



Original Article

# Analysis of the numbers of clinical trials on physical therapy in Japan: comparison with those in the North American register from 2010 to 2019

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**Abstract.** [Purpose] Information about clinical trials related to physical therapy (CTPT) in Japan, which has the highest aging rate in the world, is essential for physical therapy education, research, and policymaking to change and strengthen the education system and promote research grants. This survey aimed to clarify the proportion of CTPT in the clinical registry and compare the proportion of CTPT in Japan with that in North America. [Participants and Methods] The ClinicalTrials.gov (CTG) and National Institute of Public Health (NIPH) Clinical Trials were used. The number and proportion of CTPT were compared each year. The analyzed data spanned 10 years from 2010 to 2019. [Results] A total of 222,821 trials were registered in CTG during the 10 years. In search of “physical therapy”, 3,001 trials searched. The proportion of CTPT increased from 0.8% to 1.7%. In total 42,194 trials were registered in the NIPH Clinical Trials Search. From the CTPT, 141 trials were obtained. The proportion of CTPT increased from 0.05% to 0.5%. The proportion of CTPT in the NIPH Clinical Trials Search was one-third or less than that in the CTG. The proportion of CTPT in CTG increased yearly, but the proportion of CTPT in NIPH Clinical Trials Search has not increased since 2016. [Conclusion] The proportion of CTPT is relatively low in Japan, compared with that in North America, and it showed no increasing trend. It is important to provide education and support for clinical trials in an aging country such as Japan.

**Key words:** Physical therapy, Clinical trial, Japan

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## INTRODUCTION

According to the World Physiotherapy, “Physical therapy is services provided by physical therapists to individuals and populations to develop, maintain and restore maximum movement and functional ability throughout the lifespan. The service is provided in circumstances where movement and function are threatened by ageing, injury, pain, diseases, disorders, conditions and/or environmental factors and with the understanding that functional movement is central to what it means to be healthy”<sup>1)</sup>. At the root of guiding professionals to provide patients with the most effective treatments is evidence-based physical therapy, and clinical trials are the bedrock of evidence-based physical therapy. World Health Organization (WHO) has identified building research capacity and expanding the availability of robust evidence for rehabilitation as one of the

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action plans of Rehabilitation 2030<sup>2)</sup>. Future changes in disease structure due to aging and non-communicable diseases have led WHO to suggest that rehabilitation will only become more important<sup>3)</sup>. Therefore, more clinical trials in physical therapy are needed on a global scale.

WHO defines a clinical trial as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials which focus on, but are not restricted to, drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioral treatments, process of care changes, preventive care etc<sup>4)</sup>. According to The World Medical Association Declaration of Helsinki, the primary purpose of medical research involving human subjects is to understand the causes, development, and effects of diseases and improve preventive, diagnostic, and therapeutic interventions (methods, procedures and treatments)<sup>5)</sup>. WHO and International Committee of Medical Journal Editors (ICMJE) announced that all clinical trials must be registered at a clinical trial registry to be eligible for publication<sup>6)</sup>. There are clinical registers such as ClinicalTrials.gov (CTG)<sup>7)</sup> and WHO International Clinical Trials Registry Platform<sup>8)</sup>. In the field of physical therapy, some surveys have been conducted using these registers<sup>9, 10)</sup>.

On the other hand, little has been reported on practice trend in the practice of clinical trials related to physical therapy (CTPT). In addition, there are no surveys comparing the trend of CTPT in Japan with that of the rest of world. CTPT in Japan has an important role in global aging. The reason is that Japan has an aging rate of 28.4%, which is the largest number in the world<sup>11)</sup>. Thus, Japan is an advanced country contending with what no country in the world has faced: a growing elderly population with an emerging need for physical therapy to combat frailty, dementia, and osteoarthritis. For these reasons, the knowledge about CTPT in Japan, which has the highest aging rate in the world, is essential information for people in charge of physical therapy education, research and policy making to change and strengthen the education system and promote research grants.

The purpose of the present survey was to clarify the proportion of CTPT in the clinical registry and to compare the proportion of CTPT in Japan with that found in North America that has a similar disease structure from Japan. This international CTPT comparison is a valuable exercise to help Japan prepare for the future of physical therapy in an aging country.

## PARTICIPANTS AND METHODS

We used CTG as the North American clinical trials registry. CTG, the largest clinical trials database covering all 50 states in the USA and 209 other countries, is run by the US National Library of Medicine and the US National Institutes of Health<sup>7)</sup>. First, we assessed how many clinical trials were registered by year in CTG, from January 2010 to December 2019. Second, we searched for CTPT by year using “Physical therapy” as the search term in the “Other terms” search fields. At this time, the search for “Physical therapy” also searched for Physiotherapy. Third, using the data from these 2 searches, we calculated the proportion of CTPT in the total number of clinical trials each year. Exclusion criteria were those that were not physical therapy, those that were not directly related to physical therapy skills, and those that included physical therapy in control group (verification of additional effects was included).

We used the National Institute of Public Health (NIPH) Clinical Trials Search as the domestic clinical trials registry. NIPH Clinical Trials Search is the largest clinical trials registry platform in Japan and involves 3 Japanese clinical trials registries: the University hospital Medical Information Network Clinical Trials Registry (UMIN-CTR), the Japan Medical Association Center for Clinical Trials (JMACCT), and the Japan Pharmaceutical Information Center (JAPIC)<sup>12)</sup>. The search in NIPH Clinical Trials Search was performed in the same procedure as CTG, and the search term used was “Physical therapy” in Japanese. Exclusion criteria were the same used in CTG.

We compared the proportion of CTPT in the total clinical trials each year based on the results obtained from CTG and NIPH Clinical Trials Search.

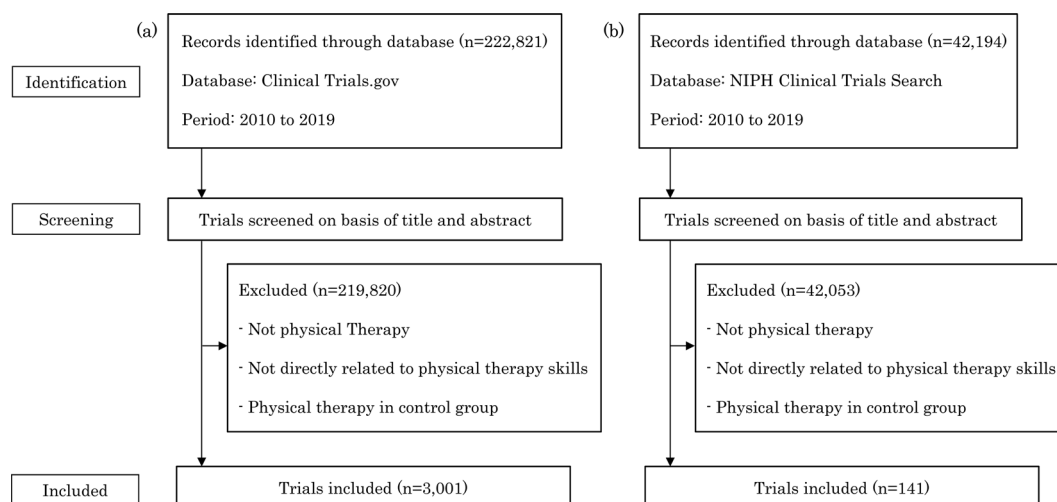
This study was conducted with a confirmation that it does not category to researches involving human subjects as stated in the Declaration of Helsinki, along with the Ethical Guidelines for Medical and Health Research Involving Human Subjects of the Ministry of Health, Labour and Welfare.

## RESULTS

A total of 222,821 trials were registered in CTG during the 10 years from 2010 to 2019. The search of “Physical therapy”, identified 3,789 trials with 788 excluded, for a final tally of 3,001 trials serving as CTPT (Fig. 1a). The annual number of clinical trials is shown in Table 1. In CTPT, the number of clinical trials registered annually has increased from 139 to 465. Similarly, proportion of CTPT increased from 0.8% to 1.7%. Both total number and CTPT showed a similar increasing trend.

In total 42,194 trials were registered in NIPH Clinical Trials Search between 2010 and 2019. A search for “Physical therapy” found 173 trials, but 32 trials were excluded, resulting in 141 trials serving as CTPT (Fig. 1b). The number of clinical trials per year is shown in Table 1. In CTPT, the number of clinical trials registered annually has increased from 1 to 29. The total number increased with a larger slope than CTG. However, there was a slight increase in CTPT. Proportion of CTPT increased from 0.05% to 0.5%.

The proportion of CTPT in NIPH Clinical Trials Search was one third or less than CTG. CTPT proportion in CTG increased year by year, but the proportion of CTPT in NIPH Clinical Trials Search has not increased since 2016 (Fig. 2).



**Fig. 1.** Flow diagram of trial selection.  
NIPH: National Institute of Public Health. (a) North America, (b) Japan.

**Table 1.** Number and proportion of trials registered from 2010 to 2019

Year	CTG (North America)			NIPH Clinical Trials Search (Japan)		
	All trials	CTPT	Proportion of CTPT	All trials	CTPT	Proportion of CTPT
2010	17,207	139	0.8	2,001	1	0.05
2011	18,082	162	0.9	2,288	3	0.1
2012	19,024	195	1.0	2,805	2	0.1
2013	19,870	213	1.1	3,205	3	0.1
2014	21,896	293	1.3	3,441	7	0.2
2015	23,415	315	1.3	4,322	13	0.3
2016	24,930	348	1.4	5,036	30	0.6
2017	25,381	402	1.6	5,212	28	0.5
2018	25,958	469	1.8	7,734	25	0.3
2019	27,058	465	1.7	6,150	29	0.5
Total/Average	222,821	3,001	1.3	42,194	141	0.3

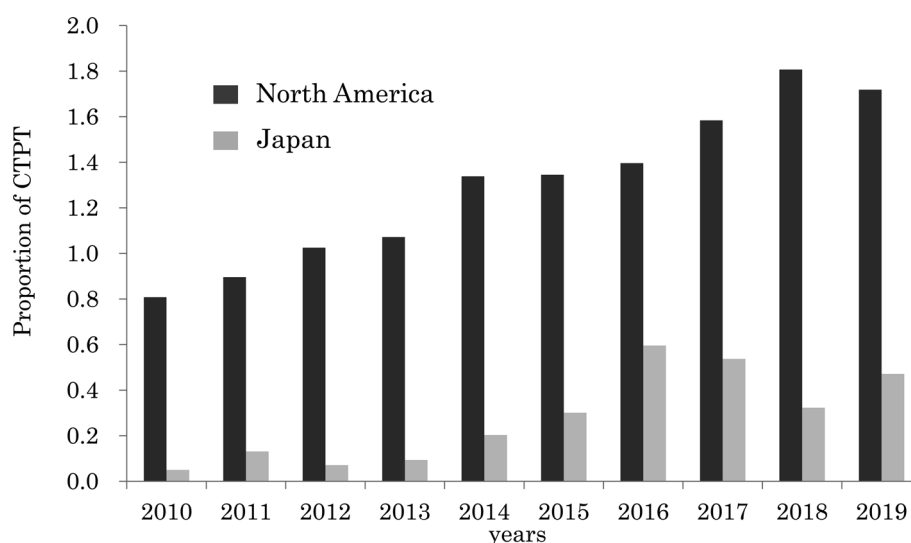
CTG: ClinicalTrials.gov; NIPH: National Institute of Public Health; CTPT: Clinical Trial related to Physical Therapy.

## DISCUSSION

This survey was conducted using CTG and NIPH Clinical Trials Search to clarify trends in CTPT in North America and Japan between 2010 and 2019. As a result, the proportion and number of North American CTPT increased year by year. While the number of CTPT in Japan has increased, the proportion has not increased since 2016. This is the first survey to compare CTPT between North America and Japan using a clinical trial registry.

The number of registered clinical trials in North America has continued to increase, especially since 2004, when ICMJE announced its trial registration statement<sup>13)</sup>. As already stated, clinical trials in Japan have also increased during the study period. CTPT searches have also increased on the Australian Physical therapy Evidence Database (PEDro)<sup>14)</sup>. These reports support our results.

There are two reasons for the low proportion of CTPT in Japan. First, the national budget for research in Japan is small compared to other countries such as the United States. According to the main science and technology indicators in Organization for Economic Co-operation and Development (OECD)<sup>15)</sup>, Gross Domestic Expenditure on Research and Development (GDER) in Japan was about 170 billion dollars in 2017. In the United States, the GDER was about 540 billion dollars, more than 3 times that of Japan. Total researchers in Japan and the United States were 660 thousand and 1.3 million, respectively, in 2016. In other words, GDER per researcher in the United States was 1.5 times that in Japan. In light of the significant impact funding has on research and development, increased research funding is essential in solving the global problem of aging in Japan.



**Fig. 2.** Comparison of proportion transition of CTPT in Japan and North America.  
CTPT: Clinical Trial related to Physical Therapy.

Second, the degree required to qualify as a physical therapist in Japan is different than in the United States and Canada. In Japan, entry level is high school graduate and available degree is diploma or bachelor<sup>16)</sup>. In the United States and Canada, entry level is bachelor and available degree is master or doctor of physical therapy<sup>17, 18)</sup>. According to survey of World Physiotherapy, the proportion of physical therapists per 10 thousand populations in North America is 5–10, while in Japan it is 10–15<sup>19)</sup>. This is an achievement for rehabilitative needs of the aging society in Japan. However, the differences in the degree required to qualify as a physical therapist may have led to differences in research skills. PEDro use in Japan was the tenth out of 26 countries, although there were gaps in Japan<sup>20)</sup>. Furthermore, rehabilitation-related research represented about 20% of Japan's scientific research grants<sup>21)</sup>, more than half of the top 10 institutions with the highest number of Japanese grants did not have physical therapy education programs. These findings indicated that the higher education system in physical therapy field is lacking in Japan compared to the US and Canada. However, as the disease structure changes, it is likely that Japanese physical therapy will also change. To respond to the changing needs, higher education systems like those in the US and Canada are also required in Japan.

This survey has two limitations. First, we only surveyed the number of CTPT. So we have not been able to compare the physical therapy sub-disciplines. However, although the aging rates are different in Japan and North America, the changes in disease structure related to aging are similar<sup>22)</sup>. Therefore, by comparing the number of trials, it is possible to clarify the research capabilities of physical therapy in Japan and North America. Second, some clinical trials published without being registered<sup>9)</sup>. Therefore, clinical trial registration may not represent research ability. On the other hand, adherence to ICMJE increases year by year, and since 2010, even timely registration rates have exceeded 70%<sup>23)</sup>. Similarly, this trend has been observed in the physical therapy field<sup>10)</sup>. In addition, governments and international organizations have been working steadily to make clinical trial information more transparent and widely available and to standardize registries and processes of registering. Thus, clinical records can be considered indicative of research capabilities.

National Academy of Medicine reported that a paradigm shift in health care is necessary because the disease structure has changed from a focus on acute diseases to chronic diseases such as a non-infectious disease<sup>22)</sup>. Aging is one of the reasons for this change in disease structure<sup>24)</sup>. Because aging is progressing worldwide, the issues and outcomes in Japan, home to the largest aging rate in the world, are important. In conclusion, this survey provides new and important information on the developing clinical trials of physical therapy in aging countries.

Our findings revealed that the proportion of Japanese CTPT was small compared with the North American CTPT, and showed no increase trend. It is important to provide education and support for clinical trials that enhance CTPT in an aging country like Japan.

### *Conflict of interest*

There are no conflicts of interest.

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