Evaluating the Significance of Health-Related Quality of Life Change in Individual Patients

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UCLA GIM/HSR Research Seminar Series

Motivation

Interest in knowing how many patients benefit from group intervention

> Tracking progress on individual patients



UCLA Center for East-West Medicine

Staff training in biomedicine and traditional Chinese medicine.

Treat chronic pain conditions (e.g., neck and back pain, headaches, fibromyalgia, sports and occupational-related injuries), and cancer-related symptoms.

Provide comprehensive care, emphasizing health promotion, disease prevention, treatment and rehabilitation.

Patient education, medication adjustments, trigger point injections, acupuncture, acupressure, therapeutic massage, dietary and herbal counseling, and mind-body exercises.

Based on Submitted Paper

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Evaluating Health-Related Quality of Life Change in Individual Patients

Submitted to Evaluation and the Health Professions



54 patients

Average age = 56; 84% white; 58% female

Self-administered SF-36 version 2 at baseline and about at end of therapy (about 6 weeks later).

SF-36 Version 2

•	Physical functioning (10 items)
•	Role limitations/physical (4 items)
•	Pain (2 items)
•	General health perceptions (5 items)
•	Social functioning (2 items)
•	Energy/fatigue (4 items)
•	Role limitations/emotional (3 items)
•	Emotional well-being (5 items)

Scoring the SF-36

Average or sum all items in the same scale. Transform average or sum to 0 (worse) to 100 (best) possible range z-score (mean = 0, SD = 1) T-score (mean = 50, SD = 10) T-score = 50 + (z-score * 10) \checkmark

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Internal Consistency Reliability Formula

$$MS_{BMS} - MS_{EMS}$$



 MS_{BMS} = mean square between, MS_{EMS} = mean square for interaction between respondents and items.

SF-36 Reliability Estimates

<u>Scale</u>	<u>Alpha</u>
Physical functioning	0.94
Role limitationsphysical health problems	0.93
Pain	0.87
General health perceptions	0.83
Social functioning	0.85
Energy/fatigue	0. 77
Role limitationsemotional health problems	0.94
Emotional well-being	0.79

Physical Health



Mental Health



SF-36 Version 2 PCS and MCS

Formula for Reliability of Composite

$$Mosier = 1 - \frac{\Sigma(w_j^2)(S_j^2) - \Sigma(w_j^2)(S_j^2)(\alpha_j)}{\Sigma(w_j^2)(S_j^2) + 2\Sigma(w_j)(w_\kappa)(S_j)(S_\kappa)(r_{j\kappa})}$$

- w_j = weight given to component J
- \mathbf{w}_{κ} = weight given to component K
- **S**_j = standard deviation of J
- α_j = reliability of J
- $\mathbf{r}_{j\kappa}$ = correlation between J and K

Reliability of SF-36 Summary Scores

SF-36 PCS = 0.94

SF-36 MCS = 0.93

Analysis Plan

* Comparison on SF-36 physical functioning and emotional well-being scale scores with other samples

* Significance of:

- Within group change

- Within individual change

t-test for within group change



 X_{D} = is mean difference, SD_{d} = standard deviation of difference

Formulas for Significance of Individual Change

Standard error of measurement (SEM)	SD _b * (1- reliability) ^{1/2}
Standard error of prediction (SEp)	SD _b * (1- reliability ²) ^{1/2}
SEM CI around Time 1 score	Time 1 +- 2 SEM
SEp CI around Time 1 score	Time 1 +- 2 SEp



Estimated True Score for Score of 60

Mean + reliability (score – mean) 50 + 0.90 (60 - 50) = 59

Reliable Change Index

$X_2 - X_1 / SEM * SQRT (2)$

Formulas for Significance of Individual Change

SEM 95% CI	1.96 * SD _b * (1- reliability) ^{1/2}
<mark>SEp 90% СІ</mark>	1.64* SD _b * (1- reliability ²) ^{1/2}
SEp 95% CI	1.96* SD _b * (1- reliability ²) ^{1/2}
Estimated true score	Mean + reliability (score – mean)
Reliable change index	$X_2 - X_1 / \sqrt{2}SEM$.

 SD_{b} = standard deviation at baseline

Minimum Delta for Individual Significance

SEM: > 1.96 **SEM**

RCI: > 1.96 * SQRT (2) * SEM

SEp-90: > 1.64 SEp; SEp-95: > 1.96 SEp

Physical Functioning and Emotional Well-Being at Baseline for 54 Patients at UCLA-Center for East West Medicine



Hays et al. (2000), <u>American Journal of Medicine</u>

Change in SF-36 Scores Over Time



Significance of Group Change

	Delta	t-test	prob.
PF-10	1.7	2.38	.0208
RP-4	4.1	3.81	.0004
BP-2	3.6	2.59	.0125
GH-5	2.4	2.86	.0061
EN-4	5.1	4.33	.0001
SF-2	4.7	3.51	.0009
RE-3	1.5	0.96	.3400 <-
EWB-5	4.3	3.20	.0023
PCS	2.8	3.23	.0021
MCS	3.9	2.82	.0067

Amount of Change in Observed Score

	SEM	90% SEp	95% SEp	RCI	Effect size
PF-10	5.9	6.9	8.2	8.4	0.47-0.67
RP-4	6.0	6.9	8.3	8.4	0.52-0.72
BP-2	7.4	8.4	10.1	10.4	0.72-1.01
GH-5	9.2	10.4	12.5	13.0	0.80-1.13
EN-4	9.0	10.1	12.0	12.8	0.94-1.33
SF-2	9.8	11.1	13.3	13.8	0.76-1.07
RE-3	6.8	8.0	9.5	9.7	0.50-0.71
EWB-5	9.5	10.6	12.7	13.4	0.90-1.26
PCS	5.0	5.9	7.0	7.1	0.43-0.62
MCS	6.9	8.0	9.5	9.7	0.52-0.73

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Proportion of 54 Cases Declining Significantly

	SEM	SEp 90	SEp 95	RCI
PF-10	9%	7%	2%	2%
RP-4	7%	6%	2%	2%
BP-2	17%	11%	9%	7%
GH-5	4%	0%	0%	0%
EN-4	4%	4%	2%	2%
SF-2	13%	11%	6%	4%
RE-3	19%	19%	15%	15%
EWB-5	9%	6%	6%	4%
PCS	7%	7%	7%	7%
MCS	13%	11%	11%	11%

Proportion of 54 Cases Improving Significantly

	SEM	SEp 90	SEp 95	RCI
PF-10	19%	15%	13%	13%
RP-4	35%	31%	30%	31%
BP-2	31%	28%	24%	22%
GH-5	9%	7%	7%	7%
EN-4	24%	17%	11%	9%
SF-2	30%	20%	17%	17%
RE-3	24%	19%	15%	15%
EWB-5	26%	20%	19%	19%
PCS	33%	30%	24%	24%
MCS	37%	30%	22%	22%

% Improved – % Declined

	SEM	SEp 90	SEp 95	RCI
PF-10	10%	8%	11%	11%
RP-4	28%	25%	28%	29%
BP-2	14%	17%	15%	15%
GH-5	5%	7%	7%	7%
EN-4	11%	13%	9%	7%
SF-2	11%	9%	11%	13%
RE-3	5%	0%	0%	0%
EWB-5	19%	14%	13%	15%
PCS	26%	23%	17%	17%
MCS	24%	19%	11%	11%



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