Evaluation of Applicability of well-established Measurement Instruments in Interdisciplinary Multimodal Pain Therapy

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Introduction

Interdisciplinary multimodal pain therapy (IMPT) is gaining increasing scientific attention in the treatment of chronic non-malignant pain. The heterogeneity of outcome measurement is present in recorded outcome domains on the one hand and the psychometric quality of measurement instruments on the other hand. This results in moderate evidence for systematic reviews and meta analysis evaluating the effectivity of IMPT.

For harmonizing outcome measurement in IMPT the VAPAIN initiative recommended a *Core Outcome Set* (COS) *of domains.* To complete the COS a related measurement instrument for each domain should be investigated for applicability and psychometric properties such as content validity, reliability and responsiveness.

Methods

The examination was conducted with secondary data (*n=282*) of instruments being used for routine record keeping at the Comprehensive Pain Center in Dresden, Germany from 2010 to 2012 (*Center for Epidemiological Studies Depression Scale*, *Chronic Pain Acceptance Questionnaire*, *Chronic Pain Grade Questionnaire*, *Coping Strategies Questionnaire*, *Fear Avoidance-Beliefs Questionnaire*, *SF-36*, *Numerical Rating Scale*, *Pain Catastrophizing Scale* und *Pain Disability Index*).

First, all instruments were investigated with regards to significance of change between start of intervention (*T1*) and the booster week (*T3*) which was after ten weeks of break following an intervention time of 4 weeks. Effect sizes were used to indicate clinically relevant changes ($\omega \geq 0.3$). For instruments showing both a correlation analysis to detect the relationship between change on instruments and subjectively experienced therapy success on a *Global Rating Scale* (*GRS*) was performed. Instruments with a correlation greater than $r_{Spearman} \geq 0.5$ were included in a regression analysis to detect the impact on the GRS (s. Figure 1).

Sample Description

Total Sample (n=282)			
Age (years)		**Duration of Pain**	
Mean (SD)	50,78 (±12)	1 to 6 months	0.0%
min-max	19-77	6 to 12 months	0.0%
Sex		1 to 2 years	10.3%
male	103	2 to 5 years	24.8%
female	179	more than 5 years	62.4%
State of Chronification (MPSS)		more than 5 years	1.4%
MPSS I	10.6%	**Occupational State**	
MPSS II	40.8%	yes	46.8%
MPSS III	35.8%	no	51.8%
no data available	12.8%	no data available	1.4%
Diagnosis		**Incapacity to Work**	
back pain	59.6%	yes	36.2%
headache	17.7%	no	9.6%
other	19.1%	no data available	54.3%

Results

75% of the tested instruments showed a significant difference between *T1* and *T3*. One third of these changes were clinically relevant due to the effect size ($\omega \geq 0.3$). None of the investigated instruments fulfilled the conditions required for a regression analysis so data analysis was terminated (s. Figure 1, detailed in Table 1).

Two (sub)scales (*NRS, SF-36*$_{BodilyPain}$) presented a significant and clinically relevant difference in change between populations with positive and negative experienced therapy success.

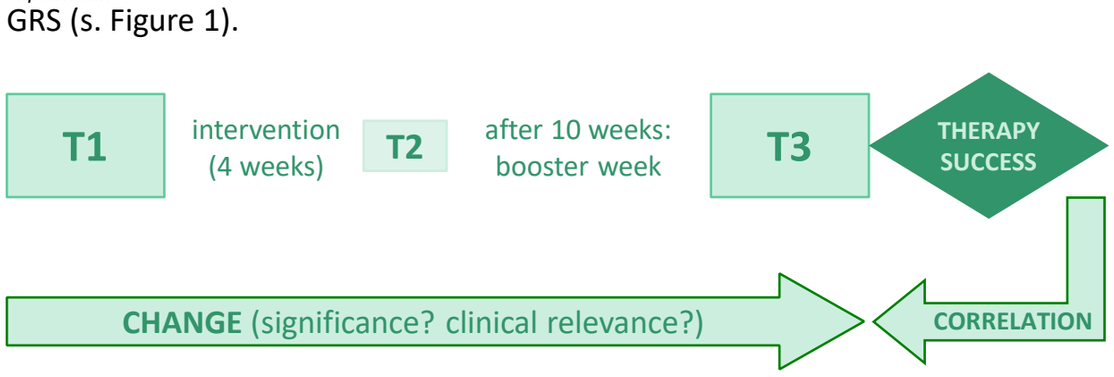

Figure 1: Study Design and Statistics

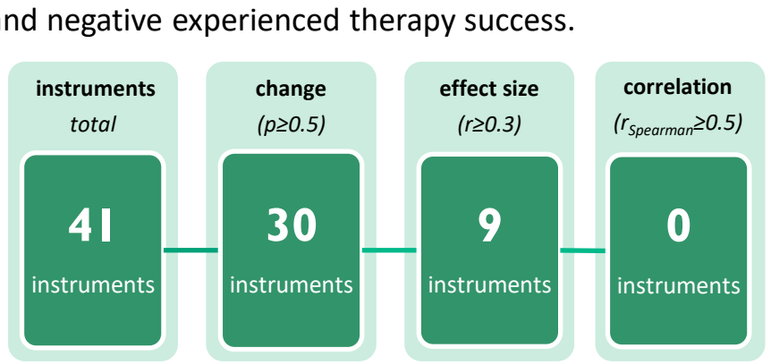

Figure 2: Results: Number of Instruments, fulfilling the Requirements for each Test

Table 1: Significance and Effect Size ω of mean differences (*T3-T1*) and Spearman Correlation with GRS at *T3*

	CES-D	CPAQ			CPGQ				CSQ								FABQ		
	Total	Activity Engagement	Pain Willingness	Total	Characteristic Pain Intensity	Disability Score	Disability Days	Disability Points	Diverting Attention	Reinterpreting Pain Sensations	Coping Self-Statements	Ignoring Pain	Praying or Hoping	Catastrophizing	Increasing Activity Level	Increasing Pain Behaviors	Pain	Prognosis	Fear-Avoidance
p value MD (*T3-T1*)	p=0.003	p=0.015	p=0.001	p=0.408	p<0.001	p=0.002	p=0.195	p=0.016	p=0.038	p<0.001	p=0.001	p=0.506	p<0.001	p<0.001	p=0.636	p=0.094	p=0.069	p=0.132	p=0.839
Effect Size ω MD (*T3-T1*)	0.17	0.14	0.19	0.05	0.23	0.19	0.08	0.14	0.12	0.21	0.19	0.04	0.32[a]	0.22	0.03	0.1	0.11	0.09	0.01
$r_{Spearman}$ with GRS (*T3*)	-	-	-	-	-	-	-	-	-	-	-	-	0.01	-	-	-	-	-	-

	SF-36											NRS					NRS	PCS				PDI
	Physical Function	Physical Role Function	Bodily Pain	General Health	Energy/ Fatigue	Social Role Functioning	Emotional Role Functioning	Emotional well-being	Health Change	Body Summary	Psychological Summary	Average Pain Intensity	Maximal Pain Intensity	Minimal Pain Intensity	Tolerable Pain Intensity	Pain Intensity in the last 4 Weeks	Disability in the last 4 Weeks	Helplessness	Ruminatio n	Magnificatio n	Total	
p value MD (*T3-T1*)	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p<0.001	p=0.286	p=0.007	p<0.001	p<0.001	p=0.056	p=0.004	p<0.001	p=0.496	p=0.022	p<0.001	p<0.001	p<0.001	p<0.001	p=0.001	p<0.001	p<0.001
Effect Size ω MD (*T3-T1*)	0.22	0.30[a]	0.33[a]	0.24	0.33[a]	0.26	0.06	0.16	0.35[a]	0.31[a]	0.11	0.17	0.22	0.04	0.14	0.27	0.29[(a)]	0.33[a]	0.38[a]	0.21	0.39[a]	0.24
$r_{Spearman}$ with GRS (*T3*)	-	-0.15	0.27	-	-0.18	-	-	-	0.26	0.23	-	-	-	-	-	-	0.24	0.13	0.08	-	0.12	-

- Not applied; adjusted α-risk according to Bonferroni-Holm-Correction: α=0.0167, α=0.025; α=0.05, all values p≤0.05 significant; [a] mid-level effect size according to Cohen (ω≥0.3);
CES-D Center for Epidemiological Studies Depression Scale; CPAQ Chronic Pain Acceptance Questionnaire; CPGQ Chronic Pain Grade Questionnaire; CSQ Coping Strategies Questionnaire; FABQ Fear-Avoidance Beliefs Questionnaire; GRS Global Rating Scale; MD Mean Difference; NRS Numerical Rating Scale; PCS Pain Catastrophizing Scale; PDI Pain Disability Index

Discussion & Conclusion

The highly heterogenous results of the present data are insufficient for evaluating the responsiveness of investigated instruments. Potential causes can be identified on different levels:

- The domain is stable and a change could not be measured.
- The collected data is inadequate for investigating responsiveness. The COSMIN initiative suggested a construct specific item for the examination of responsiveness, but a global item (*GRS*) was used in the present study.
- The outcome domains recommended by VAPAIN for usage in a COS could not be completely represented by the instruments of this study. Potential relevant contributing factors for subjective therapy success might not have been collected.
- The psychometric quality of the instruments is insufficient regarding responsiveness, content validity or reliability. There are no recent studies testing those properties on patients of an IMPT.
- The methodical idea of OMERACT failed because patients of an IMPT might have more specific demands than those represented in existing instruments.

First, existing barriers for evaluation should be corrected in future studies (collecting construct specific data, investigation of content validity, clinical relevance for patients). Then a further investigation of responsiveness following the COSMIN recommendations can be conducted. If failing the development of new instruments should be considered.

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