**DOI:** 10.1590/1980-549720190006

### **ORIGINAL ARTICLE /** ARTIGO ORIGINAL

# Profile of the judicialization of the Therasuit Method and its direct cost in the scope of the state of Rio de Janeiro

Perfil da judicialização do Método Therasuit e seu custo direto no âmbito do Estado do Rio de Janeiro

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**ABSTRACT:** *Introduction:* The lack of availability of the Therasuit Method by the Unified Health System associated with its high cost has led to the prosecution of this treatment. The study aimed to outline the profile of this judicialization, as well as to estimate the direct costs resulting from compliance with the deferred judicial decisions. *Method:* We analyzed the cases submitted to the Court of Justice of Rio de Janeiro between January 2013 and January 2017, in which the Therasuit Method was applied. Demographic, clinical, advocacy and legal data were extracted, as was the timing of the court's decision and the required technology budgets. *Results:* A total of 11 processes was analyzed. The authors had a mean age of 6.8 years and a median of 6, the majority being male, and resident in the state capital. Quadriparesis was the most reported condition. The gratuity of justice was requested by all, and the Public Defender's Office was used by 9 of the 11 processes. The judicial decisions at first instance were considered. In all of processes there was application of the legal tool called guardianship. The time of the judicial decision was on average of 266.5 days with a median of 35.5. The deferral index was 90%, totaling an annual direct cost of R\$ 501,894.09. *Discussion:* The judicialization of this treatment can cause an unforeseen displacement of public funds, transgressing the principles of equity and the integrality of Unified Health System. *Conclusion:* It was observed a high rate of deferred processes, resulting in a high cost spent by the Public Power to attend a small portion of patients.

*Keywords*: Judicialization of health. Right to health. Technology assessment, biomedical. Equipment and supplies. Cerebral palsy.

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Conflict of interests: nothing to declare - Financial support: none.

**RESUMO:** *Introdução*: O Método *Therasuit* possui alto custo e não é disponibilizado pelo Sistema Único de Saúde, o que tem ocasionado a judicialização desse tratamento. O estudo visou traçar o perfil dessa judicialização, bem como estimar os custos diretos decorrentes do cumprimento das decisões judiciais deferidas. *Método*: Foram analisados processos submetidos ao Tribunal de Justiça do Rio de Janeiro entre janeiro de 2013 e janeiro de 2017, no qual foi solicitado o Método *Therasuit*. Os dados demográficos, clínicos, advocatícios e jurídicos foram extraídos, assim como o tempo da decisão judicial e os orçamentos da tecnologia requerida. *Resultados*: O total de 11 processos foi analisado. Os autores tinham uma média de idade de 6,8 anos e mediana de 6, sendo a maioria do sexo masculino e residentes na capital do estado. A quadriparesia foi a condição mais relatada. A gratuidade de justiça foi solicitada por todos, e a Defensoria Pública foi utilizada em 9 dos 11 processos analisados. Foram consideradas as decisões judiciais em primeira instância. O tempo da decisão judicial foi em média de 266,5 dias com uma mediana de 35,5. Em todos houve requerimento da ferramenta jurídica tutela antecipada. O índice de deferimento foi de 90%, totalizando um custo direto anual de R\$ 501.894,09. *Discussão*: A judicialização desse tratamento pode ocasionar um deslocamento não previsto de verba pública, podendo impactar nos princípios da equidade e na integralidade do Sistema Único de Saúde. *Conclusão*: Constatou-se elevada taxa de processos deferidos, acarretando um alto custo despendido pelo Poder Público para atender a uma pequena parcela de pacientes.

*Palavras-chave:* Judicialização da saúde. Direito à saúde. Avaliação da tecnologia biomédica. Equipamentos e provisões. Paralisia cerebral.

### INTRODUCTION

Cerebral palsy (CP), also referred to as chronic non-progressive encephalopathy in children (NPEIC)<sup>1</sup>, comprises a heterogeneous group of permanent non-progressive clinical syndromes characterized by motor and postural dysfunctions<sup>2,3</sup>. Its therapy is focused on maximizing the quality of life through the improvement of activities of daily living, including assistance from parents and caregivers<sup>2,3</sup>.

To this end, treatment approaches may follow several aspects based on the individual need and the degree of affection of each patient. Interventions may include physical therapy, the use of orthotics and, in certain situations, corrective surgery<sup>2,3</sup>.

The Therasuit<sup>®</sup> device, used in the treatment with the Therasuit Method and belonging to the Intensive Physical Therapy Program (IPTP), has been adopted with the purpose of improving functional capacity and motor deficits<sup>4,5</sup>. It consists of a suit in up to six sizes, which has several elastics connected in different parts to the patient's body with varying tensions and dimensions<sup>4,5</sup>. Manufactured exclusively in the United States, the equipment is the only technology with this functionality registered both in the Food and Drug Administration (FDA)<sup>6</sup> and, in Brazil, by the National Agency of Sanitary Surveillance (*Agência Nacional de Vigilância Sanitária* – ANVISA)<sup>7</sup>. In addition, the Therasuit Method (including the device suit) has not, so far, been submitted to evaluation by the National Commission for the Incorporation of Technologies (Conitec)<sup>8</sup>. However, the Unified Health System (*Sistema Único de Saúde* – SUS) offers other types of treatment to neurological patients, including those with cerebral palsy, according to the Table of Procedures, Medications, Orthotics/Prostheses and Special Materials (SIGTAP), which includes: "physical therapy care in patients with neuro-kinetic-functional disorders with and without systemic complications", in addition to "physiotherapeutic care in disorders of the neuromotor system"<sup>9</sup>. Such services are performed by the health units that integrate the Physical Rehabilitation Network of the State of Rio de Janeiro<sup>10</sup>.

Thus, considering that this method is not standardized by SUS, patients have opted for the attempt to guarantee this type of treatment by judicial means in the state of Rio de Janeiro. Consequently, this behavior of health judicialization through compliance with judicial orders, according to some authors, may result in an overload of public coffers<sup>11,12</sup>.

Given this scenario, it is possible to perceive the relevance of the search for information about costs with respect to which and how resources are consumed<sup>13</sup>, with the objectives of informing actions and avoiding unnecessary investments, which disregard the logic of care of the care network, among other issues currently presented by the Brazilian health system<sup>14</sup>. Cost information becomes even more relevant, given they play a significant role in assisting decision-makers on the part of public administration actors<sup>15</sup>.

Therefore, the study aimed at tracing the profile of the judicialization of CP treatments with the Therasuit Method, in the scope of the state of Rio de Janeiro, by analyzing the judicial proceedings submitted to the Nucleus of Technical Assistance (*Núcleo de Assessoria Técnica* - NAT) of the Court of Justice of the State of Rio de Janeiro (*Tribunal de Justiça do Estado do Rio de Janeiro* – TJERJ). Secondly, it aimed to estimate the direct costs resulting from compliance with court decisions favorable to the requests of the plaintiffs.

### METHOD

The present study is a descriptive study, which included the processes submitted to the NAT of the TJERJ from January 2013 to January 2017, where treatment with the Therasuit method was requested for children (<12 years of age) and adolescents ( $\geq$  12 and < 18 years of age)<sup>16</sup> with CP.

The respective data on the profile of the Therasuit treatment judicialization were removed from the proceedings and arranged in a form filling the following fields:

- Demographic data: gender, age and municipality of residence (taken from the initial process).
- Clinical data: International Classification of Diseases (ICD-10), as well as the clinical picture presented by the author as a result of CP involvement.
- Legal data: if there was a claim of economic hyposufficiency and a request for gratuity of justice (by means of a written declaration so that the author is exempt from costs related to the judicial process due to proof of absence of one's own and sufficient economic means for the provision of expenses of the process), whether there was a search for assistance from public defenders or private lawyers, whether the protection was anticipated and the legal basis, as well as justification of the authors to substantiate the lawsuit.

 Legal data: if the NAT indicated the requested treatment, it was suggested alternative treatment standardized by the SUS (from the technical opinions issued), whether or not the judge accepted the NAT's opinion and whether or not the treatment sought was approved (from the legal decision).

Judgments were considered in the first instance, as well as the time of these decisions (indicated in number of days). Data on the direct cost of treatment with the Therasuit method were estimated in national currency — *real* (R\$) —, based on the average prices collected.

The collection of treatment values with the Therasuit method was carried out by consulting the budgets of the institutions attached to the processes, since they would be the places where the authors would carry out the treatment in case of deferment by the judge.

Considering that the budgets attached to the processes were granted in different periods, that is, in different months and years, the amounts were annualized and adjusted for the base year of 2017 (through July) according to the National Price Index to the Broad Consumer (*Índice Nacional de Preços ao Consumidor Amplo* – IPCA). The choice of this index is justified by the fact that it is an indicator used by the Brazilian federal government to gauge inflation targets<sup>17</sup>.

It should be emphasized that the presentation of the sample profile was delimited to the descriptive statistics. The characteristics of the judicialization are presented in tables and the results were weighted using measures of absolute and relative frequency. For the continuous variables, the mean and median values were estimated using the free-use statistical package R.

The study was submitted to and approved by the Ethics and Research Committee of the National Institute of Cardiology.

## RESULTS

The search identified 11 processes submitted to the NAT of the TJERJ, which had their data analyzed.

The authors' ages ranged from 2 to 15 years, with a mean of 6.8 and a median of 6 years. In the processes, the majority of subjects were male (82%) and resident in the city of Rio de Janeiro (55%).

The ICD-10s were informed in 73% of the processes analyzed and included CP, congenital hydrocephalus, epilepsy, global developmental disorders and mental retardation. Clinical pictures were described at the same frequency, with the spastic quadriparesis (4/11)being the most common condition mentioned.

Demographic and clinical data of the processes are set out in Table 1.

Table 2 summarizes the legal data and the time of the judicial decision in the first instance of the present study.

All authors (11/11) requested the benefit of gratuity of justice, and in 82% of the cases, the legal representation of the Public Defender's Office was used.

Article 196 of the Federal Constitution of 1988<sup>18</sup> (which states that "health is the right of everyone and the duty of the State, guaranteed by social and economic policies aimed

at reducing the risk of disease and other illnesses and universal and equal access to actions and services for their promotion, protection and recovery") was cited on 91% of occasions as justification for the lawsuit by the authors, while Law No. 8.080 of 1990 (which deals with the conditions for the promotion, protection and recovery of health, the organization and operation of the corresponding services and other measures) was mentioned in 55% of the processes. Arguments based on article 1, item III, of FC/88, which addresses the dignity of the human being as one of the foundations of the Democratic State of Law, were mentioned in 2 of the 11 processes analyzed.

The legal tool, guardianship, whose main objective is the urgent granting of the item pleaded to the author of the action, in order to avoid the material damages resulting from the delay of the process, was requested in all cases. The time to obtain it presented a great variation of values (from 1 to 1,140 days). The average decision time, given by the judge, was 266.5 days and the median was 35.5.

In all the technical reports of the NAT (11/11) there was a suggestion of treatments made available by SUS, as shown in the SIGTAP table, for the clinical condition of the authors of the actions.

The deferral rate of the required technology was high. In only one case (1/10) was the request dismissed on the grounds that, although the author's arguments were based on the principle of human dignity, the granting of therapies by judicial means to eligible citizens should consider proportionality, in the public sphere, is established in the area of the principle of the Reserve of Possible.

Age (years)	Gender	Municipality	ICD-10	Clinical condition
6	М	Rio de Janeiro	G80.0	NI
6	М	Campos dos Goytacazes	F84, G80.2, Q03, G40.5	Hemiparesis, motor delay
10	М	Rio de Janeiro	G80.3	Motor delay
3	М	Rio de Janeiro	G80, G40	NI
5	М	Rio de Janeiro	F70.0, G40.0	Spastic quadriparesis
15	М	Rio de Janeiro	NI	Spastic quadriparesis, athetosis
5	F	Rio de Janeiro	G80.1	Spastic diplegia
8	М	Campos dos Goytacazes	NI	Spastic quadriparesis, intellectual disability
4	М	Campos dos Goytacazes	NI	Spastic quadriparesis
11	М	Niterói	G80.0	Spastic quadriplegia
2	F	Cardoso Moreira	G80.2	Hemiparesis on the left

#### Table 1. Demographic and clinical data of the processes.

ICD-10: International Classification of Diseases; M: Male; F: Female; NI: Not informed.

The total estimated annual direct cost to meet the authors of the deferred actions totaled the amount of R\$ 501,894.09. Regarding the average annual cost, per author, the estimated amount was R\$ 55,766.01.

It should also be mentioned that the average annual cost, per author, of the treatment offered by SUS, as shown in the SIGTAP table, is R\$ 1,320.40.

## DISCUSSION

According to Ventura et al.<sup>19</sup>, Pepe et al.<sup>20</sup> and Chieffi et al.<sup>21</sup>, the judicialization of health, a phenomenon understood by the obligation to provide health goods and services to citizens,

Gratuity of justice	Legal representation	Authors' legal basis*	Alternative Treatment Suggestion	Judicial decision	Time for judicial decision (in days)
Yes	PD	5, 6 and 196 of FC/88	Yes	Deferred	53
Yes	PD	196,197,198 of FC/88; 2, 7 of Law No. 8.080/90	Yes	Deferred	6
Yes	PA	5, 6, 196, 198 of FC/88	Yes	Deferred	35
Yes	PD	1, 5, 196 of FC/88	Yes	Deferred	22
Yes	PD	5, 6, 196 of FC/88	Yes	Rejected	694
Yes	PA	5,6, 196, 227 of FC/88; 9 of Law No. 8.080/90	Yes	Deferred	6
Yes	PD	1, 5, 196 of FC/88	Yes	Deferred	672
Yes	PD	196, 197, 198 of FC/88; 2, 7 of Law No. 8.080/90	Yes	£	£
Yes	PD	196, 197, 198 of FC/88; 2 and 7 of Law No. 8.080/90	Yes	Deferred	36
Yes	PD	195, 198 of FC/88; 7 of Law No. 8.080/90	Yes	Deferred	1
Yes	PD	196, 197, 198, 293 of FC/88; Law No. 8.080/90	Yes	Deferred	1,140

Table 2. Legal and time data of the judicial decision in the first instance of the processes.

PA: private attorney; FC: Federal Constitution; PD: public defense; £: Inability to access the judicial decision; \*Articles of Law and of the FC/88.

imposed on the Public Administration by the Judiciary, in which assures the citizen access to technologies and public policies, makes it possible to identify health demands and issues more objectively, as well as to encourage the creation of solutions by SUS managers to compensate for the malfunctioning of such system.

However, given the scenario presented in the present study, this phenomenon may facilitate access to treatment, but, on the other hand, disorganize the public system since the treatments offered by the SUS to patients with neurological dysfunctions such as CP cost, on average, according to the SIGTAP table<sup>9</sup>, R\$ 5.51 per service.

Since the SUS offers a maximum of 20 outpatient visits per month<sup>9</sup>, the annual treatment, per author, would cost the public coffers, via SUS, R\$ 1,320.40 *versus* R\$ 55,766.01 using the Therasuit Method. This finding corroborates those addressed in studies which point out that the compliance with judicial orders increases public expenditures<sup>22,23</sup>.

The treatment with the Therasuit Method, when expending significant public resources, when compared to the cost incurred using SUS, can promote unplanned displacement of funds due to compliance with judicial determinations that serve few individuals, given the annual expenditure of R\$ 501,894.09 to serve only nine authors whose lawsuits were granted.

At the same time, the mobilization of part of the society requesting the materialization of their right to health through the judicialization of goods and services, together with the deferrals of the lawsuits filed by the judges, evaluates individual litigation without considering collective matters<sup>22</sup>. Although in all the analyzed processes the benefit of gratuity of justice was requested, alleging hyposufficiency of the authors of the actions and, most of them, the request of the Public Defender's aid, the judicialization of health can hurt some SUS principles, such as equity and completeness<sup>23,24</sup>, since, according to Barroso<sup>25</sup>, other patients, who are also hyposufficient and in need of health care that did not seek justice assistance due to a lack of knowledge and access, become deprived<sup>26</sup>.

According to Laranjeira and Petramale<sup>24</sup>, the principle of equity cannot be guaranteed by judicially seeking uncritical reimbursement of high-cost items in order to serve a small portion of patients, thus failing to provide basic inputs for a large part of the affected population by highly prevalent diseases, which also depend on the health system.

However, even with evidence of the negative effects of the health judicialization process regarding SUS principles and community involvement, authors mention that the possibility of fulfilling the right to health through access to justice can be considered an advantage of the process itself and does not necessarily mean a deviation from the functions of the Judiciary Power<sup>27,28</sup>. One concrete example was the claim of social rights, such as access to medicines and medical follow-up, to the Judiciary, by patients with HIV/SIDA in the 1990s. This fact led to the creation of public policies that began to contemplate this portion of the population through the free distribution of antiretroviral drugs<sup>29</sup>.

In certain situations, the Judiciary, in Brazil, in denying the provision of health goods and services in their decisions, is based on the Principle of the Possible Reserve, which deals with the limitation of available financial resources in the face of the numerous needs of the citizens<sup>30</sup>. Thus, given the progressive and high health expenditure<sup>22,23</sup>, it is understood

that the State has a reduced action, due to the lack of resources, to fully serve all users. However, only one case of dismissal by the judge was observed in the study, claiming the said Principle. It, therefore, calls for the establishment of criteria for health provision in order to allocate funds for a better management of the available resources<sup>31,32</sup>.

In this context, we have the concept of opportunity cost, which uses limited resources in a perspective of health interventions that compete with each other due to this financial shortage. Such a concept assumes that when a wrong intervention is performed, i.e., when there is no additional benefit, the opportunity to use the same monetary value in options that could bring more gains to the population is wasted<sup>33</sup>.

In addition, it is emphasized that the concept of the integrality principle<sup>23</sup>

be delimited by topics such as the regulation of technology incorporation based on the principles of evidence-based medicine, protocolized care [...], the correct sequence of care based on hierarchical services, with emphasis on primary care, and the special attention to cases that are beyond therapeutic possibility.

Thus, it is essential to discuss the scientific evidence on the effects of the technology in question in the treatment of children and adolescents with CP.

There are clinical premises on the use of the dynamic suit to alter joint alignment and assist in the strengthening and/or stretching of certain muscle groups, affecting posture, coordination, balance, fine and gross motor function and gait of children with CP and even other health conditions<sup>34-39</sup>.

In addition, Liptak<sup>40</sup> and Martins et al.<sup>41</sup> conducted studies that initially reinforced clinical claims and expectations of family members regarding the effects of such therapy on the movement and posture of children with CP. However, a systematic review with meta-analysis showed that the effect of the protocol with the Therasuit Method was of limited impact<sup>41</sup>.

It should be noted that this effect was measured using the Gross Motor Function Measure-66 (GMFM-66)<sup>42</sup> and the Pediatric Evaluation of Disability Inventory (PEDI)<sup>43</sup> instruments. The first tool estimated the change in the motor skills of patients with CP in 66 items arranged in 5 dimensions, which included lying down and rolling; sitting down; crawling and kneeling; the upright posture; and, finally, walking, running and jumping. The PEDI questionnaire, by means of 197 items, measured the functional abilities of the respective patients and the caregiver's assistance in the sphere of self-care, mobility and social function.

Considering that children with CP need an articulated care network between a multidisciplinary health team and their family, based not only on specific CP conditions per se, but also focused on adequate strategies that involve global aspects of their health, the existence of other therapeutic possibilities available, such as those offered by the SUS, according to the SIGTAP, namely: "physiotherapeutic care in patients with neuro-kinetic-functional disorders with and without systemic complications", in addition to "physiotherapeutic care in the disorders of the neuromotor system"<sup>9</sup>, through the health units that integrate the Physical Rehabilitation Network of the state of Rio de Janeiro<sup>10</sup>. The Ministry of Health, through the Directives of Attention to the Person with Cerebral Palsy<sup>44</sup>, recommends the treatments made available by the SUS for children with CP. This fact corroborates what was discussed in all the Technical Opinions analyzed, in which there was a suggestion of treatment standardized by the SUS, such as those mentioned in the SIGTAP table, as an alternative to the legal claim (treatment with Therasuit Method) by the authors of the actions.

In view of the foregoing, despite the fact that the Federal Constitution of 1988 requires the materialization of the right to health (Article 196), which includes the dignity of the human person also as a principle of economic orientation (article 1, item III and article 170), the establishment of the State's limited action (Principle of the Reserve of Possible *versus* equal universal access) is necessary<sup>45</sup>. According to Viola<sup>45</sup>, the provision could be limited only to what is necessary for the purpose of protecting human life. Such a situation is not characterized in the present demand, which refers to the treatment of a chronic condition by the use of the Therasuit Method, which, according to studies<sup>33-43</sup>, is presented with limited effectiveness.

The limitations of the present study need to be addressed. In the perspective of scientific evidence regarding the efficacy of the Therasuit Method, there was a shortage of robust studies on the subject, which reinforces the need to advocate the use of therapies offered by SUS.

The use of the SIGTAP table as a source of treatment costs offered by SUS can be considered with underestimated values, and may present different values in relation to the current prices practiced. Nevertheless, it can be useful as a source of comparison for purposes of proportionalisation of one cost in relation to another from the perspective of the SUS, as a source of payment.

It was not possible to see the judicial decision in all the processes evaluated, since in one of them the information was not attached. In addition, the research was conducted with a small number of processes, which does not necessarily represent the entire state. However, this information can serve as a useful indicator not only to direct analyses of the epidemiological profile of the state but also to foster discussions and studies to understand why treatments standardized by SUS are not used as an option for the therapeutics of these patients. It may also stimulate the creation of new public policies or the reformulation of existing ones, by means of aid, for example, in the decisions on incorporation by the SUS, according to Law No. 12.401 of April 28<sup>th</sup>, 2011.

Furthermore, the need for consistent information about the efficacy and safety of the judicial method is emphasized, considering the existence of treatments offered by SUS for the same clinical condition.

There is also evidence of a lack of monitoring of the investment result, i.e., of the effectiveness and efficiency of public investment, considering the proportionality context in relation to the total budget allocated to health in the state of Rio de Janeiro.

### CONCLUSION

The analysis of the Therasuit Method judicialization in the scope of the state of Rio de Janeiro found a high index of deferred processes, despite the indication of other therapeutic

options available by the SUS, resulting in a high cost spent by the Public Power to attend a minority of patients.

Finally, given that the legislation advocates the formulation of public policies that meet the highest number of individuals according to the local epidemiological profile, together with the participation of society, and considering financial aspects<sup>46</sup>, it is imperative to conduct future studies about the reflection on measures of health benefit, such as the concept of willingness to pay.

**Identification/approval number of the Research Ethics Committee:** The study was submitted and approved under the number 75533317.9.0000.5272 to the Ethics and Research Committee of the National Institute of Cardiology.

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### Received on: 12/13/2017 Final version presented on: 04/20/2018 Approved on: 04/23/2018

Authors' contributions: Dominique Souza de Moraes participated in the conception and design of the research, obtaining data, analyzing and interpreting the data, statistical analysis and critical review of the manuscript regarding the important intellectual content. Roberta da Silva Teixeira and Marisa da Silva Santos collaborated in the conception and design of the research, analysis and interpretation of data, statistical analysis and critical review of the manuscript regarding important intellectual content.

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