdot 3.22 \cdot \sqrt{1 + \frac{1}{12} + \frac{12 \cdot (4 - 4)^2}{12 \cdot 2 - (4)^2}}$

*Analysis
Response Model)*



Results

Initial Items

Clitoral pain (2)

Clitoral discomfort (2)

*Clitoral numbness or lack of feeling
(2)*

Labial pain (2)

Labial discomfort (2)

*Labial numbness or lack of
feeling (2)*

Labial bleeding (2)

*Labial itching, burning, swelling
(2)*

CFI = .72
TLI = .67
RMSEA = .22
Lots of local
dependence

Vulvar Discomfort



Clitoral Discomfort

Labial Discomfort

CFI = .80
TLI = .77
RMSEA = .18
Still bad local
dependence

Vulvar Discomfort



Clitoral Discomfort

Pain (2)

Discomfort (2)

Numbness or

lack of feeling

(2)

Labial Discomfort

Pain (2)

Discomfort (2)

Numbness or

lack of feeling

(2)

Bleeding (2)

Itching, burning, swelling (2)

Vulvar Discomfort - Labial



Refers to the degree of physical discomfort (including pain) of the labia during sexual activity. Higher scores indicate more discomfort.

0.96

Cronbach's α

1.00

CFI

0.04

RMSEA

0.99

TLI

Vulvar Discomfort - Clitoral



Refers to the degree of physical discomfort (including pain) of the clitoris during sexual activity. Higher scores indicate more discomfort.

0.97

Cronbach's α

1.00

CFI

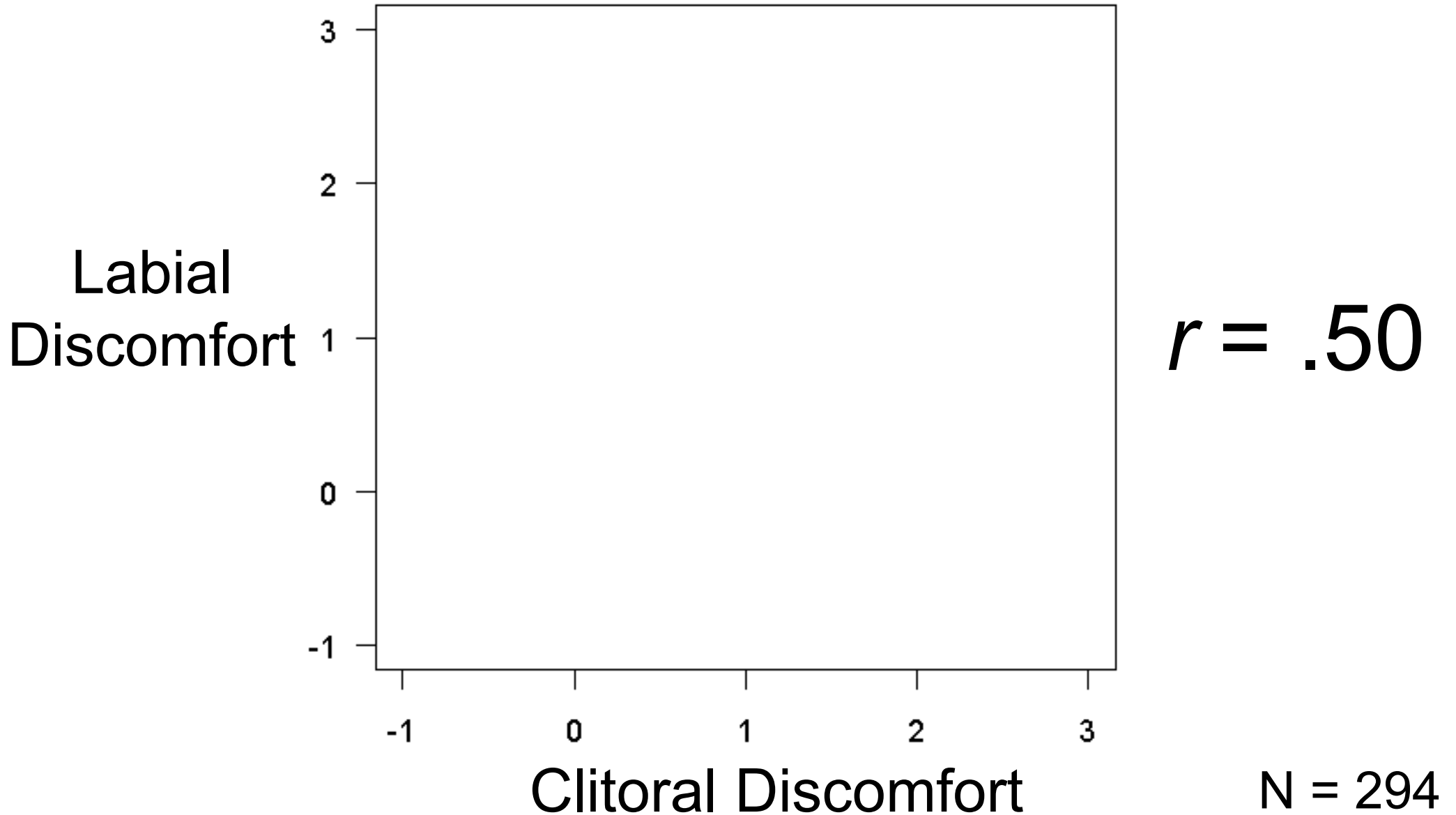
0.06

RMSEA

1.00

TLI

Unique Information Provided by Each Subdomain



Known-Groups Validity

Talk to health care provider
about problems with sex life in
past 12 months?

YES > NO

Clitoral Discomfort


.79 SDs (95% C.I. = .67,
.92)

Labial Discomfort

.77 SDs (95% C.I. = .65,
.90)



Discussion



Conceptually and empirically
distinct domains (clitoral and
labial)

Excellent psychometric properties

Brief (2 to 4 items)

Addresses major gap in
measurement for female sexual
health

Using the Items

Freely available

Contact info@nihpromis.org

PROMIS SexFS Brief Profile for Women
12-item profile for general use

*Includes 1 item from each Vulvar
Discomfort domain*

Spanish translation currently underway

SEXFS

Version 2.0

Backup Slides

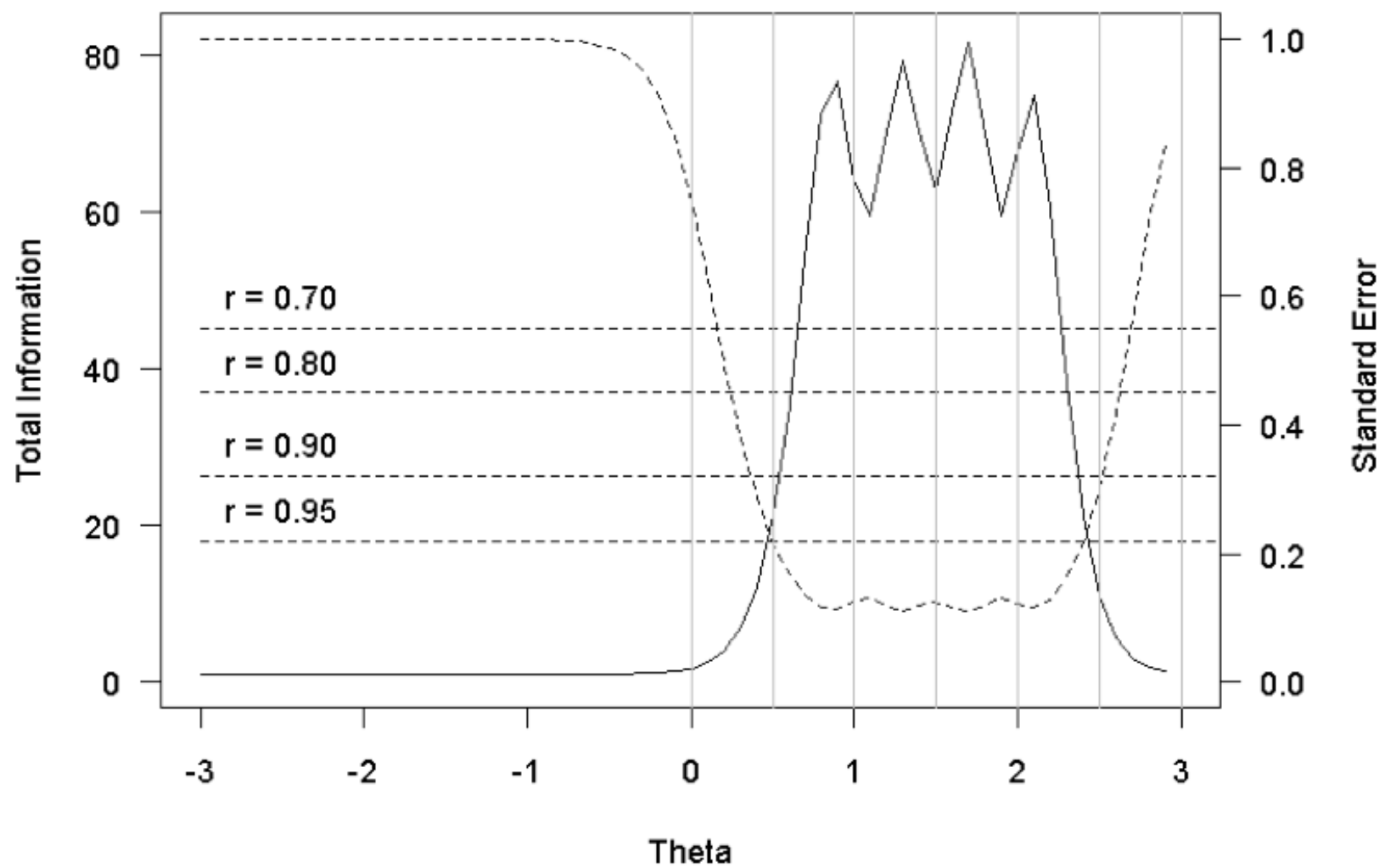
Labial Discomfort

<p>In the past 30 days, how often have you had discomfort in your labia (lips around the opening of the vagina) during sexual activity?</p>	<p>Never Rarely Sometimes Often Always</p>
<p>In the past 30 days, when you have had sexual activity, how much discomfort have you had in your labia (lips around the opening of the vagina)?</p>	<p>None A little bit Some Quite a bit A lot</p>
<p>In the past 30 days, how often have you had pain in your labia (lips around the opening of the vagina) during sexual activity?</p>	<p>Never Rarely Sometimes Often Always</p>
<p>In the past 30 days, when you have had sexual activity, how much pain have you had in your labia (lips around the opening of the vagina)?</p>	<p>None A little bit Some Quite a bit A lot</p>

Clitoral Discomfort

<p>In the past 30 days, how often have you had discomfort in your clitoris (clit) during sexual activity?</p>	<p>Never Rarely Sometimes Often Always</p>
<p>In the past 30 days, when you have had sexual activity, how much discomfort have you had in your clitoris (clit)?</p>	<p>None A little bit Some Quite a bit A lot</p>
<p>In the past 30 days, how often have you had pain in your clitoris (clit) during sexual activity?</p>	<p>Never Rarely Sometimes Often Always</p>
<p>In the past 30 days, when you have had sexual activity, how much pain have you had in your clitoris (clit)?</p>	<p>None A little bit Some Quite a bit A lot</p>

Clitoris Discomfort



Labia Discomfort

