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Ethical Dilemmas in the Interdisciplinary Approach to Informed Consent to Patients in Physiotherapy Services in Romania

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Abstract

Physiotherapists become responsible for the rehabilitation of patients in a wide range of conditions, but the bioethical questions have not been sufficiently assimilated to academic studies. A cross-sectional survey was applied to both physiotherapists and patients, related to informed consent (IC). A number of 148 physiotherapists and 397 patients participated to the study. Differences between patients and physiotherapists regarding IC are discussed. Physiotherapists are reporting less frequency than patients regarding IC obtaining both at physiotherapy admission and physiotherapy onset, disregarding the legal demands. Patients social aspects related to IC level of understanding investigations indicate that university graduates' patients have a wide perception of IC process in physiotherapy. A low educational level was associated with disregard and overestimation of ethical components regarding physiotherapy services.

Keywords: physiotherapy, ethics, information, consent, interdisciplinary, patients.

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Introduction

Physiotherapy, as a medical field is expanding and developing through the last decades, becoming an important component of the medical system. Physiotherapists have become responsible for the rehabilitation of patients in a wide range of conditions, evolving and also being included as a distinct component of emergency medicine worldwide (CSP, 2014; Farell, 2014). Physiotherapy ethical challenges have accompanied the field development, but the bioethical questions have not been sufficiently assimilated to academic studies. There is a lack of scientific literature to provide a well-defined framework for what ethical issues related to the physiotherapy specificity, including concerns about informed consent (IC) (Poulis, 2007). The medical development during the last centenary, in terms of medical practice and technology evolution, demanded the development of coherent moral and ethical policies, needed to intervene in protecting the patient and human life. One of these tools is represented by informed consent. The informed consent, in addition to protecting human subjects included in the medical research, is used to respect and promote the patient's autonomy and to protect him from mischief or harmful actions to his or her health (Parsons, 1954; Tam, 2015).

One of the physiotherapy's particularities is represented by the modality in which the most of physiotherapy sessions are unfolding. The physiotherapist has to work progressively with the patient, to change techniques and methods of treatment. Here is one of the problems of informed consent (IC) in physiotherapy: how should it be achieved and how much does interfere with the quality of the medical act? There is no framework or guidelines about how informed consent should be obtained in physiotherapy, and most of the time is related only about giving information to patients. (Delany, 2007) There is a surge need for comprehending the physiotherapy process of care with ethical implications, given the responsibilities of physiotherapists raised with new medical equipment utilization, including robotic therapy (Rogozea, 2010; Roman, 2017). Within the Romanian medical system, due to the patient's circuit in the physiotherapy services, the contact with the physiotherapist is delayed and a general consent is obtained at physiotherapy admission. The importance of an interdisciplinary approach of IC in physiotherapy is mandatory due to physiotherapy services specificity. There is a need for data collection, to create and implement a framework for IC obtaining in physiotherapy because the general IC form is realized by specialized personnel in one direction, especially physicians, and content issues of IC form are general and not specific to this medical field (Dima et al., 2014; Hall, 2012).

Important informational components are omitted in creating and implementing an appropriate IC form in physiotherapy. These are related to the analysis and the use of an appropriate language which leads to an improvement of patient's understandings. The collection and the analysis of data related to the patient's level of knowledge and behaviour are important elements for a proper information process and for the improvement of the decision-making capacity in the treatment of physiotherapy (Bottrell, 2000). This research aims to explore aspects concerning IC in physiotherapy services from an interdisciplinary perspective, related to patient's and physiotherapist's side of views. Social aspects of the patient's perception of IC are discussed and hypothesized within the context of a better perception and understanding amongst graduate patients.

Methods

We have applied two questionnaires for physiotherapists and patients to investigate elements regarding IC obtaining. In both questionnaires, there were similar items that investigate aspects related to the way IC is obtained, the frequency and level of understanding of the IC process. Each of the tools used contained items related to demographics, age, occupation, educational level. The European Data Protection Registry has been respected (European Parliament, 2016). The questionnaire for physiotherapists was made up of 39 items, with 2 open questions. The questionnaire addressed to patients contained 22 items, with one open question.

The questionnaire for patients was distributed in written form within the County Emergency Clinical Hospital in Brasov and at the Clinical Hospital of Psychiatry and Neurology in Brasov. In order to carry out the research, approvals have been obtained from the Ethics Committee of Transilvania University in Brasov, but also from Management Teams and the Ethics Committees of the County Emergency Clinical Hospital in Brasov and the Clinical Hospital of Psychiatry and Neurology in Brasov. The questionnaires were applied from May to August 2018. The questionnaire for physiotherapists was distributed through social network, within a group of physiotherapists' community in Romania, due to the lack of other ways of access according to the lack of a professional association.

The total number of respondents was 535, 148 physiotherapists and 397 patients. The rate of effective completion of the questionnaires among physiotherapists was 91.4% (148 out of 162), and among the patients 98% (397 out of 405), due to the fact that the filling out of the survey was supervised by the physiotherapist. The data were processed using the SPSS 20 statistical analysis software. A descriptive statistical analysis was used to generate a complex framework for the interpretation of data. To determine significant differences between patients and physiotherapists, the Mann-Whitney test was applied. To identify the differences in IC perception, according to education level, the Kruskal-Wallis test was used. Validation of the questionnaires was done through confirmatory factor analysis and Cronbach Alpha's appreciation (Bland, 1997; Agresti, 2013; Sheskin, 2011).

Results and Discussions

The value of the Cronbach Alpha index for the physiotherapist questionnaire was 0.836, and for the patient questionnaire, the value of the index was 0.743.

Participants

In age group distribution, 4.7% were aged between 15-25 years, 3.6% aged between 25-35 years, 11.9% aged 35-45 years, 22% aged 45-55, 31.5% aged 55-65 years, 21.4% aged 65-75 years and 4.9% aged over 75 years. A percentage of 19.6% are graduates of secondary education, 62.5% are graduates of secondary education and 17.8% are graduates of higher education. Of the total respondents, 54.3% are female and 45.7% male.

Physiotherapists participating in the study were 148. The distribution according to the level of the graduated studies was 5.4% college degree, 60.1% undergraduates, 33.1% master's graduates, and 1.4% graduates with doctoral studies. Distribution by age group of physiotherapist participants was 49.3% aged 21-30 years, 38.5% aged 31-40 years, 9.5% aged between 41 and 50 in equal percentages, 1.4% aged between 51-60 years and over 60 years. Of the total number of participants, 27.7% carry out professional activities in the public health, 67.6% in the private environment and 6.7% in the units of old people's homes, social associations or other units not in the public or private system.

Descriptive statistical analysis

Similar items of the used questionnaires, which relate to the frequency of CI at the onset of medical recovery treatment and during the course of the treatment plan, can be found in *Table 1*.

		1. IC obtain siotherapy a	0		I2. IC obtaining at physiotherapy onset				
Frequency	Physic	therapists	Pa	atients	Phys	iotherapists	Patients		
	n	%	n	%	n	%	n	%	
Never	24	16.2%	7	1,8 %	32	21,6 %	21	5,4 %	
Occasionally	15	10.1%	7	1,6 %	25	16,9%	15	3,9 %	
Average	20	13.5%	18	4,7 %	16	10,8%	33	8,5 %	
Frequent	29	19.6%	85	22, %	30	20,3%	103	26,6 %	
Always	60	40.5%	270	69,8	45	30,4%	215	55,6 %	
				%					
Total	148	100%	387	100,0 %	148	100,0%	387	100,0 %	

Table 1. Comparison of IC frequency obtaining in physiotherapy services from patients and physiotherapists perspective

Considering that physiotherapists on the territory of Romania usually carry out electrotherapy and physical therapy activities in collaboration with the Medical Rehabilitation Physician, especially for electrotherapy, the patient normally has first contact with the physician and later with physiotherapist. So initially, IC is obtained by the Medical Rehabilitation Physician. But we emphasize that the physiotherapist's duties include the functional assessment of the patient and the design of the physical therapy program, and movement therapy is a medical act and in consequences, IC must be achieved by the physiotherapist for physical therapy program approval. A percent of 69.8% of patients (*Table 1*) reported that IC at the onset of physiotherapy treatment was performed 'Always', unlike physiotherapists, who reported this frequency in the proportion of 40.5%. This aspect is strengthening the first items results and confirms the delayed patient-physiotherapist contact.

The need to obtain IC from patients is found in national legislation. Besides the aspects of professional activity related to the dynamics specific to physical therapy, the lack of a professional association, of ethical, deontological norms, and good professional practice may be factors that influence this process, leading to a poor perception of IC process. Also, the late contact of the patient with the physiotherapist during the course of the medical process might explain this misleading concerning IC (Romanian Parliament, 2003; Foster, 2012).

Regarding the aspect of IC obtaining at the moment of contact with the physiotherapist and the onset of physical therapy, there is a decrease in frequency reporting, both physiotherapists and patients. As can be seen from the data in *Table 1*, there is a mismatch in the frequencies reported by the investigated groups, so the group of patients reported a higher percentage of IC acquired frequency at the onset of kinetic therapy compared to physiotherapists.

	Criteria's									
Items	Ne	ver	Occas	ionally	Ave	rage	Freq	uent	Alw	/ays
	Р	Pt	Р	Pt	Р	Pt	Р	Pt	Р	Pt
	n/%	n/%	n/%	n/%	n/%	n/%	n/%	n/%	n/%	n/%
I3. IC obtained	14	10	7	16	8	25	47	89	72	247
verbally (V)	9.5%	2.6%	4.7%	4.1%	5.4%	6.5%	31.8%	23%	48.6%	63.8%
I4. IC obtained	62	23	33	76	14	76	14	99	25	113
written (W)	41.9%	5.9%	22.3%	19.6%	9.5%	9.6%	9.5%	25.6%	16.9%	29.2%
I5. IC obtained	64	103	29	112	16	40	20	46	20	86
V+W	43.2%	26.6%	19.6%	28.9%	10.8%	10.3%	13.5%	11.9%	13.5%	22.2%
16.	32	39	25	75	16	56	30	134	45	234
Physiotherapy	21.6%	7.2%	16.9%	13.9%	10.8%	10.4%	20.3%	24.9%	30.4%	43.5%
intervention										
I7. <3 minutes	49	115	51	91	17	97	24	44	7	40
	33.1%	29.7%	34.5%	23.5%	11.5%	21.5%	16.2%	11.4%	4.7%	10.3%

Table 2. Comparison of IC types and time spending for IC process, from patients and physiotherapists perspective

_											
	18. 3-5	18	64	35	116	26	82	54	83	15	42
	minutes	2.2%	16.5%	23.6%	30.0%	17.6%	21.2%	36.5%	21.4%	10.1%	10.9%
	I9. 5-10	14	103	47	112	31	75	38	39	18	58
	minutes	9.5%	26.6%	31.8%	28.9%	20.9%	19.4%	25.7%	10.1%	12.2%	15.0%
	I10. >15	67	208	53	77	9	7	12	17	7	78
	minutes	45.3%	53.7%	35.8%	19.9%	6.1%	1.8%	8.1%	4.4%	4.7%	20.2%

P=Physiotherapists, *Pt=Patients*

Table 2 details the similar items from the two questionnaires used in this research, which are related to the way CI is obtained. From the percentage differences of the respondents, it can be concluded that physiotherapists do not perceive obtaining IC in written form at the same level as patients. This can be explained by the fact that in the physiotherapy services, especially in hospitals, the physiotherapist is the last medical staffs that comes into contact with the patient, thus that the steps and the procedure of obtaining the CI are not considered as professional duties. Obtaining CI in both verbal and written form was similarly reported by study participants, regardless of group membership, and as can be seen from *Table 2*, it is not a frequent practice in conducting the IC process, obsessing -the IC is to be reported to one of the verbal or written variants (Fennety, 2009)

Regarding the major percentages of the participants in the three ways to obtain CI, it is easy to see from *Table 2* that the most commonly used method of obtaining CI is verbal, this aspect being reported by both physiotherapists and patients, in majority, at the same time. National legislation does not request the obligation to obtain CI in written form, except for clinical trials. So, this issue differs according to the purpose of IC obtaining, for treatment or for research on human subjects. Basically, obtaining IC for treatment application has legal resonance, particularly in relation to risk management, while obtaining IC for research has higher ethical and moral implications (Purcaru, 2014; Emanuel, 2000).

The time spent by physiotherapists for information providing regarding the physical therapy plan, with details about type of exercise applied, methods, techniques and outcomes was investigated both from patients and physiotherapists perspectives. As it can be seen in *Table 2*, the most representative percentage for the time category below 3 minutes was declared with an occasional frequency of 34.5% from physiotherapists perspective, while the highest percent of 29,7% of patients declared as never happened. A percentage of 36.5% of physiotherapists said they frequently spend between 3 and 5 minutes to inform patients, and the representative rate for patients in this category was in the occasionally category (30%). Reporting over a period of time between 5 and 10 minutes for receiving and providing information from both patients and physiotherapists was declared by both groups as being accomplished at an occasionally frequency. A period of more than 15 minutes to provide information from physiotherapists is reported by a low frequency from both groups of participants. For a better understanding

of the answers provided by physiotherapists and patients, we have applied Mann-Whitney test to identify if there are statistically significant differences concerning the physiotherapists participants and patients from our research. The results are found in *Table 3*.

Comparative statistical analysis

Table 3. Comparative analysis of items related to IC obtaining in physiotherapy, from patient and physiotherapists perspective

Item	Group	Mean Rank	Sum of Ranks	Z value	P value	
I1	Pt	196.00	29008.00	7.667	0.000	
	Р	295.53	114372.00			
I2	Pt	196.67	29107.00	7.086	0.000	
_	Р	295.28	114273.00			
I3	Pt	236.42	34990.50	3.327	0.001	
	Р	280.08	108389.50			
I4	Pt	182.94	27075.50	8.049	0.000	
	Р	300.53	116304.50			
I5	Pt	234.64	34726.00	3.183	0.001	
-	Р	280.76	108654.00			
I6	Pt	205.51	30415.50	6.133	0.000	
-	Р	291.90	112964.50			
I7	Pt	248.14	36724.50	1.895	0.058	
-	Р	275.60	106655.50			
I8	Pt	293.90	43497.00	2.462	0.014	
-	Р	258.10	99883.00			
I9	Pt	311.93	46166.00	4.164	0.000	
-	Р	251.20	97214.00			
I10	Pt	268.22	39697.00	0.022	0.982	
-	Р	267.91	103683.00			

Pt= *Physiotherapists*, *P*=*Patients*

Analysing the results presented in *Table 3* given by Mann-Whitney test applied to identify if there are significant statistically differences between physiotherapists (PT group) and patients (P group) regarding aspects of IC obtaining in physiotherapy, from 10 items analysed, only three shown no significant statistically difference between the two groups. Items in which no significant differences were found are related with the frequency of reobtain IC during physiotherapy changing program (I6), time spent less than 3 minutes to inform the patient (I7) and time spent over 15 to inform the patient regarding physical therapy plan (I10). The first item analysed and presented in *Table 3* is related with the frequency of IC obtaining at the physiotherapy admission. By observing the data regarding the differences

between PT and P groups, with p<0.001, we can confirm that it is a statistically significant difference between the two groups, corelated with a z=7.667 and mean ranks of 196.00 for Pt Group and 295.53 for P group, in the advantage of patients. By analysing this data, patients are more likely to be more aware of the process of getting IC on admission. Similar results, in the advantage of patients are obtained concerning the IC obtaining at the onset of physical therapy, meaning that there is a discrepancy between answers because physiotherapists are supposed to obtain IC in this case. But analysing the distribution of physiotherapists public or private practice, we can see that only 27.7% carry out professional activities in the public health and this might be one reason behind the results (Praestegaard & Gard, 2013).

The analysis regarding the answers between Pt and P groups related with the type of IC obtained in physiotherapy services show higher results by P group mean rank in the disadvantage of Pt group. The results of mean ranks correlated with p value <0,001 or p=0,001 prove the significant statistically difference between the two groups. The results obtained within these items confirm the fact that patients have chosen high-end options with a higher frequency for IC types, compared with physiotherapists. By these data, we point out the important aspect related to the first contact of the patient with other staff within the medical institution upon admission to the physiotherapy department. Items 8 and 9 results found in Table 3 are linked with the period of times spent by physiotherapists to explain physical therapy plan and inform patient about technical procedures and outcomes of physiotherapy exercises. Item 8 is related with a period of time between 3-5 minutes and Item 9 is related with a period of time between 5 to 10 minutes. If we analyse the data from *Table 3*, the statistically significant difference is proved by p=0.014 (I8) and p<0.001 (I9), but analysing the mean ranks of the two groups, it results that Pt group have chosen high-end options with a higher frequency for these two reported quantities of time.

Social aspects regarding patient's IC understandings regarding physiotherapy were assumed within the research. In this context, we have analysed the questionnaire items linked with IC from educational level perspective. The participants were divided into three categories: graduates of secondary education, high school graduates and university graduates. To investigate the differences between the participants according to the level of the graduated studies, the Kruskal-Wallis Nonparametric Test was applied, because the assumption of the normal distribution of data was not accomplished. After the Kruskal-Wallis test, all data were visually inspected by shape distribution. The interpretation of the test results was achieved by investigating the distribution differences and the mean ranks. The initial results of the test are shown in *Table 5*.

To identify which categories obtained higher or different scores, a comparison was made on pairs of groups, using the Dunn procedure, with a Bonferroni correction for multiple comparisons. To interpret the initial results of the Kruskal-Wallis test, the data are gathered in *Table 4*: the values of X^2 , the degrees of freedom (df), the threshold of statistical significance within each item encoded by a scalar

variable, and the values of the mean ranks according to the level of graduates' types. For an accurate interpretation Kruskal Wallis test results, it is necessary to correlate the data from *Table 4* and *Table 5*.

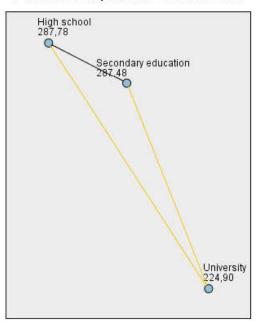
Items	Krus	kal-Wa	llis	Categories Mean Ranks			
	X ²	df	р	Secondary Education	High School	University	
I1-IC at physiotherapy admission	23.437	2	.000	287.48	287.78	224.90	
I2- IC at physiotherapy onset	34.239	2	.000	279.94	296.21	212.54	
13-IC Verbally	1.981	2	.371	287.96	268.89	261.10	
14 IC Written	22.802	2	.000	268.49	294.07	222.61	
15 IC Verbally+ Written	3.581	2	.167	270.14	278.93	250.97	
I6 Physiotherapy intervention	31.265	2	.000	305.06	288.35	214.66	
I7 < 3 minutes	1.747	2	.418	269.32	262.80	282.52	
18 3-5 minutes	2.631	2	.268	261.42	263.11	286.03	
I9 5-10 minutes	16.307	2	.000	284.42	286.65	228.66	
I10 > 15 minutes	15.012	2	.001	306.68	275.95	237.75	

Table 4. Results of the Kruskal Wallis Test based on educational level

Analysing the results regarding IC obtain at physiotherapy admission, the distribution of scores by educational level show statistically significantly differences between the groups, by X^2 (2)=23,437 and p <0.001, according to *Table 4*. To determine which of the groups obtained significant different scores, comparison in pairs using the Dunn procedure was used, whose synthesis is found in *Table 5* and correlated with the mean ranks from *Table 4*.

Thus, the results of the first item analysed show a statistically significant difference between the University (U) and Secondary education (SE) group, but also a difference between U group and High School group (HS). The mean rank of 224.90 for U group, versus 287.48 the mean rank of SE group and HS group, and p values of 0.002, respectively p<0.001, proved a statistically significant difference between the U group and SE groups, with a lower mean rank for U group (224.90, versus 287.48).

In the case of the second item analysed, with statistically significant differences, by $X^2(2) = 34.239$ and p <0.001, the differences between the groups reported in *Table 4* show a strong statistical significance in differences between U group and SE, with a mean rank of 212.54, versus 279.94 and a statistical significance level of 0.002. The second notable group difference is represented by the U and HS groups with a higher mean rank for the HS group = 296.21 vs. 212.54 for U and a statistical significance threshold p <0.001.



Pairwise Comparisons of Nivel studii

Each node shows the sample average rank of Nivel studii.

Sample1-Sample2	Test Statistic⊜	Std. Error	Std. Test Statistic	Sig.	Adj.Sig.
University-Secondary education	62,581	18,701	3,346	,001	,002
University-High school	62,875	13,471	4,667	,000,	,000
Secondary education High school	- ,294	17,092	-,017	,986	1,000

Figure 1. Dunn's procedure for mean rank differences between group categories, according to the level of education, reported at IC at the physiotherapy admission

In both items analysed, there were no differences between the SE and HS groups, and from the analysis of the results, we can state that the university graduates rated a lower frequency in IC obtaining at physiotherapy treatment admission, but also concerning the frequency of IC obtaining at physiotherapy onset. Another questionable issue is the level of perception and understanding of the analysed groups regarding IC, so SE and HS groups may overestimate what is generally related to medical services, or have a poor perception level of IC process and reasons behind it.

Items	U-SE	U-HS	SE-HS
	р	р	р
11	0.002	0.000	1.000
12	0.002	0.000	1.000
14	0.082	0.000	0.534
16	0.000	0.000	1.000
19	0.020	0.000	1.000
110	0.001	0.014	0.220

Table 5. Statistical significance thresholds by group comparison - Dunn procedure

The next item, where results were obtained with differences between the groups analysed, is related to obtaining the CI in written form. The threshold of statistical significance p < 0.001 and $X^2 (2) = 22.802$ determined the difference in group differences. Thus, statistically significant differences were found for U and HS groups with a mean rank of 222.61 for U, a mean rank of 294.07 for HS, and a statistical significance threshold p < 0.001.

The process of reobtain IC during physiotherapy intervention in treatment plan, according to the level of studies showed statistically significant differences, by p <0.001 and X² (2) = 31.265. The group differences analysed according to *Table 5* were demonstrated by p <0.001 and the mean ranks differences of 305.06 for SE and 288.35 for HS versus 214.66 for U group. Thus, study participants with higher education have again reported a lower frequency of IC reoccurrence in treatment modification.

Items 9 and 10 refer to the amount of time provided by physiotherapists for patients to give information and details about the therapeutic program. The results of the Kruskal-Wallis test in *Table 4* show statistically significant differences, by $X^2(2) = 16.307$, respectively $X^2(2) = 15.012$ and the p< 0.001 and p=0.001 respectively. From the analysis of *Tables 4 and 5*, it can be noticed that the U group has in both variants a lower mean rank compared to SE and HS groups. Thus, for the time period reported at 5-10 minutes, the SE group has a mean rank of 284.42, and U group of 228.86, with a statistical significance threshold of 0.002. In the case of the HS group, the mean rank is 286.65, and the difference from the mean of the U group denotes a threshold of statistical significance p <0.001. Similar results are also obtained with the timeframe over 15 minutes granted by physiotherapists to the patient information process.

The results of our research confirm that the process of IC obtaining in physiotherapy is poorly represented, and is usually associated from both patients and physiotherapists perspectives with IC on admission, but that is a general IC. One ethical aspect of IC is related with patient autonomy and his right to make a choice, but IC also requires background information with an educational potential. Due to the health system in Romania, where the physiotherapy component is branched out between physician, physiotherapist, nurse and caregiver, in the public system, the patient can often feel disillusioned about the issues of consent, information and perception of decision-making processes (Cassileth, 1980; Taub, 1984; Fraval, 2015; Yin, 2015). In physiotherapy services from Romania, patients with higher education levels are better informed and more aware of IC process, even if patients with lower education levels tend to overestimate their knowledge about IC, this issue being reported in other research (Miller, 1994). We argue for further research to identify the gaps of patient's knowledge regarding consent and information related to physiotherapy services. Thus, with an interdisciplinary approach, appropriate instruments for patient education can be built. Since most public health institutions have a form of CI, the interdisciplinary approach through which a useful tool to individualize the IC process can be developed must be based on appropriate information techniques, the use of appropriate language and a multidisciplinary perspective (Grady, 2015; Whitney, McGuire, & McCullough, 2004; Paasche-Orlow, 2003; Hopper, 1995).

Conclusions

The perception and understandings of IC process and the treatment aspects related to patient information, regarding physical therapy, tend to be disregarded and overrated as frequency by patients with average or lower level of education. Differences obtained from the comparison made by levels of education indicate that the study participants with higher education level are more attentive to the circumstances of the medical services, implicitly considering physical therapy, are better informed, especially regarding the IC and have a high level of expectations regarding the amount of time and information for performing physiotherapy.

Further research is needed to identify elements related to the informational level necessary to improve patient's knowledges and understandings IC in physiotherapy, from interdisciplinary perspective.

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