Research article

Quality of life outcomes evaluation after motor rehabilitation of the lower limbs using a stationary bicycle

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Abstract: Present study aims for the QoL assessment after performing a physiotherapeutic program for lower limbs rehabilitation using a stationary bicycle. Subjects are outpatients, n=7, mean age 51.86 ± 11.82, BMI (kg/m2) mean of 29.37±6.43. Before the beginning of the rehabilitation program (T0) was the first evaluation with RAND SF-36 version 1 and after eight weeks of physical therapy the second one (T2). QoL measurements assessment implies eight criteria. **Appropriateness** - the main objective of gait facilitation was fulfilled for all seven patients. **Acceptability**- response rates T0/T2 = 100%. **Feasibility** - SF-36 OrthoToolKit is licensed (Optum) and available freely online, with a completion time of 6 min in the kit tool. **Validity** was proved by specialty literature. **Reliability** Intraclass correlation coefficient - ICC (Cronbach's Alpha overall test-retest, patient/physical therapist T0/T2 =0.995/1.000) **Pearson correlation** coefficient between items - strong statistical significance (p<.05). **Responsiveness** The T-test for paired samples, Wilcoxon, Sign Test resulted significant (p<.05) for each subsequent scale. Effect size (Partial Eta Squared) based on z-score η2 = .432 physical components and .534 mental components – large effect. **Precision**- based on Likert response. **Interpretability** - Romanian version was used. QoL outcomes measuring eight criteria proved a positive impact of the intervention on patients.

Keywords: rehabilitation; quality of life (QoL); RAND SF-36 version 1; physical components, mental com-ponents; lower limbs; stationary bicycle.

1. Introduction

The concept of quality (QoL) of life refers to the overall well-being and satisfaction that a person experiences in their life. It can be evaluated by various factors, including physical health, emotional well-being, social relationships, financial stability, education, and access to leisure and recreational activities. Quality of life is subjective and can vary from person to person. It is also influenced by cultural and societal factors, as well as an individual's values and goals.

QoL is a multifaceted concept according to WHO's the definition of health "a state of complete physical and mental social well-being, and not merely the absence of disease and infirmity'" (WHO, 1948). Quality of life was accepted by Index Medicus in 1977. Short form 36 questionnaire measures health-related outcomes and emphasizes the impact of medical interventions being a generic instrument [1]. It is a self-reported tool, fulfilled by the subject of the intervention or may be completed by a family member or health professional, that uses numerical scoring systems.

This particular approach evaluates the physical and mental dimensions before and after eight weeks of therapeutic interventions on the same sample of seven patients. The eight items of instrumental applicability of the SF -36 tool as appropriateness, acceptability, feasibility, validity, reliability, responsiveness, precision, and interpretability are assessed accordingly to clinimetric and psychometric principles.

2. Materials and Methods

Participants

The present study comprises seven subjects - outpatients presented with a physiotherapy indication for gait rehabilitation from the specialist physician from whom informed consent was obtained. The research was carried out at the patient's homes following the medical credentials of the practice cabinet for physiotherapy. Exclusion criteria: any acute, infectious status or any life-threatening situation, exacerbation conditions, and decompensated diseases. The research group consists of seven subjects out of which three men and four women, mean age of 51.86 ± 11.82, BMI mean of 29.34 ± 6.43 (overweight). The physiotherapy program was applied for eight weeks for each patient from April 2022 until November 2022.

Measures

The Short Form 36 questionnaire (SF-36) is a generic instrument for measuring health status, developed and tested by the New England Medical Center within the Medical Outcomes Study [2]. Development of the Romanian version was carried out under the internationally applied instructions, with the recommendations and under the control of the New England Medical Center [3]. The SF-36 has the most evidence of responsiveness, being the most widely evaluated measure [4,5]. The SF-36, as described in the name, is a 36-item patient-reported questionnaire covering eight health domains: physical functioning PF (10 items), bodily pain BP (2 items), role limitations due to physical health problems RP (4 items).), role limitations due to personal or emotional problems RE (4 items), emotional well-being MH(5 items), social functioning SF (2 items), energy/fatigue VT (4 items), and general health perceptions GH (5 items). Scores for each domain range from 0 to 100, with a higher score defining a more favorable state of health. RAND SF-36 version 1 was used to quantify the results in SF-36 OrthoToolKit which contain one supplementary dimension - Health Change HC (1 item). RAND 36-Item Health Survey 1.0 score use precoded numerical values followed by averaged items to obtain the nine domains of interest [6–9].

Procedure

The patients were introduced into the rehabilitation program immediately after discharge at home. At T0 before beginning the rehabilitation program was the first evaluation with SF-36 OrthoToolKit and after eight weeks of physical therapy considered as T2 period.

The rehabilitation program lasted 8 weeks with a frequency of 3 times a week, in a total of 24 sessions (50 min/session) out of which static horizontal pedaling for 27, 31, or 35 minutes accordingly to risk association and the rest of time individual-specific exercises according to each pathology with progressive increasing at every four sessions [10]. The innovative system of the horizontal bike was stabilized for bed use and pressure sensors were attached to the pedals to monitor kinetic chain parameters [11].

Statistical analyses

All statistical analyses were performed using SPSS version 25, Microsoft Excel for data collection, SF-36 OrthoToolKit for averaged items of the nine domains of interest (physical functioning PF, bodily pain BP, role limitations due to physical health problems RP, role limitations due to personal or emotional problems RE, emotional well-being MH, social functioning SF, energy/fatigue VT, general health perceptions GH, Health Change HC) physical and mental components summarized. Analysis with paired samples t-test, sign, and Wilcoxon test, ICC, and Pearson was used to assess the impact of QOL by SF-36 before and after therapeutic programs were applied.

3. Results

3.1. General characteristics related to the sample of seven patients recorded a mean age of 51.86±11.82 years, a median of 52 years and for BMI (kg/m2) - a mean of 29.34±6.43 and a median of 27.80 as **Table** 1 figures.

Table 1. General characteristics of the studied sample

Descriptive Statistics - **General characteristics**					
		Age (y)	**Weight (Kg)**	**Height (m)**	**BMI (Kg/m²)**
N	Valid	**7**	**7**	**7**	**7**
	Missing	0.00	0.00	0.00	0.00
Mean		**51.86**	**82.84**	**1.69**	**29.34**
Median		**52.00**	**88.00**	**1.64**	**27.80**
Std. Deviation		**11.82**	**15.43**	**0.09**	**6.43**
Minimum		39.00	59.00	1.58	22.03
Maximum		73.00	106.30	1.80	39.50
Percentiles	25	42.00	73.00	1.60	23.81
	50	**52.00**	**88.00**	**1.64**	**27.80**
	75	60.00	91.40	1.78	36.61

BMI = Body Mass Index

According to gender, the sample includes four women (57.14%) and three men (42.86%) **Figure** 1 shows.
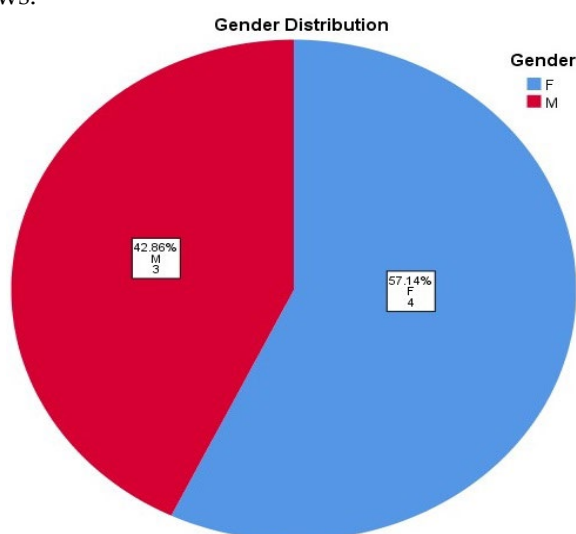
Figure 1. Gender Distribution

Four age groups 30-39 years (1 subject – 14.29%), 40-49 years (2 subjects – 28.57%), 50-69 years (3 subjects – 42.86%), and>70 years (1 subject – 14.29%), were established according to the variability of muscle mass with aging decreasing with age. (**Figure 2**)

Figure 2. Age Groups Distribution

BMI results regitered: 28.57% of the subjects have a normal weight (one subject range 30-39 years and one subject 40-49 years), 42.86% are overweight (one subject belonging to the 40-49 years group, one subject belonging to the 50-69 years group and one subject>70 years) and 28.57% obese (two subjects belonging to the 50-69 years group). (**Figure 3**)

Figure 3. BMI Results Distribution by Age

3.2. Outputs

3.2.1. SF-36 OrthoToolKit Results at T0 (before beginning the rehabilitation program) and T2 (after eight weeks of physiotherapy)
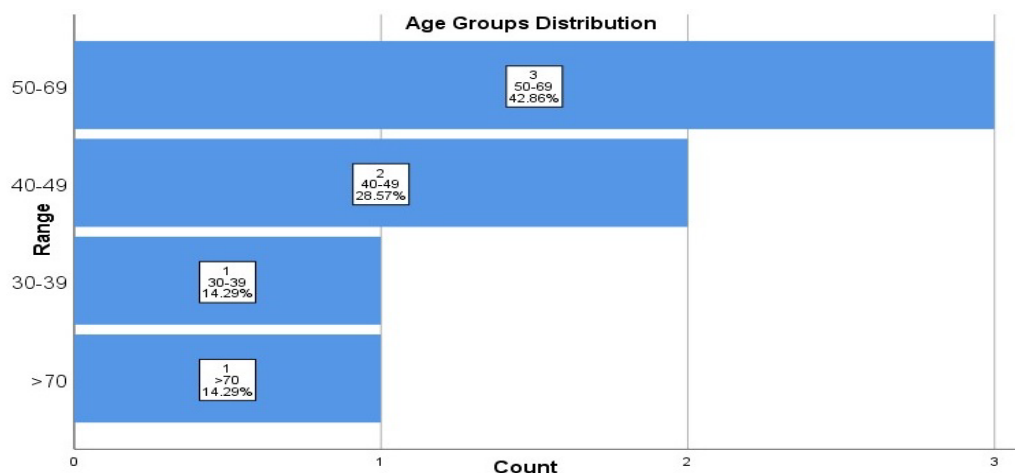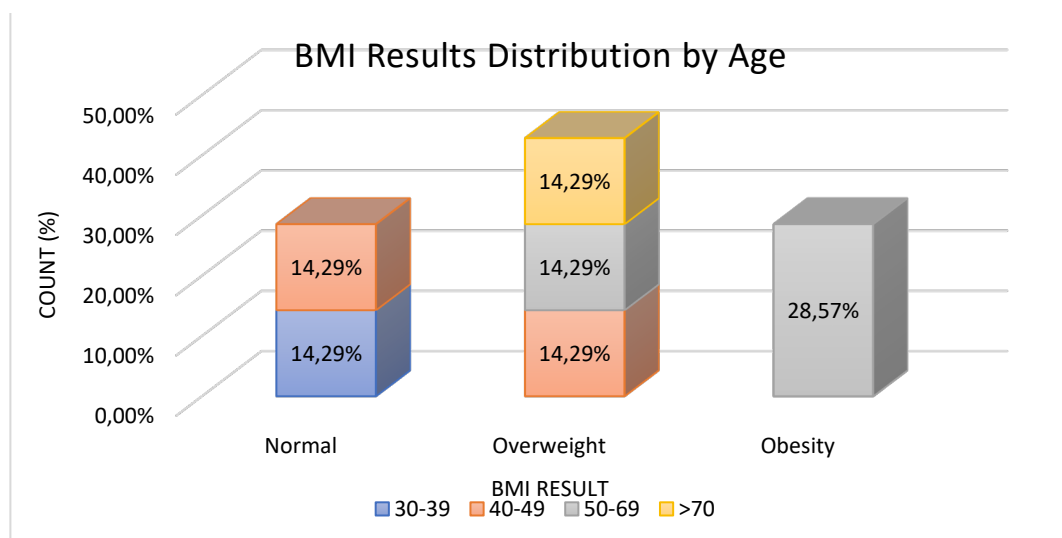
At T0, before beginning the rehabilitation program the first evaluation with SF-36 OrthoToolKit using RAND SF-36 version 1 [6–9] for seven patients included in this research, followed by another evaluation at T2 after 8 weeks of rehabilitation. (results presented in Table 2 and Table 3 after three steps accomplished). Scores for each domain range from 0 to 100, with a higher score defining a more favorable state of health. Step 1 and Step 2 are according to SF-36 Scoring Instruction. Step 3 represents personal contribution.

Step 1 The 36 items record values related to the last four weeks for 3-32 items and for the rest of items 1 and 2 at the moment of completing the questionnaire, as follows:

-items number 1, 2, 20, 22, 34, 36 with five categories range 100-0, degree of measure 25;

-items number 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12 with three categories range 0-100, degree of measure 50;

-items number 13, 14, 15, 16, 14, 18, 19 with two categories, degree of measure 0-100;

-items number 21, 23, 26, 27, and 30 with six categories range 100-0, degree of measure 20;

-items number 24, 25, 28, 29, and 31 with six categories range 0-100, degree of measure 20;

-items number 32, 33, and 35 with five categories range 0-100, degree of measure 25.

Step 2 Items from step 1 are averaged to form scales:

-PF - physical functioning, number of items 10 after recording an average of 3, 4, 5, 6, 7, 8, 8, 9, 10, 11, 12 items;

-RP - role limitations due to physical health problems, number of items 4 after recording the average of 13, 14, 15, 16 items;

-RE - role limitations due to personal or emotional problems, number of items 3 after recording the average of 17, 18, 19 items;

-VT - energy/fatigue (vitality), number of items 4 after recording the average of 23, 27, 29, 31 items;

-MH - emotional well-being (mental health), number of items 5 after recording the average of 24, 25, 26, 28, 30 items;

-SF - social functioning, number of items 2 after recording the average of 20, 32 items;

-BP – pain (body pain), number of items 2 after recording the average of 21, 22 items;

-GH - general health, number of items 5 after recording the average of 1, 33, 34, 35, 36 items;

-HC - health change, 1 item – number 2.

Step 3

RAND SF-36 version 1 is a generic tool so its components target the physical and mental status.

Physical components summarized (PCS) comprises the average of physical functioning (PF), role limitations due to physical health problems (RP), body pain (BP), and general health (GH) perception scores.

Mental components summarized (MCS) comprises the average of role limitations due to personal or emotional problems (RE), energy/fatigue as vitality, emotional well-being as mental health, and social functioning scores.

PCS and MCS calculated as average before and after eight weeks of rehabilitation therapy were compared with a Romanian study of QoL comprising n=928 patients with different medical interventions - SF-36v2-RO [12] to enhance the differences of this particular approach.

The international proposal for the PCS and MCS calculation process [13,14] is based on the z-score determined for the first eight scales reported to the general population. Because no Romanian normative is drawn up, it was selected a study with similar values on group age for urban population as normative [15] to determine the z-score for each subject by subtracting the individual scale obtained by the mean of the group age and then dividing by appropriate standard deviation. Z-scores multiplied by the factor coefficient for the eight scales are summed to determine PCS and MCS, multiplied by 10, and added to 50 to linearly transform the PCS or MCS to the T-score metric, which has a mean of 50 and a standard deviation of 10 for the general population [13,14,16].

Positive evolution in physical and mental status for each patient was registered and summarized components were accomplished. (**Figure 4**)

Table 2. SF-36 OrthoToolKit before rehabilitation program (T0)

No.	Gender	range	T0 PF	T0 RP	T0 RE	T0 VT	T0 MH	T0 SF	T0 BP	T0 GH	T0 HC	T0 PCS	T0 MCS
1	M	30-40	50	50	33.3	65	56	50	45	35	25	53.13	51.08
2	F	40-49	15	25	33.3	45	44	25	32.5	55	25	40.00	36.83
3	M	40-49	35	25	66.7	60	56	50	45	50	25	51.25	58.18
4	F	50-69	15	25	33.3	40	20	25	45	25	25	37.50	29.58
5	F	50-69	40	50	33.3	55	56	50	45	55	25	53.13	48.58
6	M	50-69	5	0	0	20	20	25	32.5	25	25	31.25	16.25
7	F	>70	35	25	0	45	44	25	45	30	25	43.13	28.50

Table 3. SF-36 OrthoToolKit before rehabilitation program (T2)

No.	Gender	range	T2 PF	T2 RP	T2 RE	T2 VT	T2 MH	T2 SF	T2 BP	T2 GH	T2 HC	T2 PCS	T2 MCS
1	M	30-40	90	100	100	80	80	87.5	100	75	75	91.25	86.88
2	F	40-49	75	75	100	80	72	75	67.5	60	75	69.38	81.75
3	M	40-49	95	100	100	75	76	75	87.5	75	75	89.38	81.50
4	F	50-69	90	75	100	70	84	75	77.5	75	100	79.38	82.25
5	F	50-69	95	100	100	85	80	100	100	70	75	91.25	91.25
6	M	50-69	45	50	66.7	55	52	50	65	45	75	51.25	55.93
7	F	>70	45	100	66.7	60	48	75	87.5	65	75	74.38	62.43

Physical functioning= PF, role limitations due to physical health problems = RP, role limitations due to personal or emotional problems = RE, energy/fatigue = VT, emotional well-being = MH, social functioning = SF, bodily pain = BP, general health perceptions = GH, health change = HC.
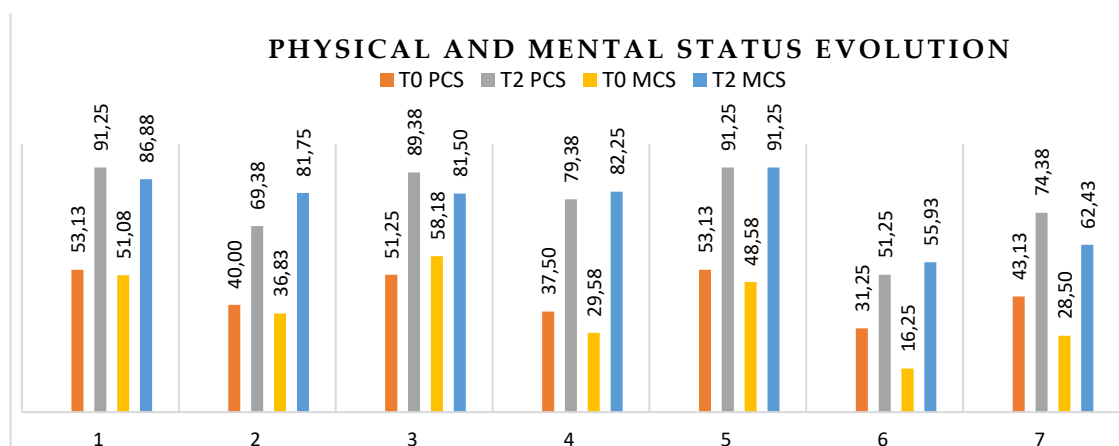
Figure 4. Physical and mental status evolution

3.2.2. Statistical Analyzes

3.2.2.1. Descriptive Statistics RAND SF-36 version1 according to **Table 4** shows that

- Before starting the rehabilitation program (T0), physical components (average) registered a mean of 44.20±8.57, median of 43.13 and mental components registered a mean of 33.43±14.86, median of 36.83.

- After eight weeks of physical therapy (T2), physical components (average) registered a mean of 78.04.20±14.64, a median of 79.38, and mental components registered a mean of 77.43±13.08, a median of 81.75.

Table 4. Descriptive Statistics RAND SF-36 version1

Descriptive Statistics RAND SF-36 version1	N	Mean	Std. Deviation	Minimum Floor value	Maximum Ceiling value	Percentiles 25th	50th (Median)	75th
T0 PF	7	27.86	16.29	5.00	50.00	15.00	35.00	40.00
T0 RP	7	28.57	17.25	0.00	50.00	25.00	25.00	50.00
T0 RE	7	28.56	23.01	0.00	66.70	0.00	33.30	33.30
T0 VT	7	47.14	14.96	20.00	65.00	40.00	45.00	60.00
T0 MH	7	42.29	16.14	20.00	56.00	20.00	44.00	56.00
T0 SF	7	35.71	13.36	25.00	50.00	25.00	25.00	50.00
T0 BP	7	41.43	6.10	32.50	45.00	32.50	45.00	45.00
T0 GH	7	39.29	13.67	25.00	55.00	25.00	35.00	55.00
T0 HC	7	25.00	0.00	25.00	25.00	25.00	25.00	25.00
T0 PCS	7	44.20	8.57	31.25	53.13	37.50	43.13	53.13
T0 MCS	7	38.43	14.86	16.25	58.18	28.50	36.83	51.08
T2PF	7	76.43	22.49	45.00	95.00	45.00	90.00	95.00
T2 RP	7	85.71	19.67	50.00	100.00	75.00	100.00	100.00
T2 RE	7	90.49	16.25	66.70	100.00	66.70	100.00	100.00
T2 VT	7	72.14	11.13	55.00	85.00	60.00	75.00	80.00
T2 MH	7	70.29	14.40	48.00	84.00	52.00	76.00	80.00
T2 SF	7	76.79	15.19	50.00	100.00	75.00	75.00	87.50
T2 BP	7	83.57	14.21	65.00	100.00	67.50	87.50	100.00
T2 GH	7	66.43	11.07	45.00	75.00	60.00	70.00	75.00
T2 HC	7	78.57	9.45	75.00	100.00	75.00	75.00	75.00
T2 PCS	7	78.04	14.64	51.25	91.25	69.38	79.38	91.25
T2 MCS	7	77.43	13.08	55.93	91.25	62.43	81.75	86.88

An increasing 76.57 % average was obtained for physical components and a 101.48% average for mental components after performing physical therapy.

3.2.2.2. Evaluation of QoL T2/T0 for each subject, mean and median values were drawn up with radar plot for each subject aged 39-73. For the nine dimensions of the SF-36, mean and median and PCS, MCS scores, n = 7, before (blue radar) and after (orange radar) the rehabilitation program improvements are according to **Figure 5**.
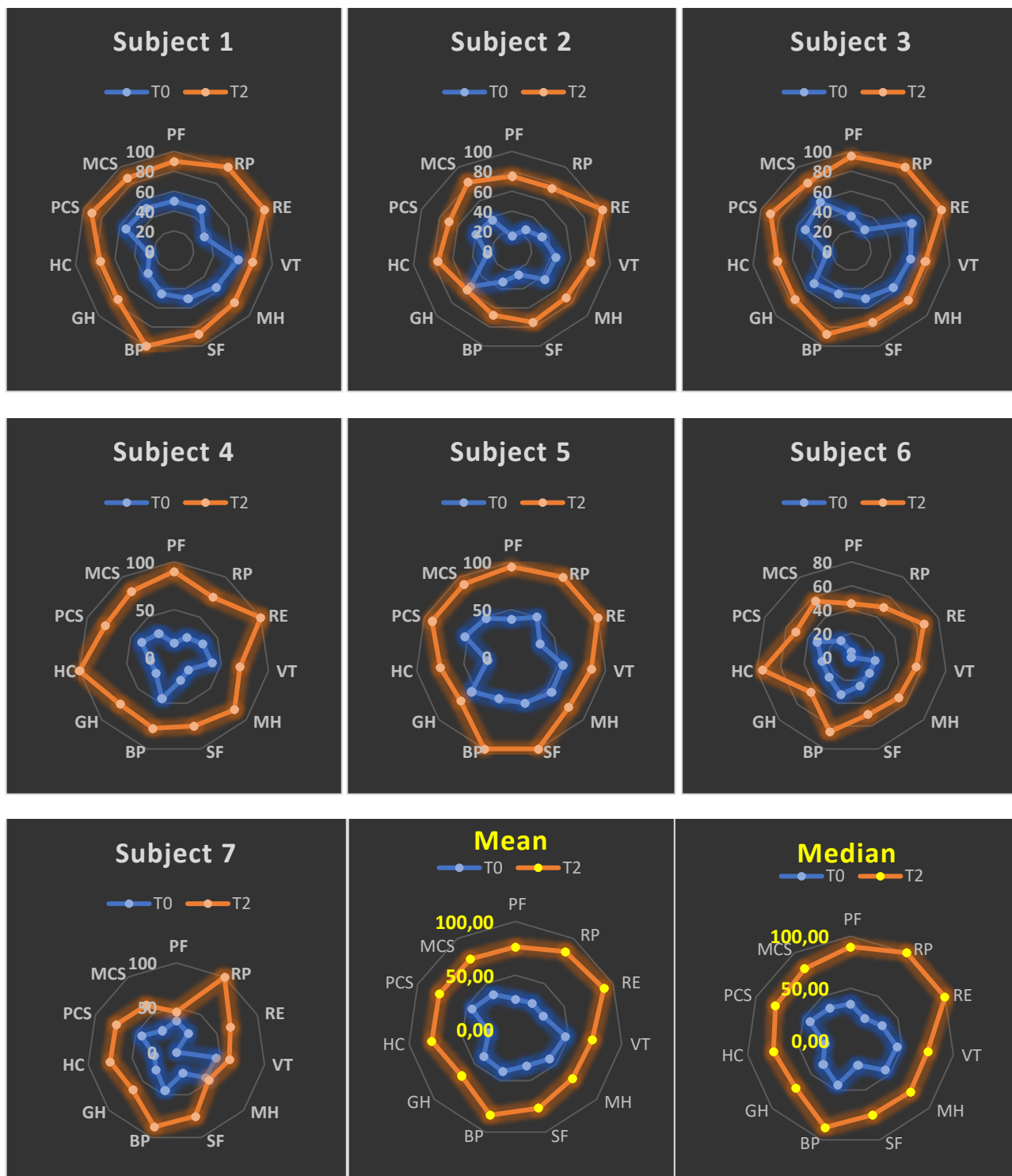
Figure 5. Evaluation of QoL T2/T0 for each subject, Mean and Median values

3.2.2.3. Responsiveness

The T-test for paired samples referring to main domains PF, RP, RE, VT, SF, BP, GH, HC, PCS, and MCS, allows the evaluation of the significance of the variation of the QoL dimensions, in the same subjects, in two different conditions "before" and "after" the rehabilitation program with T-test for pair samples. The results of the T-test prove that there is a therapeutic effect of the rehabilitation program using an innovating horizontal bicycle [11] due to a significant observed difference between the means as $p<0.05$ for all Qol items. (**Table 5**)

Table 5. The T-test for paired samples

Paired Differences	T-TEST	Mean (m)	Std. Dev.	Std. Error Mean	95% C.I. Lower	95% C.I. Upper	t	df	p Sig. (2-tailed)
Pair 1	T0 PF - T2PF	-48.57	20.96	7.922	-67.96	-29.19	-6.131	6	0.001
Pair 2	T0 RP - T2 RP	-57.14	12.20	4.611	-68.42	-45.86	-12.394	6	0.000
Pair 3	T0 RE - T2 RE	-61.93	12.62	4.771	-73.60	-50.25	-12.979	6	0.000
Pair 4	T0 VT - T2 VT	-25.00	9.57	3.619	-33.85	-16.15	-6.908	6	0.000
Pair 5	T0 MH - T2MH	-28.00	18.18	6.873	-44.82	-11.18	-4.074	6	0.007
Pair 6	T0 SF - T2 SF	-41.07	11.89	4.494	-52.07	-30.08	-9.139	6	0.000
Pair 7	T0 BP - T2 BP	-42.14	9.73	3.677	-51.14	-33.15	-11.461	6	0.000
Pair 8	T0 GH– T2GH	-27.14	15.51	5.861	-41.48	-12.80	-4.631	6	0.004
Pair 9	T0 HC - T2 HC	-53.57	9.45	3.571	-62.31	-44.83	-15.000	6	0.000
Pair 10	T0 PCS- T2PCS	-33.84	7.50	2.836	-40.78	-26.90	-11.931	6	0.000
Pair 11	T0MCS- T2MCS	-39.00	9.29	3.511	-47.59	-30.41	-11.108	6	0.000

For PF absolute mean difference 48.57, t=-6.131, df =6, p<.001
For RP absolute mean difference 57.14, t=-12.394, df =6, p<.000
For RE absolute mean difference 61.93, t=-12.979, df =6, p<.000
For VT absolute mean difference 25, t=-6.908, df =6, p<.000
For MH absolute mean difference 28, t=-4.074, df =6, p<.007
For SF absolute mean difference 41.07, t=-9.139, df =6, p<.000
For BP absolute mean difference 42.14, t=-11.461, df =6, p<.000
For GH absolute mean difference 27.14, t=-4.631, df =6, p<.004
For HC absolute mean difference 53.57, t=-15, df =6, p<.000
For PCS absolute mean difference 33.84, t=-11.931, df =6, p<.000
For MCS absolute mean difference 39, t=-11.108, df =6, p<.000
Strong positive relationships from T-test were found between PCS, RE, BP, RP, MCS, and VT after 8 weeks of rehabilitation - correlation = (.769-.922) (**Figure 6**)
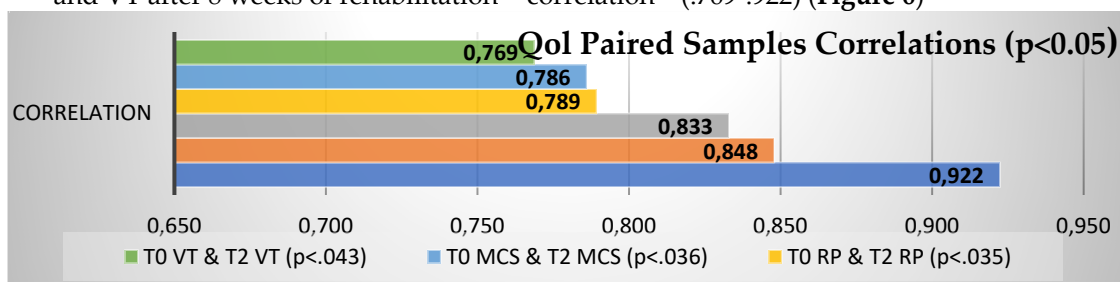

Figure 6. Relevant Pearson correlation between QoL items

　　　Nonparametric tests such as Wilcoxon Signed Ranks Test and sign test assessed the difference of QoL items at T0 and T2, mean ranks 4, sum = 28, and improved outputs after the rehabilitation program. (**Table 6**)

Table 6. Wilcoxon Signed Ranks Test Overall QoL

Ranks T2-T0	N	Mean Rank	Sum of Ranks
Negative Ranks	0[a]	0.00	0.00
Positive Ranks	**7[b]**	4.00	28.00
Ties	0[c]		
Total	7		
a. T2 < T0			
b. T2 > T0			
c. T2 = T0			

Z Statistics Test Overall QoL shows statistical significance p<.05 with p<.011 for RE and HC, p<.014 for RP, p<.016 for SF, p<.017 for VT, BP, and PCS, p<.018 for PF, MH, GH, and MCS. (**Table 7**)

Table 7. Z Statistics Test Overall QoL

Test Statistics	T2PF – T0 PF	T2 RP – T0 RP	T2 RE – T0 RE	T2 VT– T0 VT	T2 MH– T0 MH	T2 SF– T0 SF	T2 BP – T0 BP	T2 GH – T0 GH	T2 HC – T0 HC	T2 PCS – T0 PCS	T2 MCS – T0 MCS
Z	-2.375[b]	-2.460[b]	-2.530[b]	-2.392[b]	-2.371[b]	-2.414[b]	-2.379[b]	-2.366[b]	-2.530[b]	-2.384[b]	-2.366[b]
Asymp. Sig. (2-tailed)	0.018	0.014	0.011	0.017	0.018	0.016	0.017	0.018	0.011	0.017	0.018
a. Wilcoxon Signed Ranks Test											
b. Based on negative ranks.											

Sign Test Overall QoL shows statistical significance for all components p<.016. (**Table 8**)

Table 8. Sign Test

Test Statistics [a]	T2PF - T0 PF	T2 RP - T0 RP	T2 RE – T0 RE	T2 VT– T0 VT	T2 MH - T0 MH	T2 SF - T0 SF	T2 BP - T0 BP	T2 GH- T0 GH	T2 HC - T0 HC	T2PCS– T0PCS	T2MCS– T0MCS
Exact Sig. (2- tailed)	.016[b]	.016[b]	.016[b]	.016[b]	.016[b]	.016[b]	.016[b]	.016[b]	.016[b]	.016[b]	.016[b]
a. Sign Test											
b. Binomial distribution used.											

Effect size statistics were applied on PCS *and MCS* determined on Z-score (**Table 9, Table 10, and Table 11**)

PCS and MCS calculation process is based on the z-score determined for the first eight scales reported to the general population by subtracting the individual scale obtained by the mean of the group age and then dividing by the appropriate standard deviation. Z-scores multiplied by the factor coefficient for the eight scales are summed to determine PCS* and MCS*, multiplied by 10 and added to 50 to linearly transform the PCS or MCS to the T-score metric, which has a mean of 50 and a standard deviation of 10 for the general population [13,14,16].

Table 9. PCS *and MCS* determined based on Z-score at T0

T0 No.	Age	PF	z score PF	RP	z score RP	RE	z score RE	VT	z score VT	MH	z score MH	SF	z score SF	BP	z score BP	GH	z score GH	T0 PCS*	T0 MCS*
1	39	50	-2.709	50	-2.232	33.3	-3.378	65	0.281	56	-1.600	50	-3.908	45	-2.563	35	-2.712	4.275	8.424
2	44	15	-4.830	25	-3.463	33.3	-3.378	45	-1.844	44	-2.691	25	-6.008	32.5	-3.273	55	-1.429	15.598	3.592
3	42	35	-3.618	25	-3.463	66.7	-1.573	60	-0.672	56	-1.600	50	-3.908	45	-2.563	50	-1.750	8.397	6.979
4	53	15	-2.600	25	-1.913	33.3	-3.010	40	-1.823	20	-4.652	25	-5.403	45	-1.804	25	-2.503	26.943	9.875
5	60	40	-1.620	50	-1.139	33.3	-3.010	55	-0.759	56	-1.522	50	-3.465	45	-1.804	55	-0.863	24.960	9.956
6	52	5	-2.992	0	-2.687	0	-4.634	20	-3.241	20	-4.652	25	-5.403	32.5	-2.388	25	-2.503	34.487	20.706

| 7 | 73 | 35 | -0.573 | 25 | -0.841 | 0 | -5.845 | 45 | -1.006 | 44 | -1.718 | 25 | -2.406 | 45 | -0.977 | 30 | -1.585 | 36.745 | 31.899 |

Table 10. PCS *and MCS* determined based on Z-score at T2

T2 No.	Age	PF	z score PF	RP	z score RP	RE	z score RE	VT	z score VT	MH	z score MH	SF	z score SF	BP	z score BP	GH	z score GH	T2 PCS*	T2 MCS*
1	39	90	-0.285	100	0.232	100	0.227	80	0.891	80	0.582	87.5	-0.756	100	0.563	75	0.147	54.271	57.432
2	44	75	-1.194	75	-1.000	100	0.227	80	0.891	72	-0.145	75	-1.807	67.5	-1.284	60	-1.109	18.224	44.798
3	42	95	0.018	100	0.232	100	0.227	75	0.500	76	0.218	75	-1.807	87.5	-0.148	75	0.147	50.090	44.128
4	53	90	0.341	75	-0.365	100	0.244	70	0.305	84	0.913	75	-1.527	77.5	-0.285	75	0.230	49.843	50.790
5	60	95	0.537	100	0.409	100	0.244	85	1.369	80	0.565	100	0.411	100	0.766	70	-0.044	66.548	72.704
6	52	45	-1.424	50	-1.139	66.7	-1.380	55	-0.759	52	-1.870	50	-3.465	65	-0.869	45	-1.410	25.904	9.571
7	73	45	-0.304	100	0.776	66.7	-1.338	60	-0.057	48	-1.472	75	-0.357	87.5	0.664	65	-0.106	62.893	30.993

Table 11. Reference Normative (after 18) for z-score calculation

PCS								MCS							
Age groups	PF Mean	SD	RP Mean	SD	BP Mean	SD	GH Mean	VT Mean	SD	SF Mean	SD	RE Mean	SD	MH Mean	SD
18-44	94.7	16.5	95.3	20.3	90.1	17.6	77.3	68.6	12.8	96.5	11.9	95.8	18.5	73.6	11
45-64	81.3	25.5	86.8	32.3	83.6	21.4	70.8	65.7	14.1	94.7	12.9	95	20.5	73.5	11.5
>65	56.3	37.2	64	46.4	70.3	25.9	62.8	60.9	15.8	83.7	24.4	86.5	14.8	72	16.3

The effect size for PCS* between subjects n=7 at T2 vs T0 proves a partial eta squared of 0.432, R^2 = 43%, large effect (value over 40%) meaning that the rehabilitation program (independent variable) has a positive important impact on physical components (dependent variable) – **Table 12** result

Table 12. The effect size for PCS* between subjects

Tests of Between-Subjects Effects						
Dependent Variable:						
Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Corrected Model	2221.807[a]	1	2221.807	9.119	0.011	**0.432**
Intercept	16400.832	1	16400.832	67.312	0.000	0.849
PCS	2221.807	1	2221.807	9.119	0.011	0.432
Error	2923.861	12	243.655			
Total	21546.501	14				
Corrected Total	5145.668	13				
a. R Squared = .432 (Adjusted R Squared = .384)						

The effect size for MCS* between subjects n=7 at T2 vs T0 proves a partial eta squared of 0.534, R^2 = 53%, large effect (value over 40%) meaning that the rehabilitation program (independent variable) has a positive important impact on physical components (dependent variable) – **Table 13** result.

Table 13. The effect size for MCS* between subjects

Tests of Between-Subjects Effects						
Dependent Variable:						
Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Corrected Model	3425.315ᵃ	1	3425.315	13.765	0.003	0.534
Intercept	11534.352	1	11534.352	46.353	0.000	0.794
MCS	3425.315	1	3425.315	13.765	0.003	0.534
Error	2986.042	12	248.837			
Total	17945.709	14				
Corrected Total	6411.357	13				
a. R Squared = .534 (Adjusted R Squared = .495)						

3.2.2.4. Reliability

Pearson Correlation at T0 proved a strong correlation between scales according **to Table 14** and **Figure 7**.

At T0 correlation positive trend at 0.01 level (2-tailed) was found between VT with PF (r=.894), MH with VT (r=.887), PCS with PF (r=.937), VT (r=.950), MH(r=.928) and SF (r=.907) and MCS with VT (r=.937), SF (r=.893) and PCS (r=.925).

At T0 correlation positive trend at 0.05 level (2-tailed) was found between RP with PF (r=.847), VT with RP (r=.853), MH with PF (r=.858), SF with PF (r=.793), VT (r=.804), MH (r=.795), PCS with RP (r=.868), MCS with PF (r=.768) and MH (r=.872).

Table 14. Pearson Correlation T0

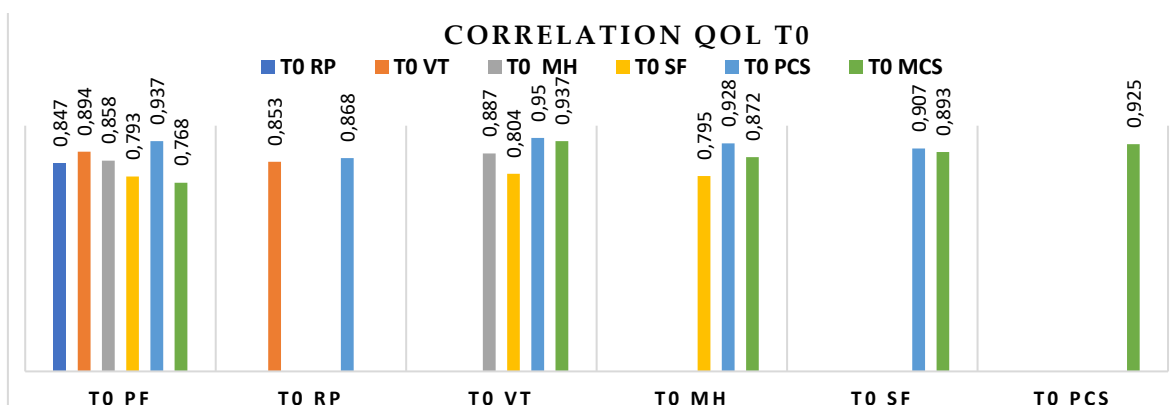| Correlations T0								
r = Pearson Correlation n = 7		T0 PF	T0 RP	T0 VT	T0 MH	T0 SF	T0 PCS	T0 MCS
T0 RP	r	.847*	1					
	p	0.016						
T0 VT	r	.894**	.853*	1				
	p	0.007	0.015					
T0 MH	r	.858*	0.744	.887**	1			
	p	0.013	0.055	0.008				
T0 SF	r	.793*	0.710	.804*	.795*	1		
	p	0.033	0.074	0.029	0.033			
T0 PCS	r	.937**	.868*	.950**	.928**	.907**	1	
	p	0.002	0.011	0.001	0.003	0.005		
T0 MCS	r	.768*	0.731	.937**	.872*	.893**	.925**	1
	p	0.044	0.062	0.002	0.010	0.007	0.003	
*. Correlation is significant at the 0.05 level (2-tailed).								
**. Correlation is significant at the 0.01 level (2-tailed).								

Figure 7 Correlation OoL scales at T0

Pearson Correlation at T2 proved a strong correlation between scales according to **Table 15** and **Figure 8**.

At T2 correlation positive trend at 0.01 level (2-tailed) was found between RE with PF (r=.954), VT with RE (r=.899), MH with PF (r=.966) and RE (r=.963), BP with RP (r=.884), PCS with RP (r=.881), BP (r=.876) and GH (r=.930) and MCS with PF (r=.945), RE (r=.953), VT (r=.960), MH (r=.930).

At T2 correlation positive trend at 0.05 level(2-tailed) was found between VT with PF (r=.851), MH with VT(r=.818), SF with RP (r=.797) and VT (r=.837), GH with PF (r=.793), RP (r=.779), PCS with PF (r=.821), VT r=(.756) and SF (r=.874), MCS with SF (r=.840), GH (r=.761), PCS (r=.830)

Table 15. Pearson Correlation T2 between QoL items

| r=Pearson Correlation n=7		T2 PF	T2 RP	T2 RE	T2 VT	T2 MH	T2 SF	T2 BP	T2 GH	T2 HC	T2 PCS	T2 MCS
Correlations T2												
T2 RE	r	.954**	0.372	1								
	p	0.001	0.411									
T2 VT	r	.851*	0.544	.899**	1							
	p	0.015	0.207	0.006								
T2 MH	r	.966**	0.311	.963**	.818*	1						
	p	0.000	0.497	0.001	0.025							
T2 SF	r	0.693	.797*	0.643	.837*	0.626	1					
	p	0.085	0.032	0.120	0.019	0.132						
T2 BP	r	0.523	.884**	0.352	0.537	0.394	.835*	1				
	p	0.229	0.008	0.439	0.214	0.382	0.020					
T2 GH	r	.793*	.779*	0.705	0.614	0.729	0.726	0.717	1			
	p	0.033	0.039	0.077	0.143	0.063	0.065	0.070				
T2 PCS	r	.821*	.881**	0.710	.756*	0.709	.874*	.876**	.930**	0.040	1	
	p	0.023	0.009	0.074	0.049	0.074	0.010	0.010	0.002	0.932		
T2 MCS	r	.945**	0.548	.953**	.960**	.930**	.840*	0.574	.761*	0.163	.830*	1
	p	0.001	0.203	0.001	0.001	0.002	0.018	0.178	0.047	0.727	0.021	
*. Correlation is significant at the 0.05 level (2-tailed).												
**. Correlation is significant at the 0.01 level (2-tailed).												
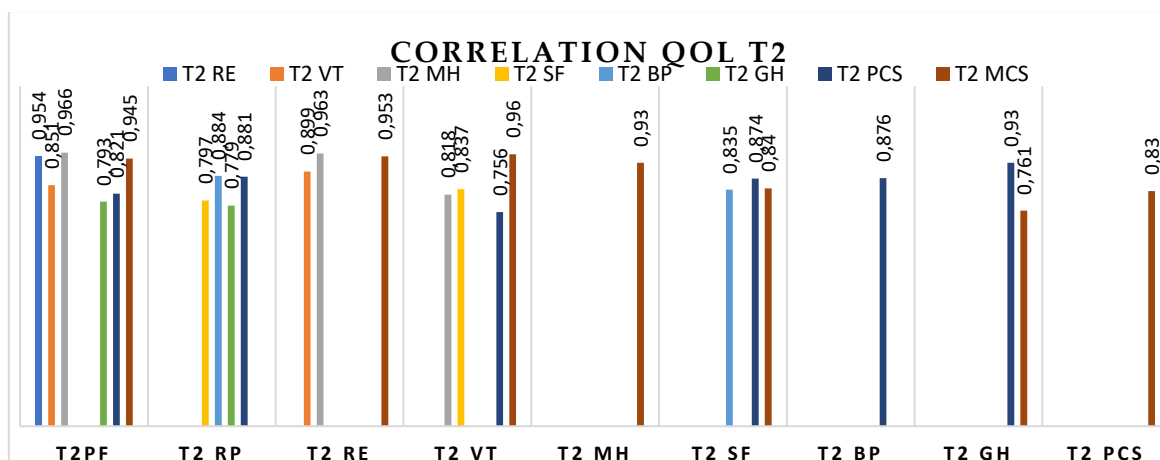
Figure 8. Correlation OoL scales at T2

Intraclass correlation coefficient (ICC) was calculated overall at T0 and T2 based on the mean values of the scales from two interviewers (patient/carer/relative and physical therapist) and over time (test-retest reliability T0 and T2)

Cronbach's Alpha =.995 at T0 and 1.000 at T2 proving a good result according to **Table 16** and **Table 17**, sig.=.000

Table 16. ICC at T0

Reliability Statistics

Cronbach's Alpha	N of Items
0.995	2

Intraclass Correlation Coefficient							
		95% Confidence Interval		F Test with True Value 0			
	Intraclass Correlation [b]	Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	.990[a]	0.958	0.998	209.114	7	7	0.000
Average Measures	.995[c]	0.978	0.999	209.114	7	7	0.000
Two-way mixed effects model where people effects are random and measures effects are fixed.							
a. The estimator is the same, whether the interaction effect is present or not.							
b. Type A intraclass correlation coefficients using an absolute agreement definition.							
c. This estimate is computed assuming the interaction effect is absent because it is not estimable otherwise.							

Table 17. ICC at T2

Reliability Statistics

Cronbach's Alpha	N of Items
1.000	2

Intraclass Correlation Coefficient							
	Intraclass Correlation [b]	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	1.000[a]	1.000	1.000	5794501.097	7	7	0.000
Average Measures	1.000[c]	1.000	1.000	5794501.097	7	7	0.000
Two-way mixed effects model where people effects are random and measures effects are fixed.							
a. The estimator is the same, whether the interaction effect is present or not.							
b. Type A intraclass correlation coefficients using an absolute agreement definition.							
c. This estimate is computed assuming the interaction effect is absent because it is not estimable otherwise.							

3.2.2.5 Measurement of QoL RAND 36-Item Health Survey

QoL outcome measure contains eight questions and criteria that need to be addressed and evaluated to see the impact of the intervention on patients. Appropriateness, acceptability, feasibility, validity, reliability, responsiveness, precision, and interpretability were assessed by applying **RAND 36-Item Health Survey version 1**, detailed in **Table 1**8.

Table 18. Measurement of QoL RAND 36-Item Health Survey (after [1,17])

No.	Criteria	Details of QoL instrument used RAND 36-Item Health Surve	Application
1	Appropriateness	content suitable to the main objectives of the study	the main objective of the present rehabilitation program is gait facilitation.
2	Acceptability	acceptable to patients/carers	response rates T0/T2 = 100%, Romanian version, under the control of the New England Medical Center, completion time is a good measure [18] completion time average in this case 11 min 15 sec.
3	Feasibility	easy to administer and process	processing the information and collection of data by the physical therapist and patient/relative during rehabilitation sessions, the short form used is easiest to manage, SF-36 OrthoToolKit for data aggregation is licensed (Optum) and available freely online (Rand) [19], completion time 6 min in the kit tool.
4	Validity	measures what it claims to measure	three main types of validity – content, criterion and construct by correlation with other tests proved by specialty literature, A valid QoL scale shows differences in the expected direction [20–22].
5	Reliability	produces results that are reproducible and internally consistent	Includes stability over time (i.e.test–retest reliability); between raters or interviewers (i.e. inter-rater reliability); and between locations, such as hospitals and homes [1] with internal consistency reliability- ICC or Kappa coefficient; ICC was applied.
6	Responsiveness	detects changes over time that matter to patients	assessed by effect size statistics, pair T-test, Ceiling and floor effects [1] Sign Test, Wilcoxon.
7	Precision	refers to the scores of the QoL	double-check control due to the fourth criterion (validity), use of Likert format response where degrees of the agreement are given progressively lower (or higher) values[1].
8	Interpretability	scores understandable for applicants	means meaningful and interpretable scores [1] , Romanian version was used.

4. Discussion

Different normative were drawn up in several countries comprising samples (e.i. from Norway, Canada, Britain, Brazil, Ireland) [23–27] grouped by age, gender as mean and standard deviation. PCS and MCS are calculated based on z-score [13,14]. Comparative value was presented based on Ro-SF36 V2 =928 Romanian patients[12] with different medical interventions (no general population) with the specification that PCS and MCS are average values from subsequent scales. (**Table 19**)

Table 19. Comparative value Ro-SF36-V1 (n=7) vs. Ro-SF36-V2 (n=928)

QoL	Present study Mean T0 n=7 Ro-SF36-V1	Present study Mean T2 n=7 Ro-SF36-V1	RO (n=928) [12]
PF	27.86	76.43	84.08
RP	28.57	85.71	78.34
RE	28.56	90.49	80.85
VT	47.14	72.14	61.77
MH	42.29	70.29	66.48
SF	35.71	76.79	77.70
BP	41.43	83.57	71.32
GH	39.29	66.43	64.34
PCS	**44.20**	**78.04**	**71.70**
MCS	**38.43**	**77.43**	**74.52**

By this particular approach implying a rehabilitation program for lower limbs injuries using a horizontal stationary bicycle, it was obtained mean score scales (T2) for PCS and MCS increased with 8.85% for PCS and 3.91% versus Ro-SF36-V2 (n=928) results.
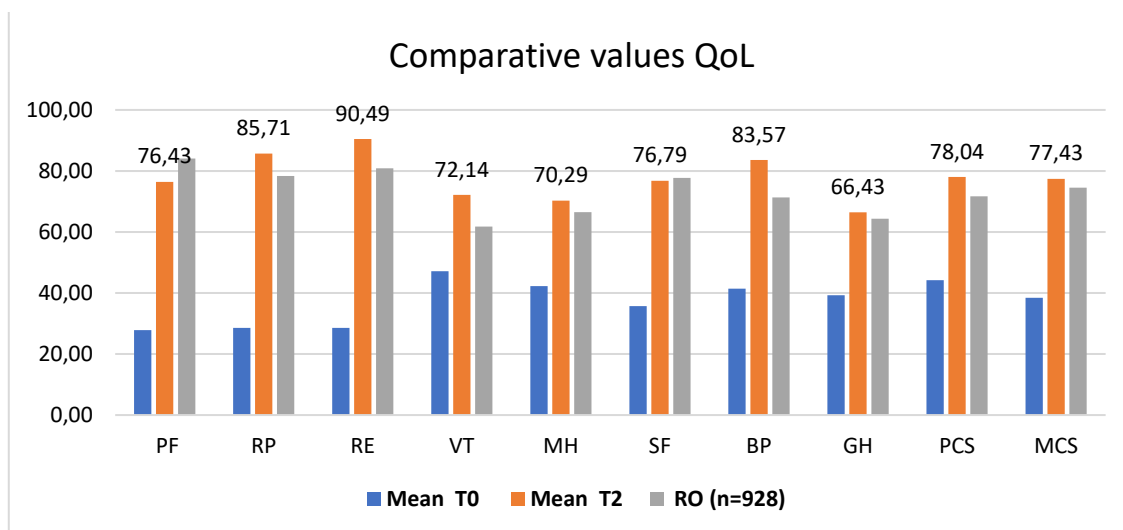

Figure 9. Comparative values QoL

PCS* and MCS* based on the z-score calculated in this study showed encouraging results with the remark that normative was chosen for similar values.

Taking into account that the number of samples was small, it required more studies to determine country norms and to report further approaches to them.

5. Conclusions

The conclusion can be summarized regarding the eight criteria of measurement:

-       **Appropriateness** - the main objective of the present rehabilitation program is gait facilitation- fulfilled for all seven patients;

-       **Acceptability**- response rates T0/T2 = 100%, Romanian version, under the control of the New England Medical Center, the completion time average in this case 11 min 15 sec for interviewers;

-       **Feasibility** - SF-36 OrthoToolKit for data aggregation is licensed (Optum) and available freely online, the completion time of 6 min in the kit tool (physical therapist);

-       **Validity** - content, criterion and construct by correlation with other tests proved by specialty literature;

-       **Reliability**

  ICC (Cronbach's Alpha overall test-retest, patient/physical therapist T0/T2 =0.995/1.000)

Pearson correlation coefficient between items statistic significant as follows

- At T2 correlation positive trend at 0.01 level (2-tailed) was found between RE with PF (r=.954), VT with RE (r=.899), MH with PF (r=.966) and RE (r=.963), BP with RP (r=.884), PCS with RP (r=.881), BP (r=.876) and GH (r=.930) and MCS with PF (r=.945), RE (r=.953), VT (r=.960), MH (r=.930).

 At T2 correlation positive trend at 0.05 level(2-tailed) was found between VT with PF (r=.851), MH with VT(r=.818), SF with RP (r=.797) and VT (r=.837), GH with PF (r=.793), RP (r=.779), PCS with PF (r=.821), VT r=(.756) and SF (r=.874), MCS with SF (r=.840), GH (r=.761), PCS (r=.830

-       **Responsiveness**

  The T-test for paired samples (p<.05) for each subsequent scale is as follows:

For PF absolute mean difference 48.57, t=-6.131, df =6, p<.001

For RP absolute mean difference 57.14, t=-12.394, df =6, p<.000

For RE absolute mean difference 61.93, t=-12.979, df =6, p<.000

For VT absolute mean difference 25, t=-6.908, df =6, p<.000
For MH absolute mean difference 28, t=-4.074, df =6, p<.007
For SF absolute mean difference 41.07, t=-9.139, df =6, p<.000
For BP absolute mean difference 42.14, t=-11.461, df =6, p<.000
For GH absolute mean difference 27.14, t=-4.631, df =6, p<.004
For HC absolute mean difference 53.57, t=-15, df =6, p<.000
For PCS absolute mean difference 33.84, t=-11.931, df =6, p<.000
For MCS absolute mean difference 39, t=-11.108, df =6, p<.000

Wilcoxon (Z Test), Sign Test (p<.05) for each subsequent scale - Wilcoxon Signed Ranks Test and sign test assessed the difference of QoL items at T0 and T2, mean ranks 4, sum = 28, improved outputs after the rehabilitation program.

Z Statistics Test Overall QoL shows the statistical significance of p<.05 with p<.011 for RE and HC, p<.014 for RP, p<.016 for SF, p<.017 for VT, BP, and PCS, p<.018 for PF, MH, GH, and MCS.

Sign Test Overall QoL shows statistical significance for all components p<.016.

Effect size as Partial Eta Squared based on z-score η2 = .432 PCS and .534 MCR – large effect (over .400).

-        **Precision**- double-check control due to the fourth criterion (validity), use of Likert format response.

-        **Interpretability** - Romanian version was used for a better understanding.

Summary Conclusions QoL						
n=7, 4F- 42.66%, 3M-42.66% 3M, mean age 51.86 ± 11.82, BMI (kg/m²) mean of 29.37±6.43						
1 subject -14.29% 30-39y, 2 subjects -28.57% 40-49y, 3 subjects - 42.86% 50-69y, 1 subject – 14.29% over 70y						
Intervention: eight weeks of rehabilitation program for lower limbs injuries (implying stationary bicycle)						
QoL evaluation RAND 36-Item Health Survey 1.0 T2 versus T0						
Appropriateness main objective- gait facilitation- fulfilled	**Acceptability** response rates 100%, Romanian version, completion time 11 min 15 sec	**Feasibility** SF-36 OrthoToolKit is licensed (Optum) and available freely online (Rand), completion time is 6 min in the kit tool	**Validity** proved by specialty literature	**Reliability** ICC Cronbach's Alpha T0/T2 =0.995/1.000 Pearson correlation between items statistic significant	**Responsiveness** The T-test for paired samples (p<.05 overall) Wilcoxon (Z Test), Sign Test (p<.05 for each scale) effect size - Partial Eta Squared based on z-score η2 = .432 PCS and .534 MCR – large effect	**Precision** double-check control due to the fourth criterion (validity), use of Likert format response	**Interpretability** Romanian version is used for a better understanding

Figure 10. Summary Conclusions Qol RAND 36-Item Health Survey 1.0 T2 versus T0

QoL outcome measuring eight criteria proved a positive impact of intervention implying a horizontal stationary bicycle rehabilitation program on patients.

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