



# Responsiveness

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## Definition

### Responsiveness

*"The ability of an HR-PRO instrument to detect change over time in the construct to be measured"*

COSMIN, 2011

*"Målbarhed af en reel ændring"*

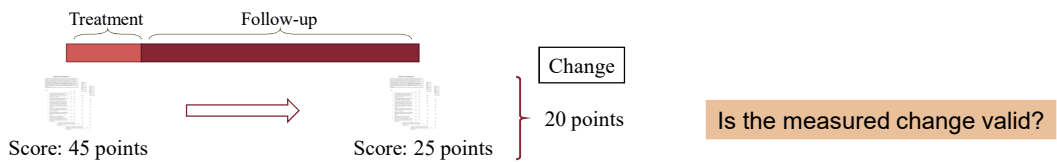
Bendix T., 2008

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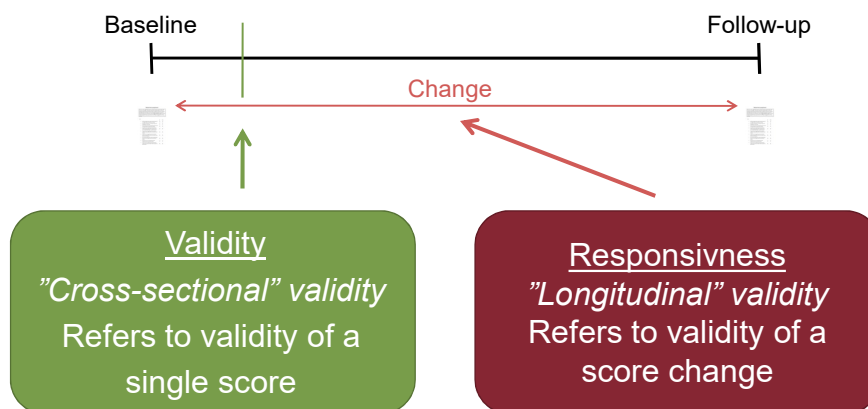
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# Measuring change



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# Responsiveness versus validity



*Consequently, validity and responsiveness have similar standards*

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# Distribution- versus anchor-based approaches

## Distribution-based methods

- Express observed change to some form of variation in the obtained sample

$$\text{Responsiveness} = \frac{\text{Observed change}}{\text{Variation}}$$

## Anchor-based methods

- Relationship between a questionnaire and an independent measure (or anchor)
- Elucidate the meaning of a particular degree of change

# Distribution-based approaches

## Effect size

- Individual change in SD of pretest

$$ES = \frac{\text{Score}_{\text{pretest}} - \text{Score}_{\text{posttest}}}{SD_{\text{pretest}}}$$

## Standardized response mean

- Individual change in SD of change

$$SRM = \frac{\text{Score}_{\text{pretest}} - \text{Score}_{\text{posttest}}}{SD_{\text{change}}}$$

## Guyatt's responsiveness statistics

- Accounts for spurious changes arising from measurement error

$$GRS = \frac{\text{Minimal Important Change}}{SD_{\text{change,stable}}}$$

$$GRS = \frac{(\text{Score}_{\text{pretest}} - \text{Score}_{\text{posttest}})_{\text{Improved pts.}}}{SD_{\text{change,stable}}}$$

# Problems with ES, SRM & GRS

## Is not a reflection of the 'true change'

- Possible reasons:
  - Instrument could have a ceiling effect
  - Instrument lack relevant items

## Highly dependent on variability (SD)

- High coefficients with small SD

Are measures of the **magnitude** and not the **validity** of change scores

Does not provide a good indication of the **importance** of the observed change

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# Two types of responsiveness

## Construct responsiveness

*The degree to which the change scores of a HR-PRO instrument are consistent with hypotheses*

- Tests hypotheses about expected change

## Criterion responsiveness

*The degree to which the change scores of a HR-PRO instrument are an adequate reflection of a 'gold standard'*

- Correlations
- Sensitivity/specificity
- Receiver Operating Characteristic (ROC) curves

Mokkink et al. (2010); Terwee et al. (2009)

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# Construct responsiveness

Specify the hypotheses before collecting data

Eg.:

- Expected correlations between score changes and changes in other variables
  - Example: function and satisfaction with treatment
- Expected differences in score changes between groups
  - Example: severe depression versus mild depression
- Expected score changes after a treatment with known effect
  - Example: treatment of tension headache with NSAID

Terwee et al. (2009)

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# Construct responsiveness

Hypothesis

- Should be specific
  - Direction of the expected correlation/difference
  - Size of the expected correlation/difference
- Should be challenging
- The more hypotheses the better

Terwee et al. (2009)

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## Example: Low Vision Quality of Life” questionnaire (LVQoL)

### 4 subscales

- Basic aspects
- Mobility
- Adjustment
- Reading

### Compared to

- VF-14
- Acuity
- Global change

- Much better
- Better
- A little better
- No change
- A little worse
- Worse
- Much worse

## Example cont'd

### Hypotheses example

Correlation between score changes on LVQoL and global change is least 0.10 higher compared to the correlation between the score changes on LVQoL and acuity

### Results

LVQoL subscale	Global change		Change in acuity
$\Delta$ basic aspects	0.26	>	0.13
$\Delta$ mobility	0.26	>	0.08
$\Delta$ reading	0.18	>	0.07
$\Delta$ adjustment	0.20	>	0.04

4 out of 4 (100%) hypotheses confirmed

# Criterion responsiveness

Requires a 'gold standard' measuring change in the domain

Eg.

- Global change
- Change in a clinical variable

## Methods

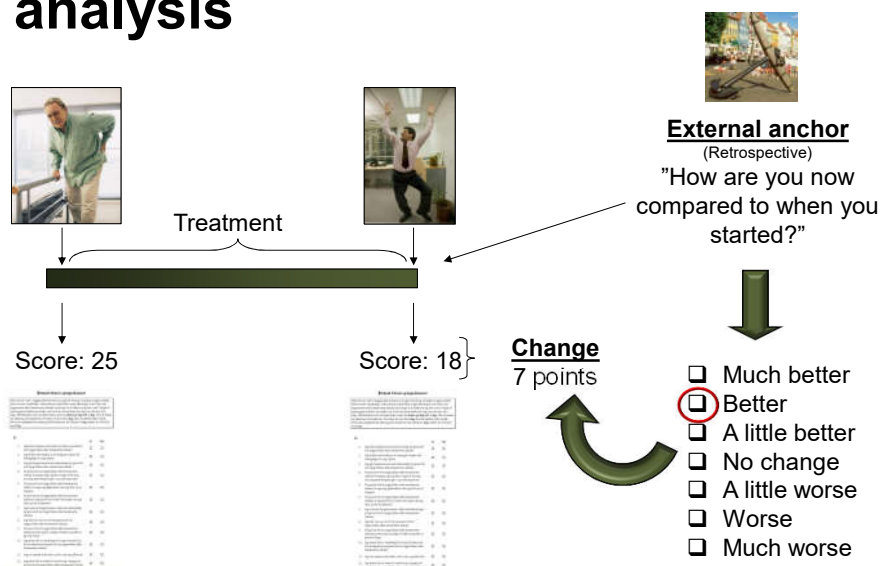
- Correlation between a 'gold standard' and score change
- Sensitivity/specificity – dichotomous variable
- Receiver Operating Characteristic (ROC) curves

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# ROC analysis



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# The external anchor (transition question)

"How are you now compared to when you started?"

Recall bias	Present state bias	Motivational bias	Contamination bias	Pleasing bias
Problems remembering prior health status	Relate to how things are now and <u>not</u> to the change	Cumbersome treatment → Overestimation of the treatment response	Comorbidity contaminates the answer  Eg. LBP patient with headache	Patients want to please the clinician

Norman et al., 1997; Hägg et al., 2002; Middle et al., 2006; Aseltine et al. 1995; Herrmann et al., 1995, Lauridsen et al. 2007



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## Bias depends on time frame

Follow-up < approx. 6 wks.

- Retrospective anchor ≈ OK

Follow-up > approx. 6 wks.

- Retrospective anchor biases

**Solution: 'The Punum Ladder'**

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# The Punum Ladder

Prospective anchor which avoids biases

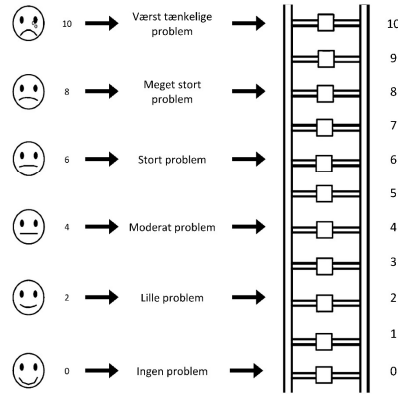
Score range: [0-10]

Applied to each dimension

Well validated:

- Validity
- Reproducibility
- Reliability
- Internal consistency
- Responsiveness

Sæt venligst et kryds på det 'trin i stigen' som bedst beskriver din overordnede livskvalitet (tilfredshed eller glæde ved livet) relateret til ... over den sidste uge.



NB: Danish version has not been tested for cross-cultural validity

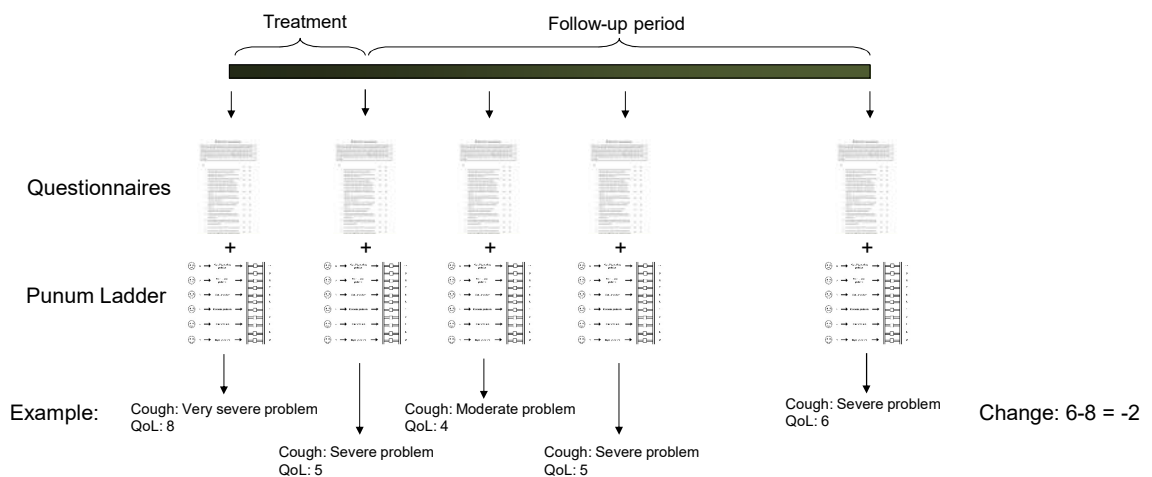
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Fletcher et al, 2010

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# Study design with Punum Ladder



Fletcher et al, 2010

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# Trichotomisation

Change score ratings	Interpretation
-2, -1, 0, +1, +2	No change
$\leq -3$	Improvement
$\geq +3$	Deterioration

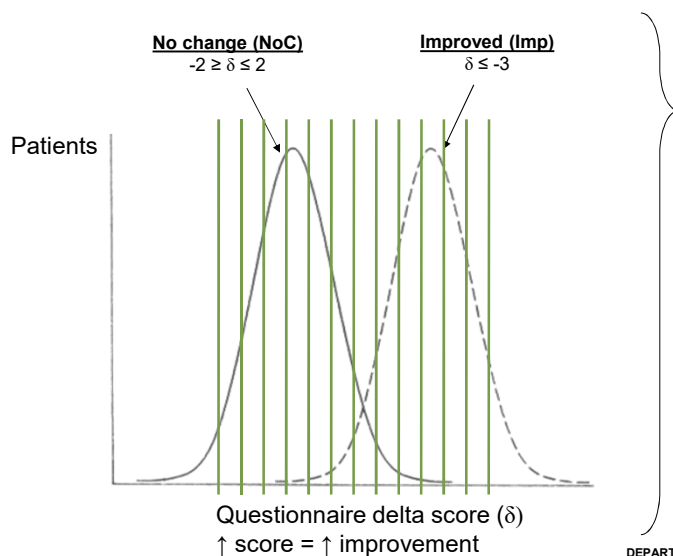
Fletcher et al, 2010

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# Sensitivity and specificity



	Anchor	
	Imp	NoC
Score $\geq \delta$	A	B
Score $< \delta$	C	D

**Sensitivity:  $A/(A+C)$**

True positive rate

**Specificity:  $D/(B+D)$**

True negative rate

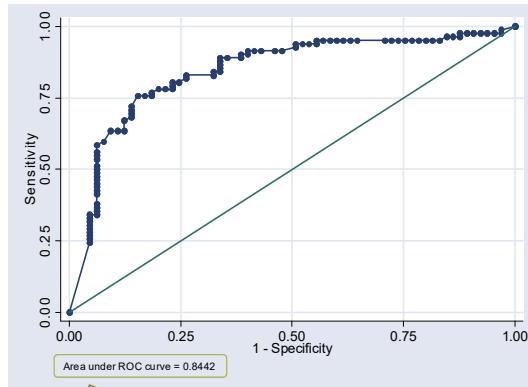
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# The ROC curve

Plots the true positive rate (sensitivity) against the false positive rate (1-specificitet)



Area under the curve = proportion of correctly identified patients, who truly have improved = responsiveness

$ROC_{auc} = 0.50 \rightarrow$  unresponsive

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# Questions?



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