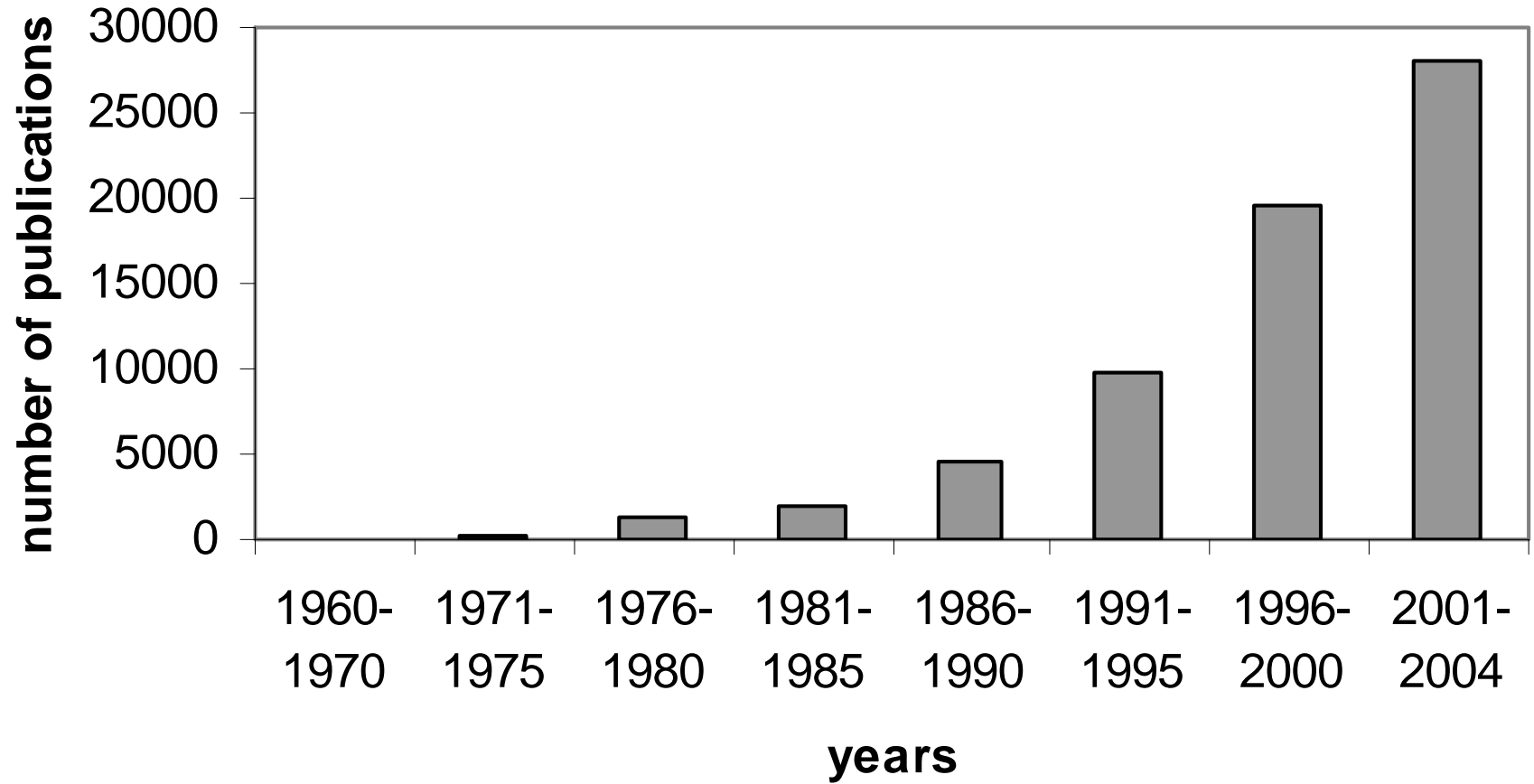


## Quality of Life

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## 'Quality of Life' as key-word in PUBMED



# What is Quality of Life?



## *Historical overview*

- 1920 First mentioning of QoL by AC Pigou in 'The Economics of Welfare'
- 1948 WHO Constitution: definition of health to include physical, emotional, and social well being
- 1966 Elkerton JR. Medicine and quality of life. Ann Intern Med
- 1976 Andrews & Withey. Social Indicators of Well Being: American Perspectives on Life Quality.
- 1977 Quality of Life becomes key word in MEDLINE

## *Some definitions of QoL*

= ‘the value assigned to opportunity, perception, functional status, impairment and death, associated with events or conditions as influenced by disease, injuries, treatments or policy’.

= ‘those attributes valued by patients, including their resultant comfort or sense of well-being; the extent to which they are able to maintain reasonable physical, emotional, and intellectual function; and the degree to which they retain their ability to participate in valued activities within the family, in the workplace, and in the community’.

= ‘individuals’ perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns’ (WHOQOL).

Patrick & Erickson.

*‘What constitutes quality of life? Concepts and dimensions’.*

Drug Ther Res 1988:

*‘Quality of Life represents the widest range of human experience’*



*-/- employment status, income, housing etc.*

Health-related quality of life (HRQL) =  
*an individual’s overall sense of well-being*  
*- physically, socially, and emotionally.*

## *HRQL is a multidimensional construct*

### *Primary Dimensions:*

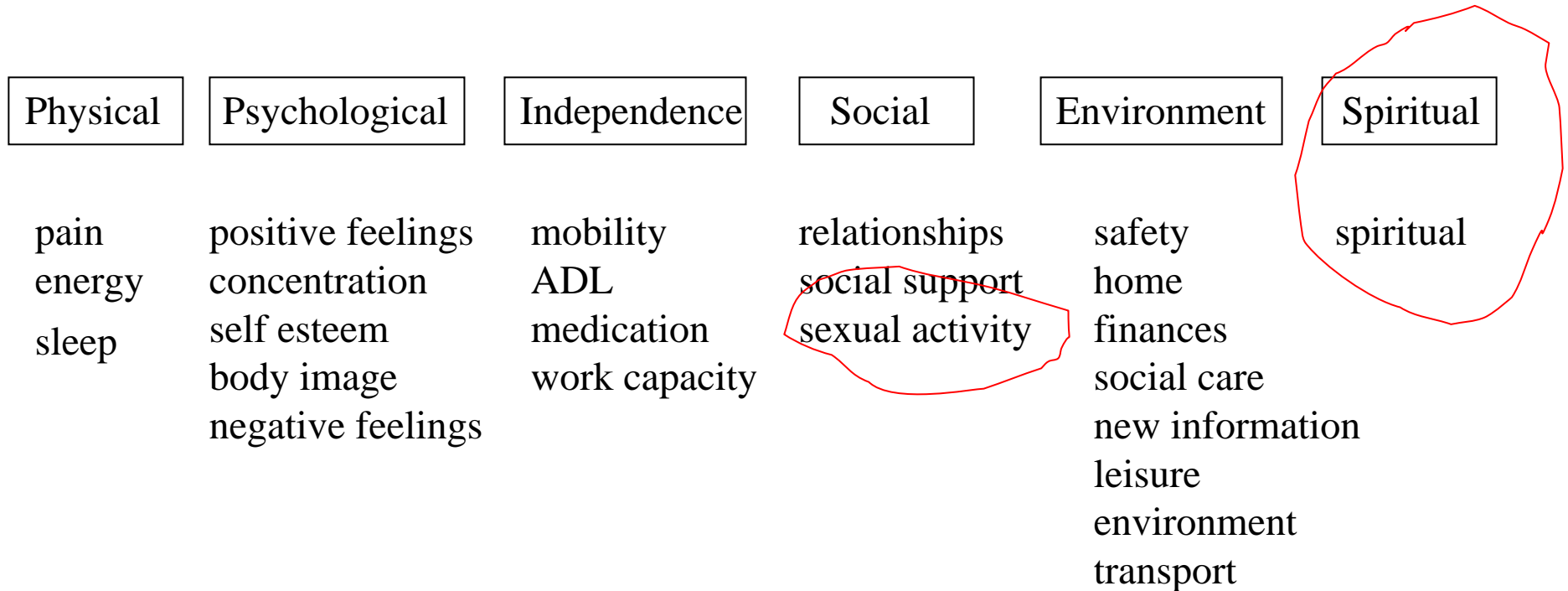
- Physical functioning (e.g. ADL)
- Social functioning
- Psychological functioning
- Overall life satisfaction/well-being
- Perceptions of health status

### *Additional Dimensions:*

- Neuropsychological functioning
- Personal productivity
- Intimacy and sexual functioning
- Sleep disturbance
- Pain
- Symptoms

# WHOQOL-100

6 domains, 24 facets



## *Why measure (HR)QoL?*

- in population surveys or as screening tools to identify the health needs of populations
- to compare ‘health gains’ in clinical trials
- as adjunct to traditional clinical or laboratory measures of disease impact
- to unveil unpredicted potential benefits or side effects
- to have some measure of a patient’s perspective

*Measuring HRQL: we're getting there...*

Generic measures: *indices versus profiles.*

- 1973 The Quality of Well Being Scale
- 1975 The Sickness Impact Profile
- 1976 McMaster Health Index Questionnaire
- 1980 Nottingham Health Profile
- 1981 Duke Health Profile, Quality of Life-Index
- 1990 EUROQoL
- 1992 36-Item Short Form Health Survey (SF-36)**
- 1994 WHOQOL-(BREF); Patient Generated Index

Disease-specific measures: e.g. RAQoL

*Methodological issues:*

Psychometric properties of HRQL instrument selected:

- reliability: internal consistency, test-retest
- validity: convergent, discriminant
- responsiveness to change (sensitivity)
- floor/ceiling effects

*General issues:*

Method of administration (self, telephone, face-to-face)

Timing of assessment

Cultural differences

Patient versus proxy respondent

Fewer items = loss of measurement precision

Uniqueness of quality of life to individual patients

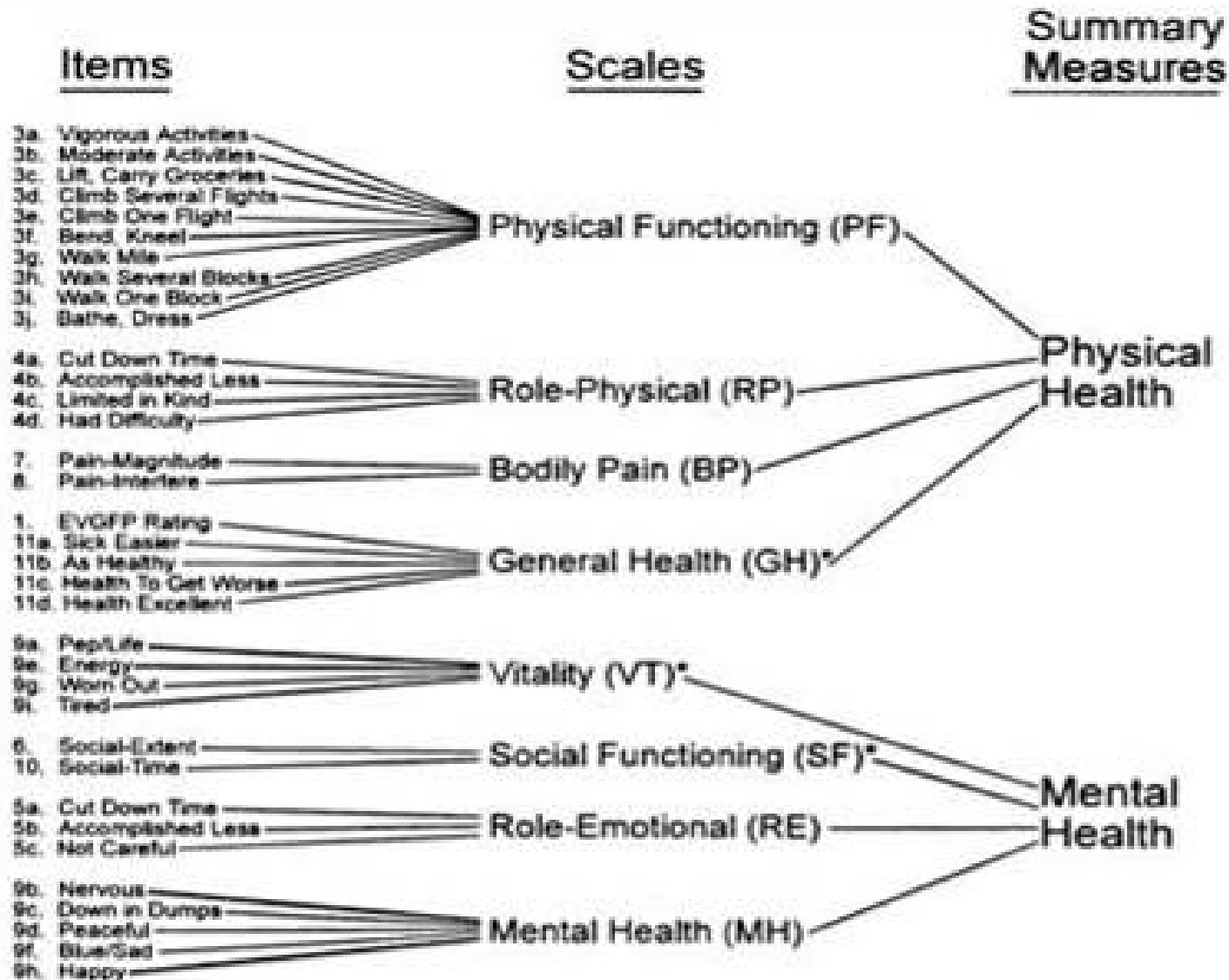
Missing data, multiple comparisons

The specific dimensions relevant for a clinical trial depend on:

1. intervention under investigation
2. disease or condition being studied
3. study population

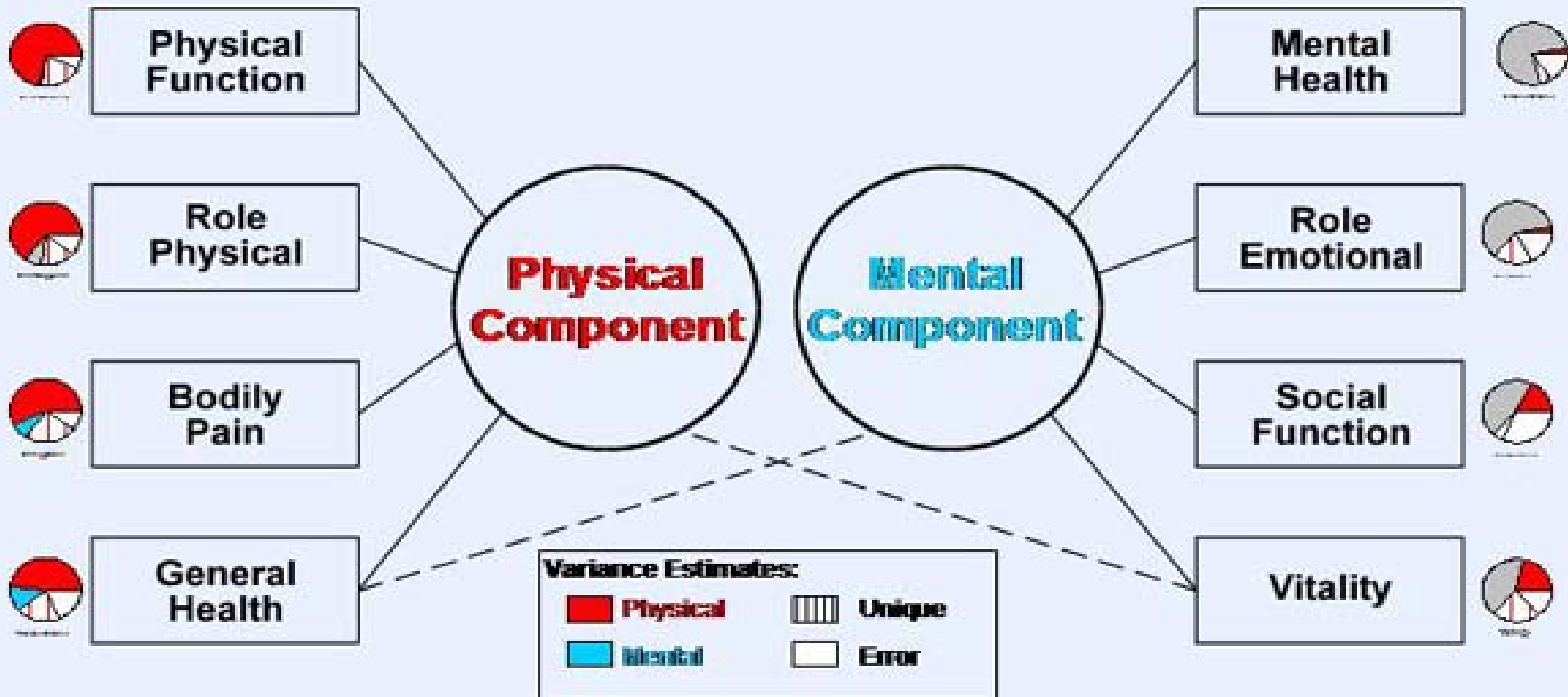
E.g. does the increase in 6-minute walking test or decrease of digital ulcers after Bosentan treatment in SSc translate into improved HRQL and if so, in which domains?

# SF-36<sup>®</sup> Measurement Model

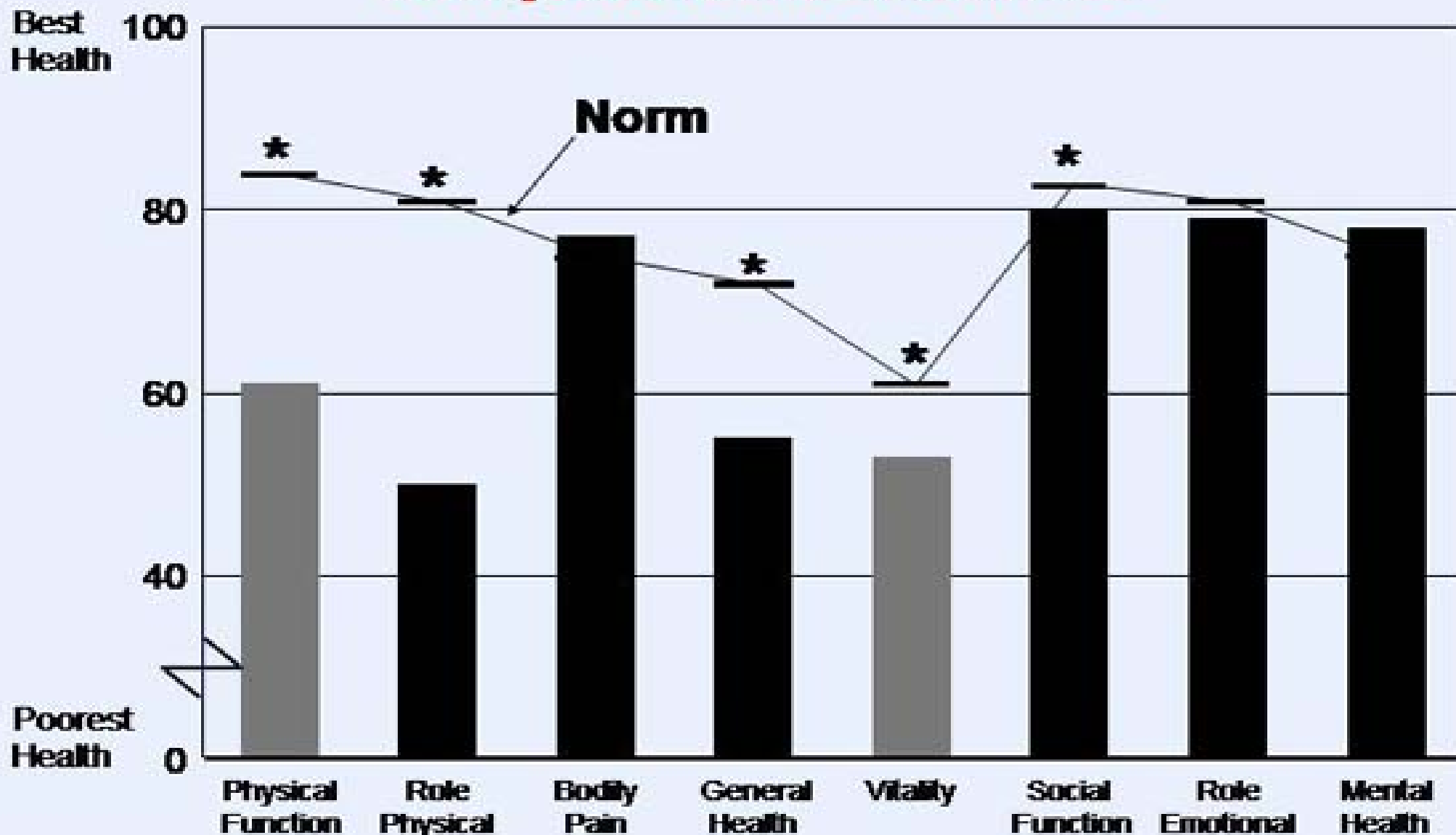


\* Significant correlation with other summary measure.

# SF-36<sup>®</sup> Scales Measure Physical and Mental Components of Health

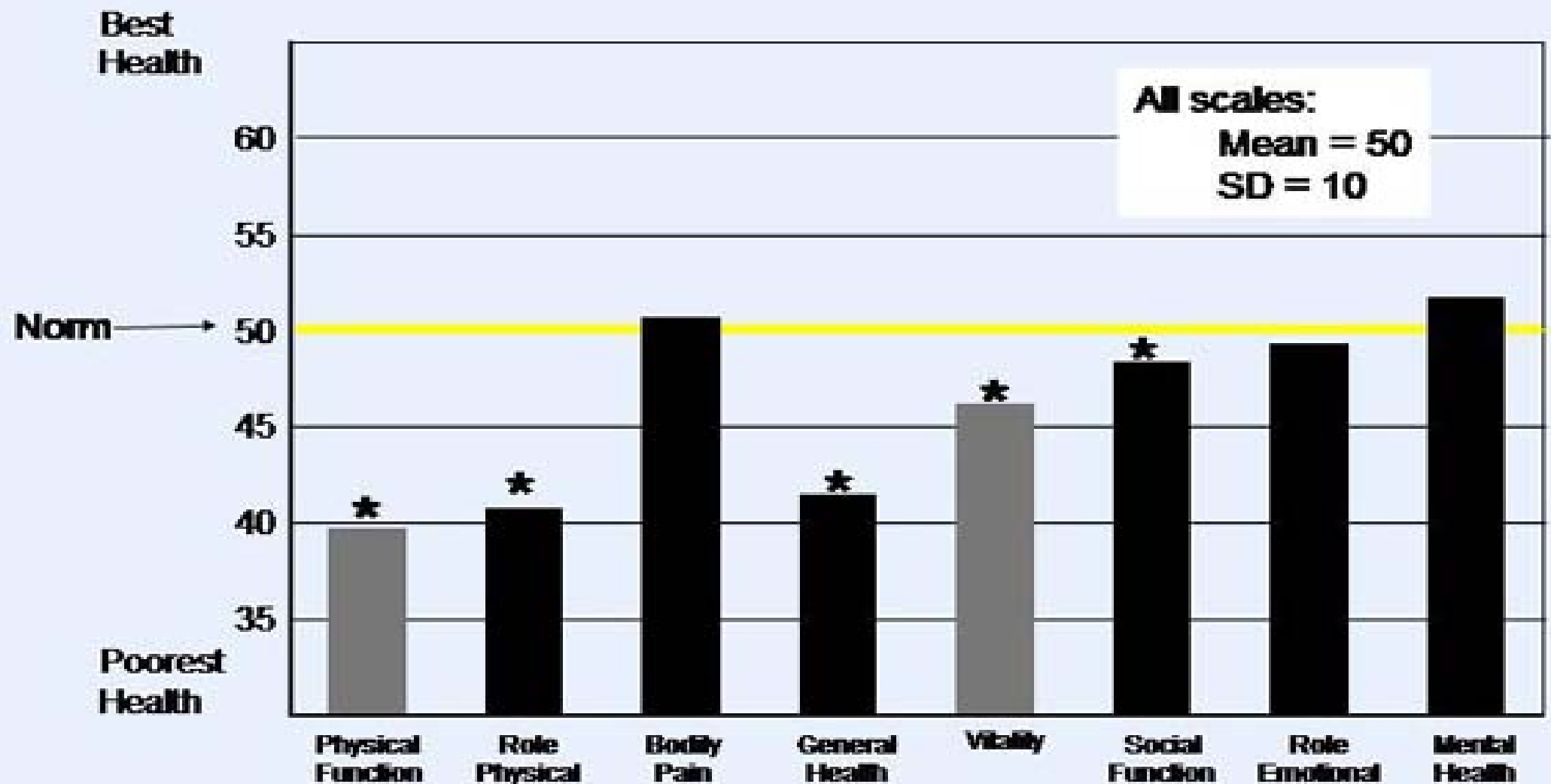


# SF-36<sup>®</sup> Health Profile: Adults with Asthma Compared with U.S. Norm



Source: Otamolo, 1996. \* Norm significantly higher

# Norm-based Scoring of SF-36<sup>®</sup> Profile, Adults with Asthma



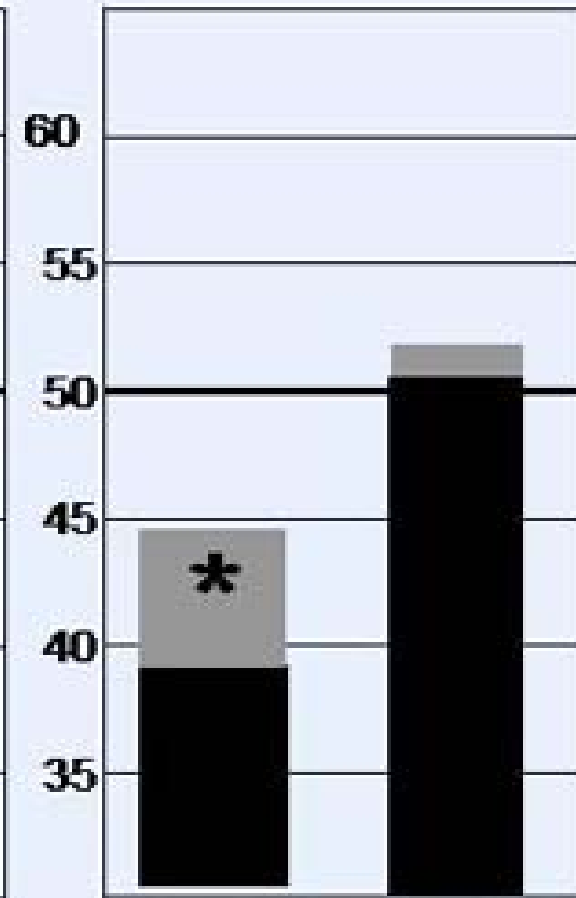
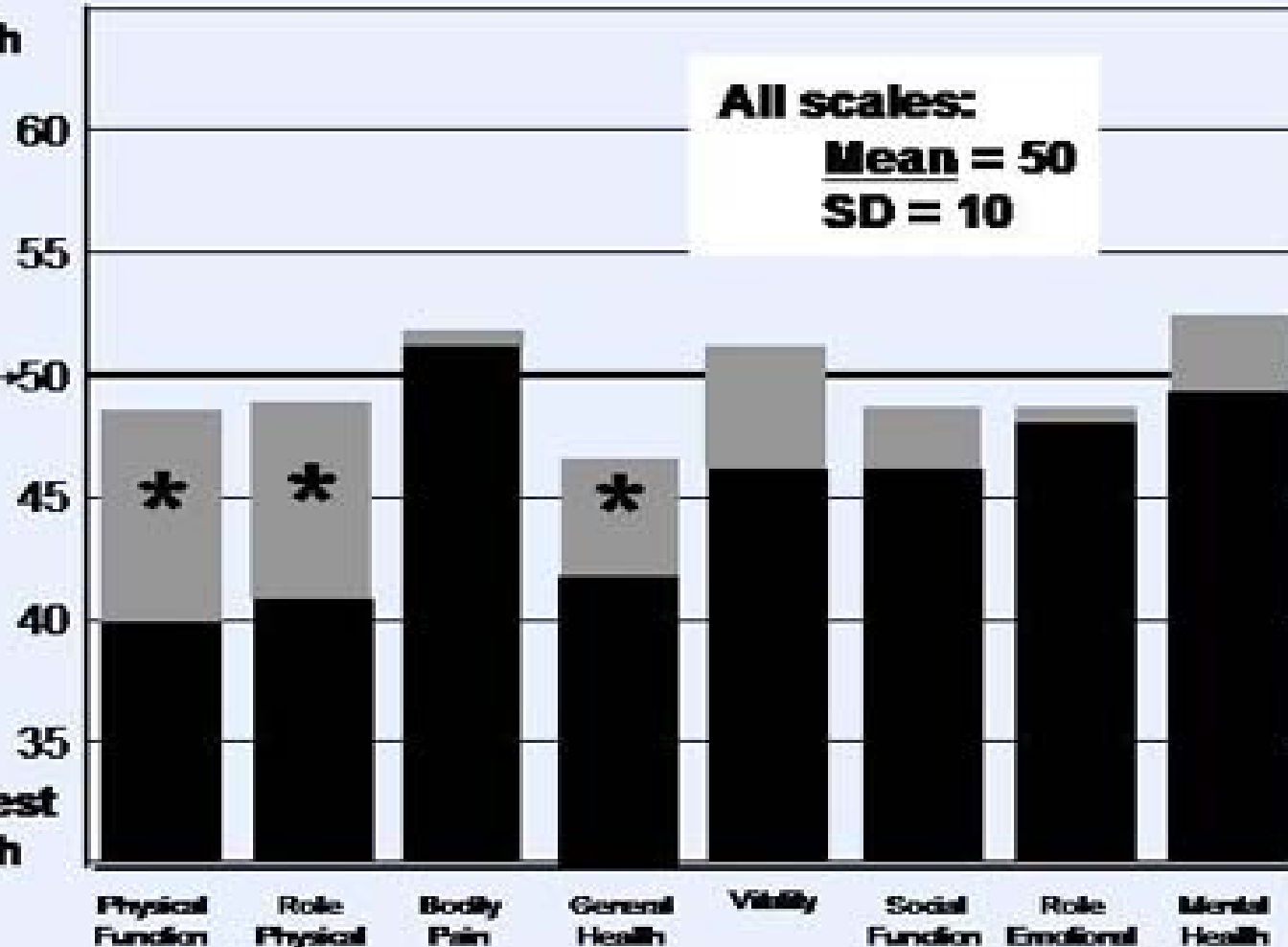
Adapted from: Okamoto, 1996

# Interpreting Treatment Outcomes Among Adults with Asthma

Best Health

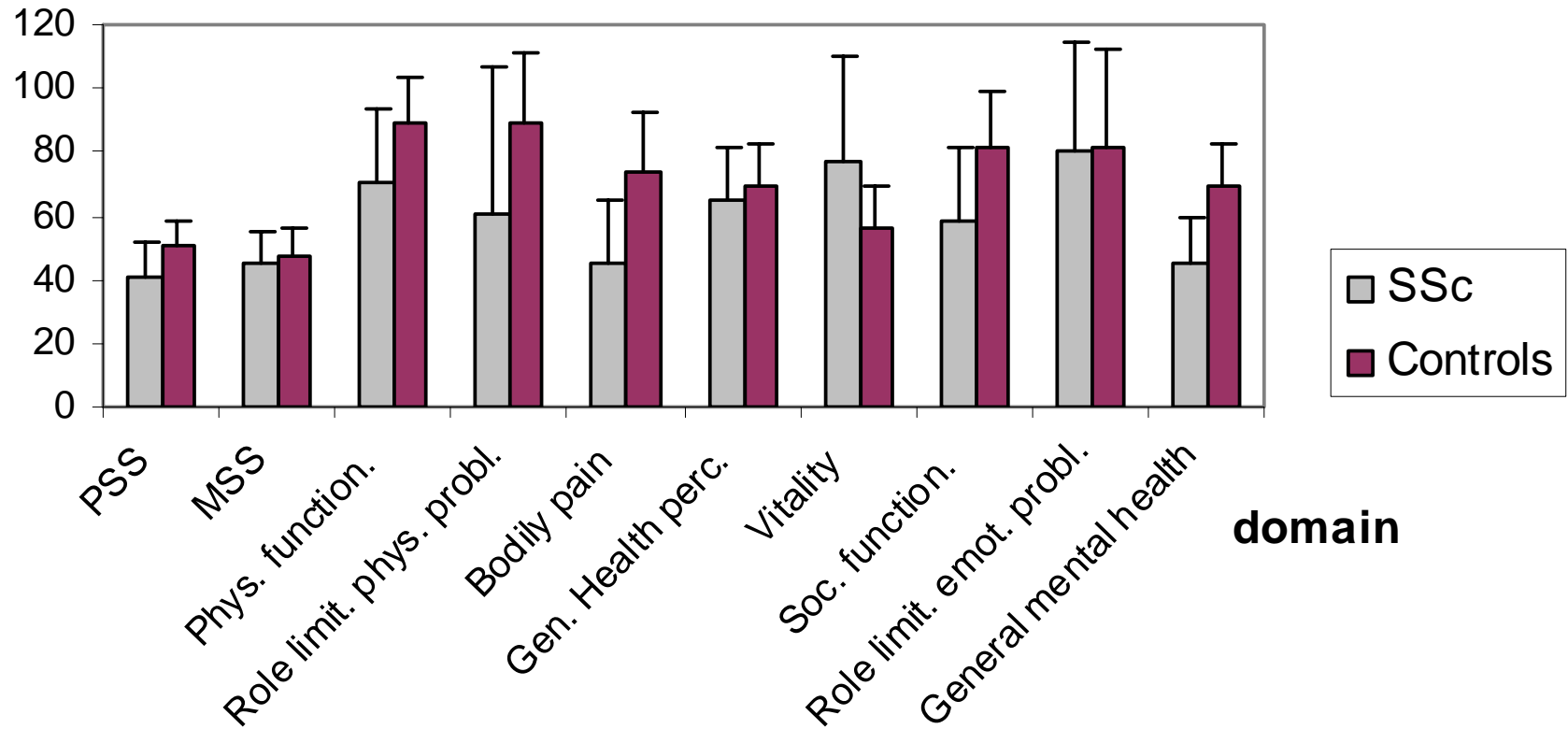
Norm

Poorest Health

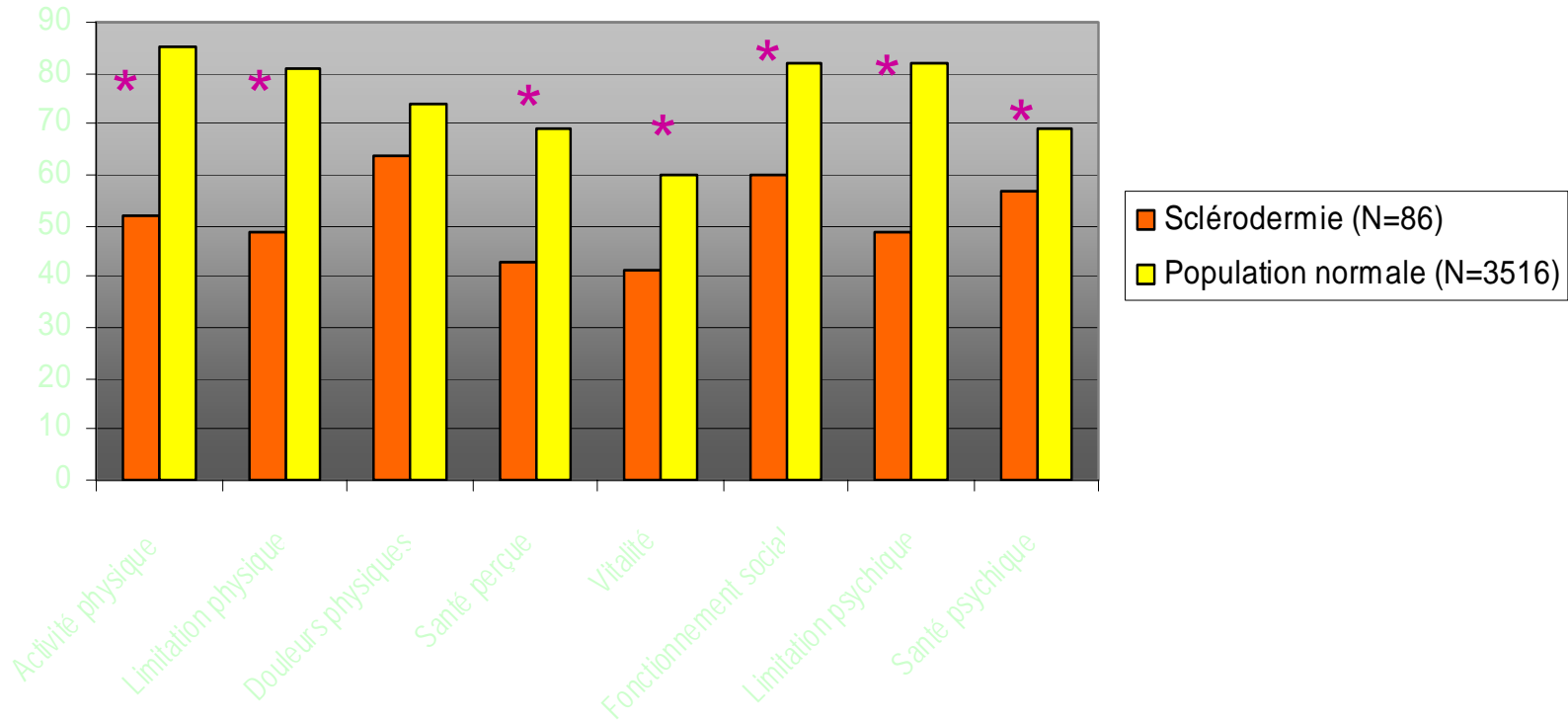


Physical Summaries  
Mental Summaries

## SF-36 in SSc patients



# SSc vs healthy controls (French study)

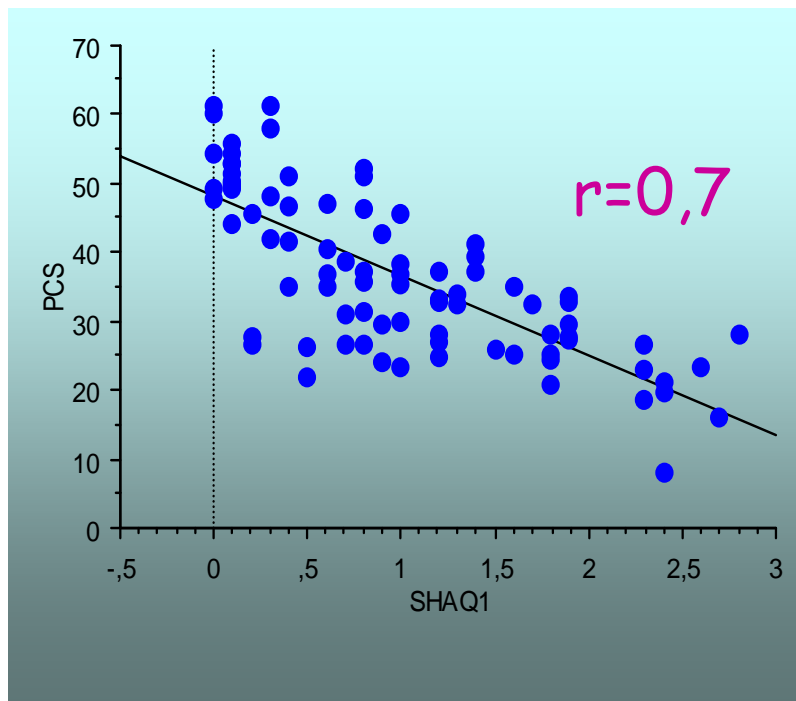


\*  $p < 0,01$

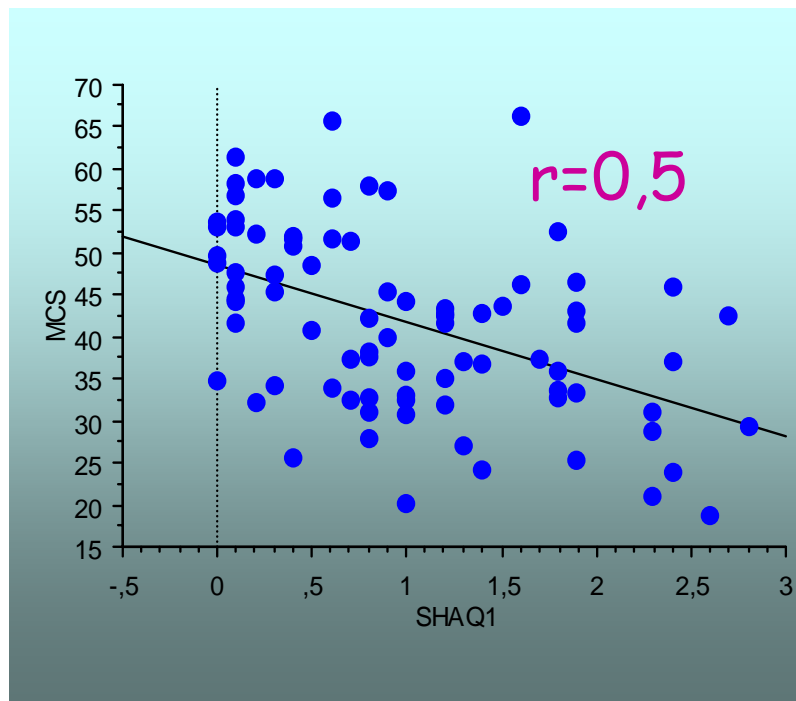
*(Leplege, J Clin Epidemiol 1998)*

# QoL and SHAQ

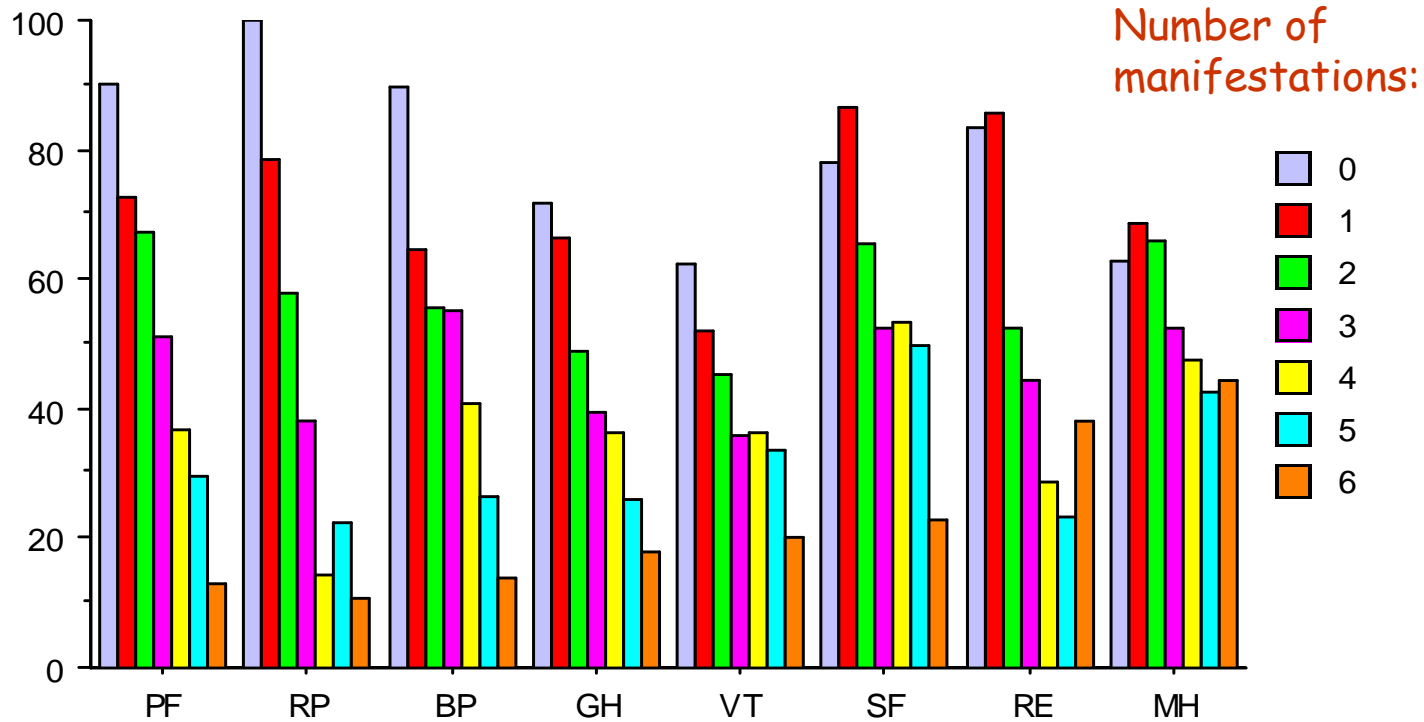
PSS



MSS



# QoL and degree of clinical involvement (Raynaud, ulcers, GI, lung, joint, contractions)



•Autologous•Stemcell•Transplantation•  
•International•Scleroderma•Trial•

patients with severe systemic sclerosis

***Immunoablation + SCT =***

1. Mobilisation (*CYC 2x2 g/m<sup>2</sup>, G-CSF 10 µg/kg*)
2. Leukapheresis/CD34-selection
3. Conditioning (*CYC 200 mg/kg, rabbit ATG 7.5 mg/kg*)
5. Reinfusion CD34+ cells

***Control treatment =***

**12x monthly  
i.v. pulse CYC 750 mg/m<sup>2</sup>**

**F-u 2 yrs - Mortality**

**- Heart, lung or kidney failure**

**- Skin thickness**

**- Disability, Quality of Life (SF-36)**

**Primary**

**endpoint**

*Q. Do the benefits of SCT outweigh the risks, in comparison with pulse-therapy cytoxan?*

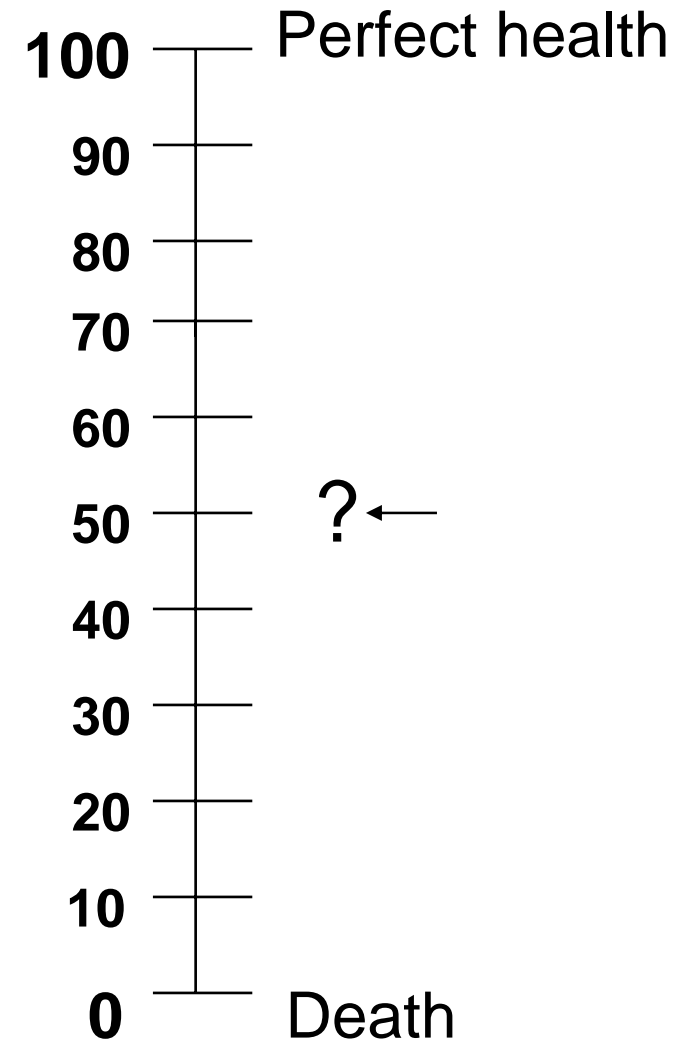
1. Assess SF-36 and compare profiles

2. Measure utility and determine QALY's = quality-adjusted life years, by multiplying number of years x utility.

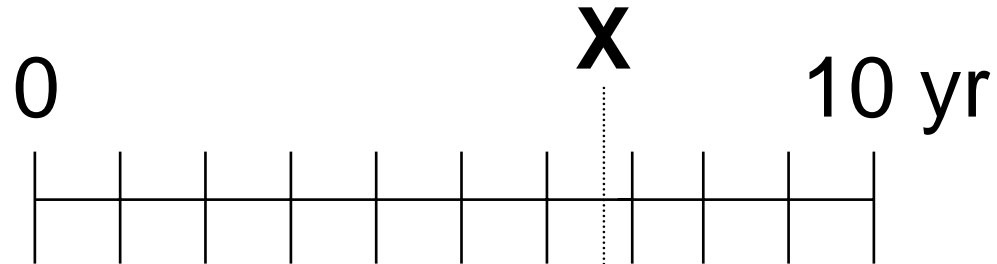
Utility is a unitary value of health state (0= death, 1 = perfect health).

*How do you get a utility from your patient?*

- *VAS*
- *Time Trade-off*
- *Standard Gamble*



# Time Tradeoff



Option A:

Severe impairment

Option B:

Perfect Health

$$\frac{X}{10} = \text{utility}$$

# Standard Gamble

Option A: 

severe impairment
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 Remaining years

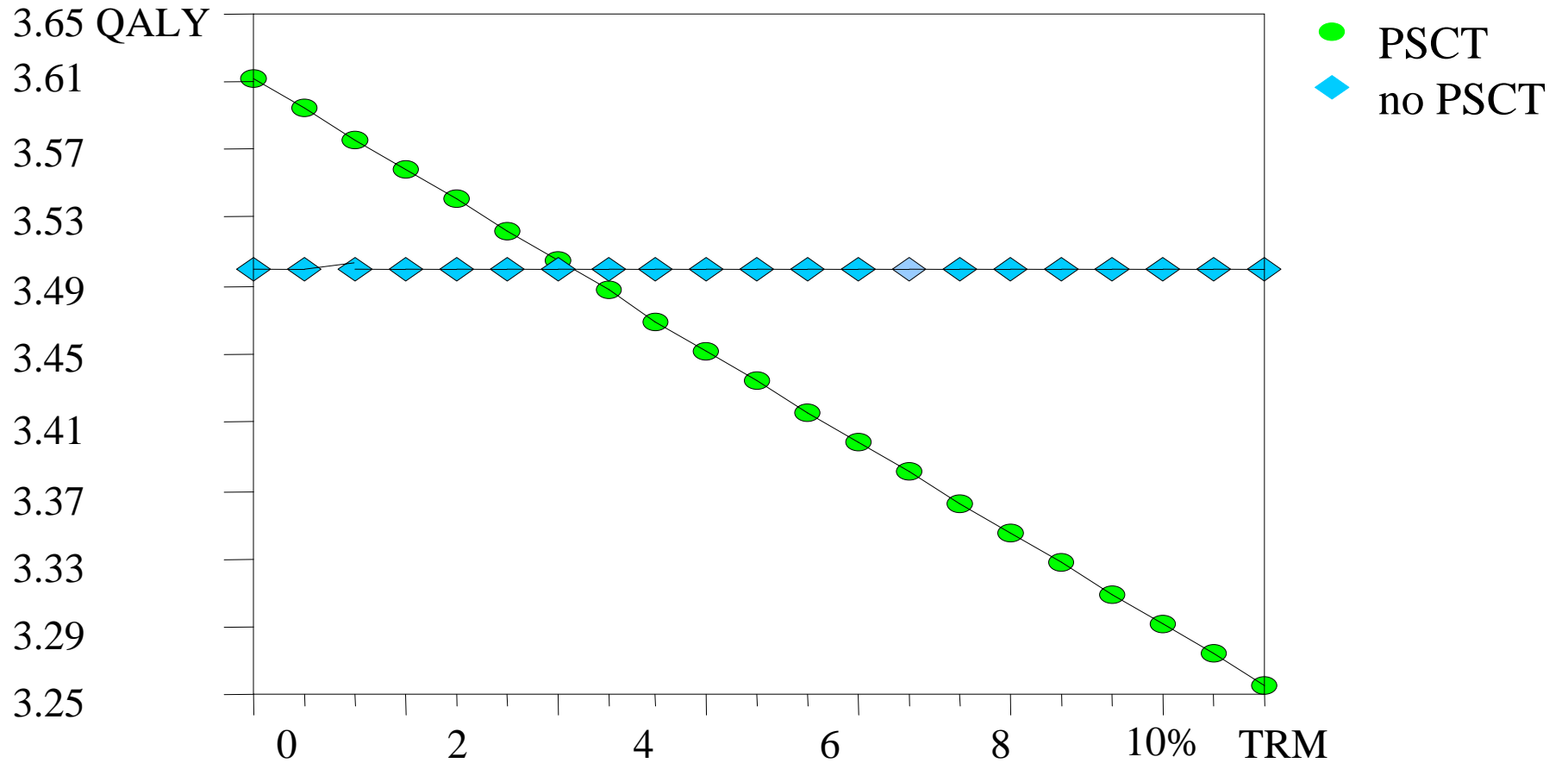
Option B: 

P
1-P

 Remaining  
years in perfect  
health  
Immediate  
death

utility:  $p$

# Influence of TRM on QALYs



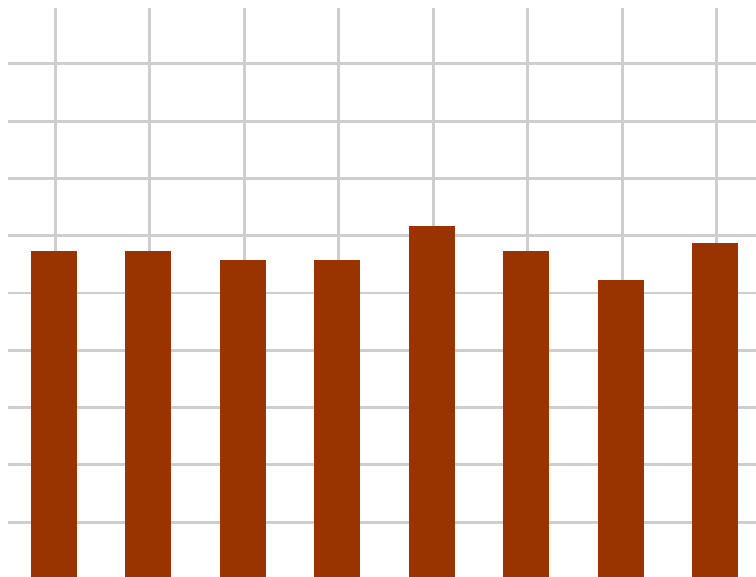
[www.who.int/evidence/assessment-instruments/qol/index.htm](http://www.who.int/evidence/assessment-instruments/qol/index.htm)

[www.sf36.org](http://www.sf36.org)

Quality of Life and Pharmacoeconomics in Clinical Trials, Spilker B (Ed.)

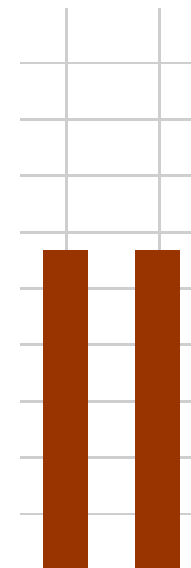
# SF-36v2™ Health Survey Scoring Demonstration: Jacob M. van Laar, January 12, 2005

*SF-36v2 Scale Scores*



PF	RP	BP	GH	VT	SF	RE	MH
57.0	56.9	55.4	55.3	61.5	56.8	52.0	58.5

*SF-36v2 Summary Scores*



PCS	MCS
56.4	56.4